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ROYAL DECREE 1302/2006 of 10th November 2006, that establishes the foundations of the procedure to designate and accredit benchmark centres, departments and units of the National Health Service

The Spanish Constitution contemplates health as a two-fold fundamental human right (Article 15), endowed with reinforced legal guarantee, with services entrusted to the public authorities who will be in charge of arranging and protecting public health through preventive measures and appropriate services (Article 43).

This second aspect of services is implemented by Law 16/2003 of 28th May 2003 on Cohesion and Quality of the National Health Service (NHS) that acknowledges that all users of the NHS have the right of genuinely equal access to health care services irrespective of the part of the country where they live. In particular, this law guarantees that all users will have access to benchmark facilities, as previously stipulated in Article 15.2 of the General Law of Health 14/1986 of 25th April 1986.

These benchmark facilities exist to treat any disease with characteristics that require highly specialised care; this entails the need to concentrate, in a reduced number of centres, the cases to be treated or the preventive, diagnostic or therapeutic, techniques, technologies or procedures, needed to guarantee the quality, safety and efficiency of health care.

Benchmark facilities will be designated by the Interterritorial Council of the National Health Service that will also determine the number of benchmark facilities required and their strategic location within the NHS, with comprehensive based approach planning. In connection with the criteria followed to determine benchmark facilities, the foregoing law and this Royal Decree will include the Autonomous Regions of the Canary Islands and the Balearic Islands as strategic components of the National Health Service.

The Ministry of Health and Consumer Affairs must accredit facilities that are designated benchmark facilities in line with the quality criteria established for each one, and must also re-evaluate them.

From the financial point of view, healthcare at a benchmark facility will be funded by the Healthcare Cohesion Fund as it is stipulated in Article 4.B) c) of Law 21/2001, of 27th December, which regulates tax and administrative measures in the new funding system for Autonomous Regions and Cities with Statute of Autonomy, governed by Royal Decree 1207/2006 of 20th October 2006, which regulates the management of the Healthcare Cohesion Fund.

All of the foregoing indicates the importance of this Royal Decree that states the principles established in the Spanish Constitution and in Law 16/2003 on Cohesion and Quality in the National Health Service, and determines the foundations of the procedure to designate and accredit benchmark centres, departments and units of the National Health Service.

This Royal Decree has already been endorsed by the Interterritorial Council of the National Health Service.



By virtue of the foregoing, at the request of the Minister of Health and Consumer Affairs, following approval by the Minister of Public Administration, in accordance with the State Council and after deliberations held by the Council of Ministers at its meeting of 10th November 2006,

I HEREBY DECLARE:

Article 1: *Aim*

The aim of this Royal Decree is to guarantee equal access to high-quality, safe, and efficient healthcare for persons with diseases whose characteristics require highly specialised care, and the need to concentrate the cases to be treated in a small number of centres, as well as to establish the foundations of the procedure to designate and accredit benchmark centres, departments and units of the National Health Service, in accordance with a comprehensive planning, thereby implementing Law 16/2003, of 28th May 2003 on Cohesion and Quality in the National Health Service.

Article 2: *Benchmark Centres, Departments and Units*

For the purposes of this regulation:

1. The following terms have been established:

- a) Benchmark centre: a centre that is essentially engaged in caring for particular diseases or groups of diseases that meet one or more of the criteria stipulated in section 2 of this article.
- b) Benchmark department or unit: a department or unit that is engaged in performing a technique, technology or procedure or in caring for particular diseases or groups of diseases that meet one or more of the criteria stipulated in section 2 of this article, even if the department or unit also provides care for other diseases for which it does not have benchmark status.

2. Any diseases or groups of diseases for which prevention, diagnosis or treatment are provided using techniques, technologies or procedures included in the common health service portfolio provided by the National Health Service, at benchmark centres, departments or units of the National Health Service, must meet one or more of the following criteria:

- a) Diseases that require, for their appropriate treatment, highly specialised preventive, diagnostic and therapeutic techniques, technologies and procedures, for which experience is essential, and which can only be achieved and maintained through certain volumes of activity.
- b) Diseases that require high technologies for their prevention, diagnosis or treatment, and for which a minimum threshold number of cases must be concentrated together as a result of their cost/effectiveness ratio and the available resources.



- c) Rare diseases that, due to their low prevalence, require concentration of cases for their adequate care. This does not entail continuous patient care at the benchmark centre, department or unit, but these may provide support by confirming diagnosis, defining treatment and following-up strategies, as well as acting as a consultant body for clinical units that regularly care for these patients.

3. For the purposes of awarding benchmark status to centres, departments and units, healthcare, provided to citizens that for reasons of proximity or geographical accessibility or for other reasons visit a hospital or a medical institution in an autonomous region different from the one where they reside, will not be taken into account unless the provisions established in section 2 are met.

4. The benchmark centres, departments and units of the National Health Service will provide care for the whole country, and must guarantee all NHS users that need them equal access, regardless of their place of residence.

Article 3: Criteria for the Designation of Benchmark Centres, Departments and Units

1. The criteria developed for the designation of benchmark centres, departments and units must address at least the following:

- a) Show proof of sufficient knowledge and experience in handling the disease, technique, technology or procedure in question;
- b) Have sufficient past or forecasted volume of activity in the technique, technology or procedure for which designation as a benchmark hospital, department or unit is being requested, guaranteeing appropriate levels of quality and safety for patients;
- c) Count on the necessary equipment and staff to carry out the activity in question;
- d) Have required resources available for appropriate patient care, in addition to those of the benchmark department or unit itself;
- e) Gather-appropriate outcome indicators before designation;
- f) Have a reporting system that can be used to find out activities and to assess the quality of the services provided; and
- g) Have training resources for other professionals in the activity designed as benchmark.

2. The Benchmark Centre, Department and Unit Designation Committee will draw up a list of proposed specific designation criteria for benchmark centres, departments and units, in line with the type of activity for which they are designated. This will be presented to a plenary session of the Interterritorial Council of the National Health Service.



Article 4: *Benchmark Centre, Department and Unit Designation Committee*

1. The Benchmark Centre, Department and Unit Designation Committee is hereby created. It is dependent on the Interterritorial Council of the National Health Service, to which this Committee will present its proposals. It is entrusted with the following tasks:

- a) Analysing the needs and proposing the diseases or diagnostic or therapeutic techniques, technologies and procedures for which it is necessary to designate benchmark centres, departments or units, and to determine the appropriate number thereof and their strategic location, on the basis of the criteria stated in this Royal Decree;
- b) Proposing the procedure for the designation of benchmark centres, departments and units in the National Health Service;
- c) Proposing criteria for the designation and accreditation of benchmark centres, departments and units in the National Health Service, based on the provisions of this Royal Decree;
- d) Providing information on the procedure to certify benchmark centres, departments and units;
- e) Evaluating the received designation requests and making proposals for the designation of benchmark centres, departments and units to the Interterritorial Council of the National Health Service;
- f) Examining and proposing the renewal or revocation, as applicable, of the designation of benchmark centres, departments and units;
- g) Proposing the procedure for referring users to benchmark centres, departments and units;
- h) Drafting the Committee's internal regulations; and
- i) Other matters entrusted to it in connection with benchmark centres, departments and units.

2. The Benchmark Centre, Department and Unit Designation Committee will be chaired by the head of the Directorate General for Cohesion of the National Health Service and Senior Inspectorate. Its members will include a representative of each autonomous region, the National Institute of Healthcare Management, the Sub Directorate of Economic Analysis and the Cohesion Fund, the Carlos III Institute of Health, the Quality Agency of the National Health Service, and the National Transplant Organisation.

In order to guarantee the execution of the tasks entrusted to this Committee, a Secretarial Department is hereby established. This will be managed by the head of the Sub Directorate of Health Service Portfolio and New Technologies.

The Benchmark Centre, Department and Unit Designation Committee may invite experts in any fields it deems appropriate to its sessions as advisors. These experts



would have the right to speak but not to vote. The Committee may promote the creation of working groups in any events or circumstances in which it deems necessary.

Article 5: Procedure for the Designation of Benchmark Centres, Departments and Units

1. Any proposals to initiate a procedure to designate benchmark centres, departments and units will be made by the Ministry of Health and Consumer Affairs or by the autonomous regions through the Benchmark Centre, Department and Unit Designation Committee.

2. The procedure for designating benchmark centres, departments and units will be implemented through the Benchmark Centre, Department and Unit Designation Committee regulated by Article 4.

3. Benchmark centres, departments and units included in the proposals must always:

a) Hold the necessary medical permit according to the provisions of Royal Decree 1277/2003 of 10th October 2003, which establishes the general foundations for the authorisation of medical centres, units and institutions, and applicable autonomous regions' regulations on the subject.

b) Hold a favourable report from the relevant authority of the autonomous region in which they are located.

4. The Ministry of Health and Consumer Affairs, through the Quality Agency of the National Health Service, will accredit the centres, departments and units proposed by the Benchmark Centre, Department and Unit Designation Committee, subject to the responsibility areas in this field of the autonomous regions.

5. Benchmark centres, departments and units will be designated via a resolution issued by the Ministry of Health and Consumer Affairs, following an agreement adopted by the Interterritorial Council of the National Health Service, for a maximum term of five years. Before the resolution expires, the designation must be renewed, provided that the Quality Agency of the National Health Service has re-evaluated the centre, department or unit, and the criteria for their designation continue to be met.

6. The Ministry for Health and Consumer Affairs will publish and keep updated a list of the benchmark centres, departments and units of the National Health Service.

Article 6: Review of the Designation of Benchmark Centres, Departments and Units and the Techniques, Technologies and Procedures Performed

1. If a centre, department or unit no longer meets one or more of the criteria according to which it was awarded benchmark status, the Ministry of Health and Consumer Affairs, following a resolution adopted by the Interterritorial Council of the National Health Service, will revoke this status.

2. The Ministry of Health and Consumer Affairs, following a resolution adopted by the Interterritorial Council of the National Health Service, will review the techniques, technologies and procedures for which benchmark centres, departments or units have



been designated at least once every five years, in order to determine whether they should retain benchmark status or whether they should be considered general facilities within the National Health Service.

Article 7: Accreditation of Benchmark Centres, Departments or Units

The Ministry for Health and Consumer Affairs, through the Quality Agency of the National Health Service, will draw up the auditing handbook and procedure for the accreditation of benchmark centres, departments and units of the National Health Service, with the criteria established by a proposal of the Benchmark Centre, Department and Unit Designation Committee of the National Health Service.

Article 8: Obligations of Benchmark Centres, Departments and Units

The designation of a benchmark centre, department or unit entails the following obligations:

1. To establish and maintain the reporting system stipulated in Article 3.1.f);
2. To provide any information requested at any time to verify that the designation criteria have been met;
3. To report any change in the criteria according to which it was awarded benchmark status;
4. To report any incidents affecting care for the diseases or diagnostic or therapeutic techniques, technologies and procedures for which it was awarded benchmark status; and
5. To undergo the renewal of designation stipulated in Article 5.5.

Article 9: Funding

The Healthcare Cohesion Fund, stipulated in Article 4.B).c) of Law 21/2001 of 27th December 2001, will fund any healthcare referred among autonomous regions to a benchmark centre, department or unit of the National Health Service. This funding will apply only to the diseases or diagnostic or therapeutic techniques, technologies and procedures for which the centre, department or unit has been awarded benchmark status, and in the conditions and quantities reflected in the relevant appendix to the Royal Decree governing the Healthcare Cohesion Fund. For the Autonomous Regions of the Canary Islands and the Balearic Islands, compensation will also include care for processes of patients transferred from islands within the autonomous region other than the island on which the benchmark centre, department or unit is located.

Sole Clause of Revocation: Revocation of Regulations

Any provisions whose status are of equal or lower rank than this Royal Decree and that contradict the provisions of this Royal Decree are hereby revoked.



First Final Provision: *Jurisdiction*

This Royal Decree is hereby issued according to the provisions of Articles 149.1.1 and 16 of the Spanish Constitution.

Second Final Provision: *Enabling Regulations*

The Ministry of Health and Consumer Affairs will issue any provisions required for the application of the provisions of this Royal Decree.

Third Final Provision: *Effective Date*

This Royal Decree will come into force on the day following its publication in the Official State Gazette.

Issued in Madrid, on 10th November 2006.

H.M. JUAN CARLOS

ELENA SALGADO MÉNDEZ,
Minister for Health and Consumer Affairs