PORTUGUESE MINISTRY OF HEALTH[1]

Ordinance no. 194/2014

from September 30th

The improvement of healthcare services, making them more effective and efficient, and its harmonization with the best practice of other European countries is one of the goals of the XIX Constitutional Government Programme.

In fact, all European health systems are currently facing the challenge of increasing their efficiency while reducing their costs, thus assuring an improvement in the healthcare quality as well as in the achieved results, in order to assure their sustainable growth and success.

In most health systems we can actually see that there is a strong relationship between scale and quality, being a given fact that services with a greater scale tend to ease the communication between different specialities, strengthen multidisciplinary work, assure optimal use of different technologies and create a favourable environment for permanent education and research. Therefore - and considering the witnessed synergies - the healthcare services that benefit from scale economies should be concentrated.

In this sense, Directive no. 2011/24/EU of the European Parliament and of the Council from the 9th of March 2011, which regards the exercise of the rights of patients concerning cross-border healthcare, established that the European Commission supports the creation of European reference networks between healthcare providers and centres of expertise throughout the Member States, particularly in the area of rare diseases. According to this directive, Member States are encouraged to participate in the development of the European reference networks by the creation of National Reference Centres.

Within this framework, the report presented by the Technical Group for Hospital Reform, created by Order no. 10601/2011 of the Ministry of Health, and published in the Official Gazette, 2nd series, no. 162 from the 24th of August of 2011, also determines eight strategic initiatives, with the extension, depth and density required for a structural reform of the hospital sector within the National Health Service . One of these initiatives includes the identification, recognition and implementation of reference centres that are able to concentrate case history and diagnosis, treatment and scientific research resources of different medical and surgical pathologies, by involving multi-disciplinary teams and a more demanding scientific and medical control regarding quality and safety, with a relevant role in research and education, and which may become potential healthcare providers to European citizens and to those who are part of the Community of Portuguese-Speaking Countries.

For such reasons, and having the Government assumed the aforementioned priority, a Workgroup was established, pursuant to the Order no. 4319/2013 of the Deputy Secretary of State of the Ministry of Health, published in the Official Gazette, 2nd series, no. 59 from the 25th March 2013, in order to determine the concept of reference centre, establish requirements for its creation and recognition by the Ministry of Health, propose its implementation and financing model, as well as the design of the integration procedure in the

[1] **English Translation**

Portuguese Hospital Network, whereas the proposals thereto are set out in this Ordinance.

The Law no. 52/2014 from the 25th of August, transposing into the internal legal system the Directive no. 2011/24/UE of the European Parliament and of the Council from the 9th of March 2011, concerning the exercise of the rights of patients regarding cross-border healthcare, consecrates that the Ministry of Health shall be responsible for the official identification, approval and recognition of national reference centres, namely those for rare disease diagnosis and treatment, as well as to promote the participation and integration of national reference centres that are voluntarily willing to integrate the European Reference Networks.

Thus, the Portuguese Health System will be in better conditions to gain competences, prestige and competitiveness compared with the European and international health systems. On the other hand, it could become an attractive feature for patients of the European zone regarding highly specialized and specific areas, thus strengthening the interest in its strategic positioning, as recognised in the Major Planning Options for 2014.

The recognition process of the reference centres has therefore a strategic value for the Health System, and it should be built considering the concentration of case history analysis, experience and resources, thus allowing referral based on a hierarchy of competences and on the coordination either with the hospital reference networks or other similar national, European or international centres, thus maximising the use of existing resources, susceptible to increase the diagnosis and treatment capacity of a series of pathologies, namely rare diseases. The recognition process of the reference centres can and shall also definitely contribute towards a structural reform of the hospital sector in the Portuguese Health System.

Through the recognition process of the reference centres, based on the hierarchy of knowledge and competences far wider than the geographical one, it is foreseen that the offer of highly specialized healthcare shall result in significant improvements in quality, effectiveness and safety. On the other hand, the innovation potential of medical science and health technology will be maximised by an essential and intrinsic share of knowledge and training of both healthcare professionals and consortia with research centres of excellence.

Thereby, there is still the expectation that once the national process of identification, approval and recognition of reference centres is underway - as a mandatory action for the development of competences and differentiation of the Health System - synergies may be created for the purpose of European cooperation in the field of highly specialized healthcare, by promoting economies of scale, maximising efficiency, assuring the cost-effectiveness of performed services, encouraging innovation and spreading good practices.

Therefore:

The Government, represented by the Minister of Health and under the provisions of article 16 of Law no. 52/2014, from August 25th:

Article 1

Object

This ordinance establishes the concept, and the process for identification, approval and

recognition of the National Reference Centres for the provision of healthcare, namely for diagnosis and treatment of rare diseases.

Article 2

Reference Centre

For the application purposes of this ordinance, "Reference Centre" shall mean any health service, department or unit, recognised as the most highly skilled in the provision of high quality healthcare concerning medical situations demanding a concentration of both highly differentiated technical and technological resources, and also knowledge and experience, due to the low prevalence of the disease, its diagnosis or treatment complexity, and/or its high costs - while being able to direct post graduated training and scientific research in the correspondent medical areas.

Article 3

Goals of the Reference Centre

The Reference Centres shall have the following goals:

a) To enhance the diagnostic and treatment capability of several medical and surgical pathologies;

b) To aggregate the ability for synergic response around nosological entities with similarities regarding manifestations, as well as diagnostic and therapeutic approaches;

c) To maximise the innovation potential of medical science and health technology, by carrying out scientific research with international impact;

d) To offer highly specialized healthcare, which shall allow relevant improvements in quality, cost-effectiveness and safety;

e) To provide effective and affordable highly specialized healthcare to patients whose medical condition requires a special concentration of highly differentiated medical knowledge;

f) To disseminate good practices;

g) To contribute towards the structural reform of the hospital sector.

Article 4

Duties and obligations of the Reference Centre

1 – The Reference Centre shall:

a) Integrate in its constitution experienced multidisciplinary teams, highly qualified in their field of action;

b) Acquire highly specialized facilities and equipment that should be preferably concentrated;

c) Guarantee that the health services and healthcare are provided according to the highest quality standards, in compliance with the available medical evidence and with the national clinical guidelines in force;

d) Possess competences in education, training and research areas, by being constituted as an innovation agent, namely in the transfer of their research results.

e) Promote the necessary mechanisms for an efficient liaison between other health units and Reference Centres.

2 – The Reference Centres shall have the following obligations:

a) To promptly and fully comply with the general and specific requirements, which were the bases for their recognition;

b) To publically and regularly publish the results of their activity;

c) To report to the National Committee for Reference Centres any changes or incident that may put at risk the assumptions regarding their recognition;

d) To initiate, within one year time after their recognition, the quality and safety certification and accreditation process for provision of healthcare, by complying with the accreditation model set out by the Directorate-general of Health.

Article 5

Operation of the Reference Centre

1 – The operation of the Reference Centres shall comply with the following principles:

a) Increased quality;

b) Referenced access;

c) Cost-effectiveness;

d) Performance focused on medical results;

e) Decrease of medical risks and improvement of healthcare safety;

f) Transparency of proceedings and results;

g) Assistance activity duly integrated with clinical research and post-graduated training.

2 – The Reference Centres may cover a single or a group of pathologies, as well as techniques and procedures.

Article 6

Recognition process

1 – The recognition process of the Reference Centres shall comply with the following steps:

a) Annual preparation of an assessment on the status and needs of the highly specialized intervention areas, pathologies, techniques or procedures, regarding which Reference Centres must be recognised;

b) Approval by the Government body responsible for the Health sector of the highly specialized priority areas, pathologies, techniques or procedures, regarding which the Reference Centres must be recognised;

c) Definition of specific criteria - based on scientific evidence – according to which the services, units, departments or hospitals intending to obtain recognition as a Reference Centre must comply;

d) Public, objective and transparent application process for services, units, departments or hospitals, regarding recognition as a Reference Centre;

e) Recognition as a Reference Centre.

2- The application process to obtain recognition as a Reference Centre is set out in the regulation attached to this Ordinance, and which is an integral part thereto.

Article 7

Formalisation of recognition

1 – The recognition of a Reference Centre by the Ministry of Health is officialised by an order of the Government body responsible for the Health sector, published in the Official Gazette, and it shall be valid for four years.

2 – The Reference Centres are subject to a periodic evaluation, by an external auditing, regarding the compliance with the general and specific requirements, which were the basis of their recognition.

3 – The recognition of a Reference Centre shall cease by means of an order from the Government body responsible for the Health sector, published in the Official Gazette, if any of the requirements which were the basis of its recognition are no longer met.

Article 8

National Committee for Reference Centres

The National Committee for Reference Centres, hereinafter referred to as Committee, shall be constituted with the following goals:

a) To evaluate the needs in healthcare provision and to identify major intervention areas, for which the Reference Centres should be recognised;

b) To present the national planning of Reference Centres by intervention area;

c) To propose to the Government body responsible for the Health sector, the recognition decision or the correspondent recognition cessation, as a Reference Centre;

d) To determine the specific criteria that applicants must comply with, and which are mentioned in the provisions of paragraph c) no. 1 article 6 of this Ordinance;

e) To design the auditing model to be performed to the services, units or hospitals which are applying to recognition as Reference Centre;

f) To verify the compliance of general and specific criteria, which applicants must comply with;

g) To perform visits to applicants, as they may be necessary under the scope of the evaluation process;

h) To verify the human resources related to the applicant and their suitability;

i) To verify the professional experience of the applicant's professional team, namely the minimal assistance activity, the basic, continuous and post graduate training, as well as teaching and research activities;

j) To verify the disclosure and sharing of knowledge and experience by the applicant, duly attested by the publishing of scientific articles, participation in scientific conferences and articulation with other similar European or international centres;

k) To verify the suitability of infrastructure and equipment of the applicant, as well as the clinical registration method and information systems used;

l) To analyse specific action protocols and programs of the applicant, as well as outcome indicators of clinical intervention.

Article 9

Composition of the National Committee for Reference Centres

1 – The National Committee for Reference Centres is composed by:

a) A physician of renowned merit, who chairs, has a quality vote and represents the Committee;

b) Three physicians of renowned merit, one of which is the vice-president;

c) A personality of renowned merit in the areas of health law, management, administration or economics;

d) A personality of renowned merit in the areas of life sciences, namely in the research field;

e) The representative in the Committee of Cross-border Healthcare of the European Commission, for the areas of European Reference Networks;

f) A representative of the Directorate-General of Health;

g) A representative of the Central Administration of the Health System, I.P.;

h) A representative of the Ministry responsible for the science area;

i) A representative of the Portuguese Medical Association.

2 – The members of the Committee are appointed by means of an order of the Government entity responsible for the health sector, for the duration of five renewable years, and the position may be ceased at any time.

Article 10

Operation of the National Committee for Reference Centres

1 – The Committee operates in plenary meetings summoned by notification of and under the direction of its president or, in his/her absence, of its vice-president.

2 – The Committee may be organised in subcommittees:

3 – The Committee passes a resolution based on a qualified majority of votes.

4 – The Committee executes and approves its internal rules of procedure.

5 – Minutes shall be executed for the meetings of the Committee.

6 – The Committee annually elaborates and submits a report about priority areas for the creation of Reference Centres to the Government body responsible for the Health sector.

7 – The performance of duties within the Committee shall not be remunerated.

8 – The Committee operates within the Central Administration of the Health System, I.P.

9 – The Committee shall have the technical and scientific support of the Portuguese Medical Association, the Directorate-general of Health and the Central Administration of the Health System, I.P.

10 – The Directorate-general of Health and the Central Administration of the Health System, I.P. may, under the provisions of the law and at demand of the Committee, resort to national or international experts according to their professional and scientific experience, considering the necessary pathologies, techniques, procedures or technologies.

Article 11

General criteria for recognition of Reference Centres

1 – For the purposes of recognition, the Reference Centres shall guarantee the compliance with the following general criteria:

a) Total availability of the healthcare services for the area, pathology, technique or procedure, as well as for the clinical, technological and scientific specialisation in which they are a reference;

b) Easy access to other specific resources, units and services, needed for the provision of healthcare to patients, either their own services, or by means of agreements with other services and facilities that guarantee the complementarity and continuity of healthcare;

c) The use of standardized information and coding systems of national, European or international renowned level;

d) Transparency when reporting results, treatment options and quality and safety standards in force at the Reference Centre;

e) Compliance with national laws and regulations in force, namely in terms of informed and clarified consent, guarantee of privacy, claim systems, access to medical records and clinical information, as well as personal data protection of patients;

f) The guarantee of informed consent to patients;

g) The existence of a patient satisfaction evaluation system;

h) The existence of a system for measuring and disseminating the patients' experience;

i) The publication of prices practiced by the Reference Centre.

2 – For purposes of recognition, the Reference Centres shall have:

a) The capacity to provide vital medical healthcare in case of sudden fail of resources or guarantee referral to alternative resources;

b) Systems that allow sharing knowledge and expertise at national, European or international level, by means of communication and electronic tools in the scope of telemedicine and e-health;

c) The capacity of cross-border communication after patient discharge;

d) The capacity for education and training, including distance learning, at specialized and academic levels, in their field of knowledge and expertise;

e) The capacity for research in their field of knowledge and expertise, including collaborative research and participation in European and international research networks;

f) The capacity to create and maintain databases and biological material banks in their intervention areas, which will be made available pursuant to the strictest best practice guidelines of national and international level, to all interested Portuguese and foreign researchers/physicians;

g) Indicators of quality, structure, process and outcome;

h) The capacity to compare quality and safety results, as well as national, European and international dissemination of best practices;

i) A plan for the continuity of activities that ensures sustainability, namely in terms of human resources and technological updating, within a five year timeframe.

3 – For the purposes of recognition, the Reference Centres shall demonstrate:

a) The development of multidisciplinary activity;

b) Their competence, expertise and activity;

c) A case history analysis according to international standards;

d) The production of good clinical results, according to the available scientific evidence;

e) The type, number, qualifications and competences of human resources;

f) The characterisation of specific equipment, including that of e-health, in order to demonstrate that they have the ability to process, manage and exchange imaging information with other healthcare providers;

g) The ability to ensure the quick access to specific equipment within or outside the Reference Centre;

h) The ability to cooperate with other Reference Centres, either at national, European or international level;

i) The availability for technical monitoring of other national services or units in specific areas of cooperation;

j) The evidence of explicit and transparent administration and management rules and practices, that include procedures related to cross-border patients management in their field of knowledge and expertise.

Article 12

Affiliated Centre of the Reference Centre

1 – Other similar services or units called Affiliated Centres may become associated at any given time to the Reference Centre, since they do not fulfil every condition and requirement to be recognised as Reference Centres.

2 – The Affiliated Centre of a Reference Centre is subject to technical monitoring, in the specific field of cooperation, by the Reference Centre to which it is associated to.

3 – The previous association and the mutual acceptance of the technical monitoring by the Reference Centre shall be officialised by means of a cooperation agreement.

4 – The Affiliated Centre of the Reference Centre holds the knowledge and expertise within a specific and allotted area of the Reference Centre.

5 - The Affiliated Centre of the Reference Centre provides healthcare, training or research activity, in a complementary way to the one of the Reference Centre it is affiliated to.

6 – The cooperation agreement mentioned in no. 3 shall specify the complementary activity of healthcare provision, training and research carried out by the Affiliated Centre of the Reference Centre, under the scope of the cooperation agreed with the Reference Centre it intends to be associated to, and this shall be notified to the National Committee for the Reference Centres.

7 – An Affiliated Centre may also be a Research Unit - licensed by the Foundation for Science and Technology/Ministry of Education and Science - that supports the Reference Centre in the execution and direction of the scientific research carried out by the Reference Centre.

Article 13

Hospital Referral Model of the National Health Service

1 – The integration of the Reference Centres of the National Health Service, or those that agree provision of healthcare with the latter in the National

Networks of Hospital and Referral Specialities is based on a new cooperation model between medical specialities, conveying two newly created realities:

a) Hospital services organized in referral networks;

b) Reference Centres constituted as highly specialized centres of multiple hospital referral networks with Affiliated Centres.

2 – The recognition of the Reference Centres determines:

a) The preparation of strategic plans by the Central Administration of the Health System, I.P., ensuring the adequate articulation between services and the organized flow of patients;

b) The immediate reformulation of the National Networks of Hospital and Referral Specialities covered by the considered intervention area, pathology, technique or procedure, according to the plans mentioned in paragraph a).

Article 14

Temporary standard

The existing centres of high differentiation, centres of excellence, treatment centres or others alike, will gradually cease such qualification, insofar as the recognition of Reference Centres occur in their correspondent intervention area.

The Minister of Health, Paulo José de Ribeiro Moita de Macedo, on the 26th of September 2014.

ANNEX

REGULATION OF THE APPLICATION PROCESS FOR THE RECOGNITION OF REFERENCE CENTRES

Article 1

Applicants

The healthcare providers may apply for recognition of a Reference Centre by the Ministry of Health, whenever there are services, units or departments that fulfil the general and specific requirements described in the opening notice of the application process.

Article 2

Definition of intervention areas

The priority intervention areas under which Reference Centres should be recognised are annually defined by means of an order of the Government body responsible for the Health sector, under proposal of the National Committee for the Reference Centres until the 31st of December of the previous year to which it applies.

Article 3

Opening of applications

1 – The opening of applications for recognition of a Reference Centre shall be preceded by a proposal for the intervention areas, pathologies, techniques and/or procedures, under which the Reference Centres should be constituted, defining the national implementation ratios, according to transparent principles, centred, among others, in population rate analysis, accessibilities, balance between supply and demand, epidemiology and available services.

2 – The above mentioned proposal shall be submitted to the Government body responsible for the Health sector by the president of the National Committee for the Reference Centres.

3 – The recognition process of a Reference Centre by the Ministry of Health shall be initiated with the publishing of a notification by the Directorate-general of Health for submission of applications, and establishing the specific applicable criteria.

4 – The opening notice of the application process shall be published by the Directorate-general of Health in the Official Gazette and on its website.

5 - The opening notice establishes the terms and conditions for submission of applications.

6 – The application process shall be supported by documents demonstrating evidence of compliance with the general and specific applicable requirements, as well as of the legal standards applicable to the healthcare provision activity.

Article 4

Evaluation of applications

1 – The National Committee for the Reference Centres is responsible for the application evaluation.

2 - The National Committee for the Reference Centres evaluates the applications according to the requirements described in the opening notification of the application process.

3 – Whenever necessary, the National Committee for the Reference Centres may require additional documents and clarifications from the applying entities.

4 - The National Committee for the Reference Centres prepares an evaluation report of each application, which is then notified to the board of the applying institution, in compliance with the provisions of the Code of Administrative Procedure regarding a fair hearing.

5 - The National Committee for the Reference Centres prepares a final report involving all applications for the purposes of article 8, paragraph c) of this Ordinance.

Article 5

Periodic evaluation

1 – The periodic evaluation, by external auditing, of the compliance with the general and specific requirements, which were the basis for recognition of the Reference Centres, shall be carried out of the National Committee for the Reference Centres, without prejudice towards the support given by other institutions of the Ministry of Health.

2 - The National Committee for the Reference Centres shall prepare an annual report on the periodic evaluation activities foreseen above.