This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

Civil law

**National law database**

- **Language**: Spanish
- **Link**: [www.boe.es](http://www.boe.es)
- **Nature**: Official state gazette
- **Organisation responsible for the website**: Official state gazette agency, a public body attached to the ministry of the presidency of Spain

**Legal UHC start date**

1986


**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
Search list of contents:

Regulation

Overview and publication details .................................................. 2
Regulation Spain ............................................................................ 3
Regulation

Spain

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Spain: Regulation

4. Regulation and planning

4.1 Regulation

Chapter 2 has already described many key regulatory arrangements in Spain from the organizational perspective (e.g. the relationship between the public and the private sector, the respective roles of the central and regional governments, population coverage, entitlements and benefits, patients’ rights, etc.). This section will now review some additional regulatory aspects and elaborate further on a number of issues already outlined in the preceding sections.

Regional governments usually have their functions regarding health divided between a health authority, that is, the regional health ministry or health department (Consejería de Salud) and the regional health service. Normally, apart from being the health authority, the health department is responsible for regulation and strategic planning (including health care planning) while the regional health service is responsible for operational planning, management of the services network and coordination of health care provision. A previously integrated formula (authority, planners, purchasers and providers being part of the same organization) gave way to this split in the early 1990s, when the need to introduce market-simulation elements to achieve efficiency in highly integrated public health care systems became “common wisdom”. In this same spirit, regional health services have adopted a variety of legal statutes in an attempt to gain flexibility and autonomy, making the provider role more credible; thus 11 regional health services have taken on the form of “administrative autonomous body”; another 5 have adopted the form of “public entities” and the remaining 1 is a “regional public corporation”.

In reality, however, “purchasing” decisions are closely related to the running of the existing facilities and staff. Obviously, the consequences of letting one of these providers fall out of the market are unbearable for any health administration accountable for maintaining access to care and obliged to find an immediate replacement (quite unlikely, given the huge costs for newcomers to enter the market and the lack of existing alternatives, whether private profit-making or not, in most of the territory). Thus, the actual approach in this split of functions is mainly modernization of managerial formulas within the SNS to enhance flexibility, rather than the introduction of market elements. In this sense, a positive consequence can be pointed out, neatly derived from the progressive introduction of an evaluative culture that the system lacked before. The link between budget and activity has been stressed, with the aim of enhancing efficient use of resources, and thus output measurement has become routine practice, although outcome and costs measurement are still lagging behind. Nevertheless, the current speeded-up progress in refining and standardizing information systems (see Section 4.2 Planning and health information management) is starting to boost meaningful benchmarking and outcome assessment is gaining some momentum.

The basic tool mediating the relationship between the health department and the regional health service is the contract-programme, already described in Chapter 3. Basically, the contract sets the objectives (derived from the regional health plan and the regional strategic plan), the budget and the evaluation system. It is negotiated every year, forcing both parties to reflect on what they produce and how; this exercise should ground strategic thinking on performance improvement. Beyond the rhetoric, evidence of that effect is hard to detect, partly because of the continuing relative weakness of information systems and the well-known resistance to change of organizations and individuals.

As mentioned in Chapter 3, each regional health department has drawn up a health care map stipulating administrative territorial subdivisions (health areas and zones), which often do not correspond with municipalities or other political-administrative landmarks. These basic units are conceived as the cornerstone of the managerial structure, building up the organization of the regional health system. In fact, they were already set before the completion of the devolution of health competences; however, most regional health authorities have reshaped their health care maps to match demographic changes and other local needs. According to the 1986 Health Care General Act, health areas are defined accounting for geography, socioeconomic standards, demography, employment, epidemiological factors, cultural...
concerns, transportation and health facilities available; each area should cover a population of no less than 200,000 inhabitants and no more than 250,000.

The following services are provided in the health areas:

- primary health care: defined as care for individuals, families and the community at large through programmes including health promotion, prevention, curative care and rehabilitation; and
- specialized (outpatient and inpatient) care: each health area is linked to, or served by, at least one general hospital. Specialized ambulatory care is provided through a public network of community polyclinics (centros de especialidades), integrated with hospitals, and in most cases staffed by the same teams (with members rotating to cover visits at the polyclinics).

Usually, two managerial structures coexist in each area, one in charge of primary care and the other dealing with specialized care. This two-tiered structure was intended to give primary care a new status and relevance, as required by the political reform in the 1990s, and to counterbalance the traditional power and influence of hospitals in the health services structure (see Chapter 2 for an explanation of the historical development of both networks). Managerial teams, both primary and specialized, are appointed by and accountable to the regional health service; their specific organizational arrangements depend on the region. This two-headed approach has created a fair amount of issues in terms of coordination of care: its role in disrupting continuity of care has been part of the expert debate for the last two decades (SESPAS 2008). Initiatives to improve continuity of care have multiplied over the years, adopting the form of clinical paths and coordination protocols (Andalucía can be cited as a prolific example). However, the underlying rivalry between the two levels of care and the organizational barriers set by different management priorities have rendered all these initiatives hard to implement and evidence about outcomes is still scarce. Several ACs have initiated innovations shifting to integrated area management schemes; this is still not the most frequent arrangement, and even in those regions (Andalucía, Aragón, the Balearic Islands, Canary Islands, Catalonia, Galicia, Navarra) integrated area schemes remain at a pilot scale; nonetheless, progress in that direction seems to be gaining momentum across the SNS.

A further subdivision of the territory is contemplated; basic health zones are the smallest units of organization. Each is defined in accordance with the degree of concentration of the population, the epidemiological characteristics and the facilities and health resources in the area. The criteria used in defining them is standard travelling time – set as maximum of 30 minutes away from the location of services; therefore the range of variation in population covered per basic health zone is wide: between 5000 and 25,000 inhabitants. They are usually organized around a single PCT, which is also the main management unit of the zone, coordinating prevention, promotion, treatment and community care activities. The director of the PCT (usually a medical doctor who continues his/her clinical work) generally reports to the primary care area manager.

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13 Set out by the regional health department, these plans are normally renewed every four or five years.

14 Generally, health maps do not include, or necessarily overlap with social services maps, which in most cases depend upon a different regional administration (with the notable exception of Catalonia; see: Generalitat de Catalunya, Departament de Salut 2007). Nevertheless, in most cases, social workers are part of the staff both in PCTs and hospitals and some long- to medium-term care facilities are included in the health care provision structure, exemplifying the presence of “paradisexual” split while overlapping of health and social services administrations.

### 4.1.1 Regulation and governance of third-party payers

In the structure just described, there is not much room for third-party payers. Nevertheless, two ACs – Catalonia and Madrid – have explicitly regulated for the existence of a third-party payer in charge of purchasing services in their territory.

In Catalonia, the Health Department (Departament de Salut) is in charge of financing, planning and monitoring health services; the Regional Health Service (CatSalud) is the purchaser and provision is made through the Catalan Hospital Network of Public Utilization (XHUP). This Network includes both public and private providers (the historical justification for this peculiarity was provided in Chapter 2), some of which are directly under the management of a separate organization within the regional government (Institut Català de Salut (Catalan Institute of Health), ICS). However, the majority comprises a variety of providers,
including consortiums and municipal associations, public corporations, private foundations, workers’ mutualities, religious charities, private firms and professional associations/ cooperatives constituted to manage PCTs (Entitats de Base Associativa, associative-based entities/EBAs) (see further details in the next subsection Regulation and governance of providers).

The model in Madrid differs slightly. The Regional Health Service (SERMAS) is the purchaser in charge of shaping and allocating the health care budget, while the Health Department (Consejería de Salud) is responsible for the health authority and planning functions. The main difference from the Catalan model is that SERMAS itself is also the main provider. Nevertheless, besides a long-standing concession to the international health care corporation that manages the Hospital de la Concepción (originally a private foundation) for the provision of specialized care in one of the basic areas, SERMAS has recently embarked on some private sector partnerships. Most of this innovation is linked to eight new hospitals built with the participation of private initiative (the exact formula is administrative concession for building and management of public services), staffed by SERMAS and owned and managed by the companies who rent them out for public use (see next subsection Regulation and governance of providers).

The third-party role of SERMAS might be reinforced with the adoption of the single area. As outlined in Chapter 2, Madrid is about to collapse the current health care map, with its 11 health care areas, into a single area covering more than 6 million people. The aim is the full achievement of patient choice as regulated in Law 6/2009, 16 November, on the freedom of choice in health care in the Autonomous Community of Madrid, opening the way for patients to pick the centre or professional of their choice among the public providers and eventually, depending on factors such as waiting lists for certain procedures or specialist’s visits, they would also be covered to go to private providers. This project has aroused some controversy; it is unclear how this freedom of choice would work with the existing gatekeeping function of family doctors in the system. On the other hand, some experts (Repullo 2009) question the need to eliminate territorial management structures in order to achieve free choice of providers for patients; instead, these experts stress the potential for expanding the share of profit-seeking private providers as the real driving force of the reform. In any case, should the project of single area be implemented, the role of SERMAS as a third-party payer would probably be strengthened. It is worth recalling that voluntary private insurance purchasing in Madrid is quite well above the national average – more than 20% of the population – and the concentration of profit-making private providers is quite high compared to other parts of the country. This measure could provide a further stimulus for activity in this sector.

17 This change in organization requires the approval of two draft decrees currently under discussion at the regional parliament. Both are intended to develop the framework set by the mentioned Law 6/2009. One of the draft decrees regulates the mechanics for exercising freedom of choice and the other sets the basic management structures for primary care under the new single area scheme (Comunidad de Madrid 2009, 2010)

4.1.2 Regulation and governance of providers

As detailed above, most of the providers of the SNS are within the public sector and the predominant governance model still has many elements of direct management inherited from the original integrated structure. The main tool of this model is also the contract-programme described earlier in this section and in Chapter 3. The contract-programme signed between the health department and the regional health service every year cascades down the managerial structures: each primary care area and specialized care area management team will negotiate their specific contract-programme with the regional health service and, in turn, will negotiate one each with the PCTs and hospital management in the area. Obviously, the objectives, budget and evaluation system of these contracts originate in the mentioned annual contract-programme negotiated between the regional health service and the regional health department. Indeed, the vast majority of final providers of care are part of the regional health service structure and are not autonomous legal entities. Thus, the contract-programme works as a tool of management by objectives, incorporating incentives to reinforce certain strategic lines. There is no stated penalty for failure to achieve objectives, nor any real risk-transfer to the providers; nevertheless, intervention is warranted to identify the reasons behind underperformance and eventually correct them. Some positive financial incentives derived from the accomplishment of certain strategic goals (for example, rational prescription, use of generic drugs, reduction of waiting times for certain procedures, etc.) are at stake for teams, and eventually for individual professionals, even so they are always marginal to the bulk of remuneration.

Besides this prevailing model, as shown in Fig 4.1, there are some other forms of provider governance.
where providers are still under direct management but have a legal personality that is separate from the regional health service. 18 Fig4.1 also recapitulates the different legal formulas available. All these direct management formulas can be placed on a gradient based on the regimes of contracts, staff and budget; at one extreme would be the strict constraints imposed by the public administration law, while the other end of the range corresponds to frameworks resembling private firms that are subject to private law (although the property may remain public and the mission of the organization is still public service). The relaxation of the straitjacket of public law and the move into private law may affect some or all of these three elements, presenting regional governments with a whole range of formulas to choose from. Table4.1 summarizes the main features of the existing direct management formulas.

The consortium formula has been widely used in Catalonia (though not exclusively there) as a legal mechanism to pull together different administrations that already provide a service (mainly hospital care) to a certain population of reference, or that own the structures required to provide it, in order to do so more effectively. Some examples are the Consorci Hospitalari de Vic, Consorci Sanitari Hospitals de Barcelona or Corporació de Salut del Maresme i la Selva, all of them in Catalonia.

Public foundations constitute a particular variant of these direct management formulas established under the 30/1994 Act on foundations and tax incentives for private participation in general interest activities. Hospital foundations are entities with their own legal status, which are run by a board supervised by the public health authorities (the same bodies that contract their services and thus decide on their income). Some hospitals in the Balearic Islands, Galicia and Madrid have taken this form. It is worth noting that this formula has been applied in order to launch new hospitals rather than for existing institutions to make the shift.

Some other organizational innovations have come about in recent years aimed at enhancing care quality and fostering health professionals’ involvement in decision-making. Several clinical institutes (grouping together different services subject to internal coordination) and clinical units have been created. They have generated an ample catalogue of experiences in delegating different forms and ranges of power to clinical groups. Examples of clinical institutes are the Cardiovascular Institute of the Ramón y Cajal Hospital in Madrid, the Oncology Institute of the Virgen Arrixaca Hospital in Murcia and the Heart Institute of Hospital Juan Canalejo in Coruña, Galicia. Virgen del Rocio Hospital in Andalucia has been totally reorganized into clinical departments or institutes following a clinical management logic.

Regarding the formulas of indirect management, in most of the ACs contracting out is confined to the provision of complementary diagnostic tests and ambulatory procedures, and to ancillary services such as hospital catering, laundry, maintenance, cleaning and security. In fact, the outsourcing of auxiliary services to private companies has become quite an extended practice, to the point that integrated provision is being abandoned in most of the system. These contracts, subject to public tendering, usually take the form of concession to a private firm of the management and provision of such specific services within public premises using their own means. The public administration holds the right of inspection to monitor the conditions of service provision. The duration of the concession may vary, but generally exceeds a one-year period.

On the other hand, when it comes to clinical services, the most common contracting methods are covenants or agreements for provision of very specific diagnostic or surgical services with private providers. 19 The providers can present any of the legal formulas listed in Fig4.1 under the heading indirect management. Once this type of arrangement is in place, the patient in need of the service is identified by health professionals in the regional health service structure; patients can be referred to the private provider (normally depending on priority or relative simplicity of their condition) who delivers the intervention and sends the patient back to the system. These providers are generally paid on a “fee-for-service” basis; a minimum threshold for volume of cases can be set in the contract based on estimated need; rates for this agreed package may entail different fees, which are negotiated in advance. This contracting out is often related to the reduction of waiting lists; however, in some cases it can be linked to the decision to buy high-technology services for a certain population from an already established private provider rather than bearing the costs of installing the new equipment.

Two of the legal formulas that providers can adopt under the indirect management model deserve some further description due to their peculiar nature. The first is the Entitats de Base Associativa (EBAs); they were introduced in Catalonia in the 1990s in experimenting with the GP-fundholders model. An EBA is a
group of primary care professionals constituted as an enterprise with its own legal personality. EBAs contract with the regional health service to manage a basic health zone, becoming the PCT of reference. They may be also given a budget for purchasing intermediate products and for outpatient consultations. This contract introduces explicit financial co-responsibility mechanisms.

The second legal formula has given rise to the most radically new (and also most controversial) experiences in the organization of care provision; it is the administrative concession to a corporation or a temporary union of enterprises for the provision of care to an entire basic health area. The model was first introduced in the Alzira area in Valencia. In 1999, the regional government granted a concession for hospital care provision in Alzira to a temporary union of companies led by a private insurer, Adeslas; the contract was established for a 10-year period in exchange for the building of the local hospital La Rivera. Payments to the concessionaire are made on a per capita basis. However, the original concession ended in 2003; the profitability of the formula was under question and finally the concessionaire, UTE Ribera Salud, was reimbursed by the regional administration for the initial investment in running the hospital, plus compensation for the six-year benefit forgone because of the early termination of the contract. A new concession replaced the previous deal, increasing the per capita payment and expanding in scope to include primary and ambulatory care; thus, virtually all publicly funded health care in Alzira is to be provided by the concessionaire. The contract was assigned to the same group, this time with a foreseen duration of 15 years, until 2018. Theoretically, citizens have the possibility to choose where they will be treated; thus, if an Alzira protected patient decides to seek care outside the integrated area, the concessionaire should reimburse the alternative provider with 100% of the average cost of DRG. If the situation reversed, that is, a patient from another area chooses Alzira services, the concessionaire would be reimbursed 80% of the average cost of DRG by the regional health service.

The main source of controversy is whether there are enough efficiency gains to offset the costs, which must include the companies’ profit (or compensate them for income lost), the transaction and monitoring costs derived from follow-up, and quality and equity concerns. The Valencia Health Service (SVS) pioneered and advocated this model as a way to obtain needed health care structure (a new hospital) without compromising the regional budget (the classic private finance initiative (PFI) argument). Critics have argued that costs have in fact escalated (though spread out over time, putting a 20-year mortgage on Valencia health budgets) with no demonstrable outcome benefit for the population served. Nevertheless, the model has been extended within Valencia, with four other administrative concessions already running in Torrevieja (2006) and Denia, Manises and Eix-Crevillente (2009). Overall, about 16% of Valencia’s population is served under this model. Madrid has also adopted the formula for one of the eight new hospitals (Valdemoro) and the four additional planned hospitals, all included in its General health infrastructures plan 2007–2011. The “administrative concession” has actually become the “flagship” of health policy for conservative regional governments. Unfortunately, the debate about the pros and cons of the formula has suffered from too much partisan struggle and propaganda, and too little data and rigorous comparative assessment. Indeed, the recent parliamentary call to carry out an independent expert assessment of the functioning and impact of these innovations in the SNS is a welcome development, and will hopefully shed some light on the issue.

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18 Many of them came as “brand new” formulas derived from the Organic Law for new management formulas in public administration (60/97 LOFAGE), approved in 1997.

19 Another typical case is the contracting out of medium- and long-stay services to non-profit-making private institutions (often owned by religious orders). These services normally involve dependent elderly patients and chronic psychiatric patients. These contracts often constitute a support for regional health services in coping with the scarcity of resources of these sorts within the SNS.

20 The other seven new hospitals were also built under PFI schemes, but health care management is run by a public enterprise and the staff regime comprises a mix of statutory and general labour law contracts. Some other examples of this formula can be found in Catalonia, Castilla-León and the Balearic Islands.
Fig41: Health care organizations’ governance models in Spain

Diagram showing the governance models in Spain:
- Health services management
  - Indirect management
    - External contracting methods/contractual linkage
      - Covenant
      - Agreement
      - Concession
      - Renting
  - Legal formulas
    - Cooperative
    - Labour corporation
    - Corporation with a majority of private ownership
    - Private foundation
  - Integrated/direct management
    - Public body with no differentiated legal entity
    - Autonomous administrative organization
    - Consortium
    - Public foundation
    - Public corporation
    - Administrative body
    - Public firm entity
Table 41: Formulas for providers under direct management in the SNS

Source: Martín Martín 2003.
4.1.3 Regulation and governance of the purchasing process

As outlined in the sections above, the purchasing process in the SNS is overwhelmingly framed within the described contract-programme, with public providers subject to different direct management modalities. As the system matured, new contract-programmes came to include far more specific clauses prescribing the nature and quality of services and assessment procedures.

Regarding contracting with legally independent providers (those detailed under the indirect management category in the previous section), the regional ministry of health/health department sets an overall budget and issues guidelines to be followed by the regional health services (or the INGESA in the case of the two Spanish autonomous cities located in the African continent), which have delegated powers for using those pre-established resources. Thus, in most cases, the regional health services or INGESA are the actual counterpart in contracting services from those providers. There is an enormous degree of variation in contractual details. These agreements may be of either one-off or ongoing nature. In the latter case, specifications should allow for ensuring both financial viability and the possibility of mid-term investments necessary to ensure a technological fit with the purchasers’ needs.

4.1.4 Regulating quality of care

The SNS Cohesion and Quality Act clearly sets out the basis for establishing a national framework to monitor and improve quality across the country. Chapter 2 has already covered the role of the National Agency for Quality of the SNS in promoting quality standards through its Quality and Planning Office for the SNS and by acting as the secretariat of the CISNS for the implementation of the National Quality Plan. Originating in the second Conference of Regional Presidents and supported by specific funding, this Plan has become the main tool for setting and disseminating quality norms and standards of practice, indicators, clinical guidelines, best practice registries and adverse events registries. Emanating from the CISNS, its governance reproduces the same consensus-building approach, with active participation and voluntary endorsement by ACs, that characterizes that governing body. The Plan, in place since 2005, is articulated around four axes:

1. National health strategies. These are aimed at improving care for patients with prevalent diseases which entail a high social burden. Nine national strategies are already in place, approved by the CISNS: they cover diseases such as cancer, ischaemic disease, diabetes, rare diseases, COPD, stroke, or specific services such as palliative care and mental health services. Three more strategic actions are expected to be launched by the end of 2010 (diseases of the musculoskeletal system, pain management and chronic patients). These strategies are to be assessed periodically and contain a set of indicators of both good practice and implementation against which they will be evaluated.

2. Women’s health. In addition to the implementation of a national strategy on care for normal delivery in childbirth, there is a specific strategy on prevention and management of violence against women. The role of the Observatory of Women’s Health has been already outlined in Chapter 2, describing the National Agency for Quality of the SNS.

3. Knowledge management

a. Clinical practice guidelines. Development and dissemination of clinical guidelines linked to the implementation of national health strategies. The main tool is Guía Salud, a body of the SNS, that reports directly to the CISNS, and in which all ACs participate. It was created as the national methodological reference for elaboration and implementation of evidence-based instruments (including clinical guidelines). The secretariat is in Aragón Health Department. Its main goals are:
• the standardization of methodology for the production of clinical guidelines;
• the assessment of guidelines produced in different parts of the SNS for dissemination;
• the development of clinical guidelines (often coordinating teams located in different regional systems) and methods for their implementation;
• the assessment of the implementation and penetration of their evidence-based products; and
• training professionals in the use and production of clinical evidence.

b. National health information systems (see Information systems in Section 4.2 Planning and health information management). The priorities under the National Quality Plan are:

• enhancement of the national primary health care information system (SIAP), leveraging it to hospital linked sets;
• developing a unified e-clinical record, building on the existing regionally specific versions;
• consolidating the unified individual health information card and a unique patient identifier valid across all ACs.

4. Process re-engineering

a. Patient safety. This field has generated a considerable amount of work and initiatives. Funded under the National Strategy for Patient Safety, it has a great deal of involvement by ACs; the issue is high on all regional agendas and the timing was such that the National Agency for Quality in the SNS had time to take the lead in orchestrating a shared approach before the ACs had developed their singular regional patient safety strategies. The approach taken is two-fold; on the one hand, there is a focus on knowledge dissemination and fostering a culture of safety in the SNS; on the other hand, there is an effort to generate a corpus of evidence on the actual situation in the SNS, and to refine and adapt internationally agreed methodologies for its measurement. Several lines of work feed in:

• patient safety training for health professionals, managers and patients groups, involving funding and technical support to the ACs for the implementation of these activities;
• design, implementation and development of learning-oriented information systems for the notification of adverse events in the SNS (eventually leading to a national register of adverse events and incidents) and implementation of “safe practices” recommendations for the SNS hospitals;
• research on:
  • epidemiology of adverse events in SNS hospitals (ENAES study 2006), primary care (APEAS study 2008), long-term care centres (EARCAS, starting in 2010) and epidemiological analysis of nosocomial infections;23
  • evaluation of safe medication use across SNS hospitals; validity
  • for the Spanish context of patient safety indicators used internationally (OECD);
• setting care quality standards for patient safety and assessment of compliance to them across SNS hospitals (SENCA project; see MSPS 2009e);
• implementation of safe practices recommended by international organizations through specific agreements with the health regions, in particular the following in collaboration with WHO: Hand Hygiene Campaign; “Bacteraemia zero” project: to prevent bacteraemia related to catheter use in intensive care units (ICUs);
• empowerment of patients and citizens through the development of the Patients Trainers Network on patient safety and studies on perception of the safety of SNS hospitals; and
• active international collaboration in European country networks such as EUnetPAs,24 EU Patient Safety and Quality of Care Working Group,25 WHO Patient Safety Programme26 and OECD Health Care Quality Indicators project.27

b. Standards and recommendations for sensitive health care units/departments in the SNS.28 In addition to specific health care units, these can also address care for specific types of patients (such as multiple-pathology) or procedures (certain types of surgery) that are considered especially sensitive in terms of safety and quality of care. To illustrate, the list issued so far covers the following topics:
- hospital care for highly complex patients with multiple chronic conditions
- surgical theatres
- day-surgery units
- ambulatory major surgery
- hospital maternity units and childbirth care.

Developed by the National Agency for Quality of the SNS in close collaboration with expert groups appointed by the main professional associations, these documents do not have a normative character in authorizing the opening of a new unit or re-accrediting the functioning of an existing one, though; instead, they are conceived as a support tool for health authorities, managers and professionals, offering criteria for quality and patient safety assurance in these priority areas. The recommendations tackle key aspects of care in these contexts, such as patient safety and rights, organization and management, resources (structure and staff), as well as some indicators appropriate for health care quality assessment.

In line with the excellence-fostering approach that follows from the initiatives described, the Agency for Quality also exerts a normative side in regulating the audit and accreditation of health care centres and services; this accreditation by a national authority²⁹ is required for them to host specialist training and teaching, as well as to be appointed as an SNS reference centre/service/unit (CSUR-SNS). The figure of the CSUR-SNS was created by Royal Decree 1302/2006; the objective is the protection of equity in access to high-quality, safe and efficient care for patients with conditions requiring such highly specialized resources and skills that cases need to be concentrated in a few sophisticated tertiary level centres/services. There is a national committee in charge of the designation of CSUR-SNS and the final decision requires the approval of the CISNS. Since 2007, 43 very specific conditions have been determined as requiring a corresponding CSUR-SNS to be designated (see MSPS 2009b). As an illustration, in 2008, 4 clinical units in 4 hospitals were designated for specific conditions in the area of oncology, 39 units in 17 hospitals in ophthalmology, 30 units located in 13 hospitals for transplantation and 10 units belonging to 9 hospitals for certain plastic surgery procedures (MSPS 2009b).

According to the information reported by ACs to the SNS Annual Report 2008 elaborated by the Observatory of the SNS, all regional health systems apply models of continuous quality improvement based either on the International Organization for Standardization (ISO) or on the European Foundation for Quality Management (EFQM). Different levels of implementation seem to coexist though, with some ACs having completed the accreditation and even re-accreditation process for all their organizations, centres, services and processes, while others are still at the stage of drawing up process maps.

Formative and training activities to enhance quality and a safety culture targeting all levels of their organizations are also reported by all ACs. The creation or consolidation of quality units at each basic health area level, and functional units of patient safety seem to be common across regional health services, as well as involvement in national programmes such as “Hand-washing” for the prevention of nosocomial infection, and “Bacteraemia zero” aimed at reducing catheter-related infections, the prevention of accidental hospital falls and pressure ulcers.

²⁹ For documents see MSPS (2009d, 2009f, 2009o).
²⁷ Further information is available at: http://www.minsalud.es/home.asp
²⁸ These reports can be found at: http://www.segundaldepaciente.es/index.php/lang-es/informacion/pUBLICACIONES/Epidemiological-studies.html
²⁹ See: http://www.eunetpas.eu/
³⁰ See: http://ec.europa.eu/health
³¹ See: http://www.who.int/patientsafety/about/en/index.html
³² See: http://www.oecd.org/health/hcqi
³³ For documents see MSPS (2009d, 2009f, 2009o).
³⁴ Regional health authorities hold full responsibility for regular accreditation and authorization of health care centres in their territory. In addition, the National Quality Plan foresees the agreement across ACs on a common minimum set of requirements, and quality and safety guarantees enforceable for new centres to be authorized.