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:* Dutch  
*Link:* [www.wetten.overheid.nl](http://www.wetten.overheid.nl)  
*Nature:* Official law database  
*Organisation responsible for the website:* SDU uitgevers, a private company that falls under the ministry of finance of the Netherlands

**Legal UHC start date**  
1966

**Source:** [http://www.euro.who.int/__data/assets/pdf_file/0008/85391/E93667.pdf](http://www.euro.who.int/__data/assets/pdf_file/0008/85391/E93667.pdf)

**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)
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Regulation

Netherlands
HIT: 2010 - Schäfer W, Kroneman M, Boerma W, van den Berg M, Westert G, Devillé W
HSPM Members: NIVEL, Netherlands Institute for Health Services Research
Netherlands: Regulation

4. Regulation and planning

The 2006 health care reform has brought completely new regulatory mechanisms and structures to the Dutch health care system. The government has changed its role from direct steering of the system to safeguarding the process from a distance. Responsibilities have been transferred to insurers, providers and patients, and the government only controls the quality, accessibility and affordability of health care. The establishment of new “watchdog” agencies in the health sector aims to avoid undesired market effects in the new system. What is more, in long-term care as well, competition among providers of outpatient services changes the system considerably. The delegation of the responsibility for domestic home care services to the municipalities has resulted in more diverse care arrangements. Traditionally, self-regulation has been an important characteristic of the Dutch health care system. Professional associations are responsible for re-registration schemes and are involved in quality improvement, for instance by developing professional guidelines.

Obviously, a regulated market system is not compatible with extensive central planning. Institutions are subject to governmental licensing, but decisions on construction plans or other capital investments are largely left to facilities based on (local) economic considerations. The health workforce, however, is subject to strict central capacity planning. The inflow of medical students and the volume of training for medical specialties is strictly regulated and based on forecasting and capacity plans.

In addition to a well-developed advisory structure the Dutch health care sector can rely on an extensive infrastructure for research and development, covering medical research, health technology assessment and health services research (see Section 2.3 Organizational overview). Table 4.1 at the end of this chapter provides an overview with all relevant actors and their tasks in the Dutch regulatory system.

4.1 Regulation

The government should ensure that managed competition results in safe, accessible and affordable health care of good quality. Only a few instruments have been left to the government to directly interfere in the health care system. An essential competence of the government is setting the budget for health care expenditures. Other important competences of the central government are taking decisions on the content of the basic health insurance package (see Box 4.1), on cost-sharing, tariffs for health services if not negotiable (based on advice by the Dutch Health Care Authority, NZa) and extending the share of freely negotiable services. Furthermore, in order to prevent preferred risk selection, the government sets the rules for risk adjustment among health insurers (see Section 3.4.2 Mechanisms for allocating funds among health insurers). In the care sector, the central government has a number of explicit responsibilities. These include creating the preconditions for quality, accessibility, safety and affordability of the care for people with chronic conditions; strengthening the position of citizens, in particular patients and their representatives; and stimulating innovation. To meet these responsibilities, the government has supervisory and advisory bodies in place such as the Dutch Health Care Authority (NZa), the Health Care Inspectorate (IGZ) and the Health Care Insurance Board (CVZ). For more information on these bodies see Section 2.3 Organizational overview, and later in this section.

The municipal public health departments (GGDs) have a major role in public health at local level. For prevention in enterprises and companies the agencies for occupational medicine (ARBO Diensten) play an important role. Some specific preventive services are provided outside the preventive sector and are integrated, for instance, in primary care and general practice (Minister of Health, Welfare and Sport 2007). Examples are influenza vaccination for high-risk persons and cervical cancer screening. For the preventive care sector, the tasks of the authorities are defined in the Public Health Act (Wet Publieke gezondheid, Wpg). Although municipalities are responsible for the implementation of this Act, the central government is obliged to produce a policy paper with the main targets for prevention every four years.
Table 41: The regulation system: actors and their role in the regulatory process, 2009

<table>
<thead>
<tr>
<th>Sort of actor</th>
<th>Actors (non-exhaustive)</th>
<th>Specific tasks</th>
</tr>
</thead>
</table>
| Government    | Central government      | • Setting the national health care budget  
                         • Deciding the content of the basic health insurance package  
                         • Setting tariffs for the services not yet subject to free negotiations  
                         • Setting public health targets  
                         • Deciding capacity in long-term care institutions  
                         • Safeguarding affordability, efficiency, accessibility and quality of health care in the Netherlands |
| Municipality  |                         | • Setting local public health targets  
                         • Decides on budget for social support and home care |
| Advisory bodies | Dutch Health Care Authority (NZa) | • Monitoring the transparency and functioning of health care markets  
                         • Establishing tariffs for non-negotiable care |
|              | Health Care Insurance Board (CVZ) | • Explanation of contents of benefit package  
                         • Promotion of harmonized provision of health care in both curative and long-term care  
                         • Advises Ministry of Health, Welfare and Sport on contents of basic health insurance benefit package  
                         • Advises on including new medicines in medicine reimbursement system (GVS)  
                         • Advises Ministry of Health, Welfare and Sport on budget for long-term care (AWBZ)  
                         • Administers Health Insurance Fund and General Fund for Exceptional Medical Expenses (AFBZ)  
                         • Carries out risk adjustment |
|              | Health Council | • Advises Ministry of Health, Welfare and Sport on preventive care and other health issues |
|              | Regional Support Structures (RGS) | • Stimulates cooperation in primary care |
|              | Capacity body (Capaciteitsorgan) | • Advises Ministry of Health, Welfare and Sport on workforce planning for all specialized postgraduate training programmes |
|              | Medicines Evaluation Board (CPG) | • Evaluates safety, efficacy and quality of pharmaceuticals  
                         • Authorizes pharmaceuticals |
|              | Council for Public Health and Health Care (RVZ) | • Advises Ministry of Health, Welfare and Sport on health policy agenda |
| Supervisory bodies | Dutch Health Care Authority (NZa) | • Enforcement of the Health Care Market Regulation Act (Wm) |
|              | Health Care Inspectorate (HZ) | • Inspects safety and quality of providers  
                         • Investigates complaints and accidents  
                         • Supervises implementation of Health Insurance Act (Zvw) and Exceptional Medical Expenses Act (AWBZ) |
|              | Committee on Pharmacetical Care (CPH) – part of CVZ | • Assesses pharmaceuticals on efficacy, side effects, applicability and ease of use before inclusion in the benefit package |
| Professional bodies (self-regulation) | Royal Dutch Medical Association (KMG) | • Postgraduate medical education  
                         • Accreditation of medical specialists (including GPs)  
                         • Promoting professional quality |
|              | Dutch College of GPs (NHG) (part of KMG) | • Development of guidelines for GPs |
|              | Association of Medical Specialists (OMS, part of KMG) | • Development of guidelines for medical specialists |

4.1.1 Regulation and governance of third-party payers

Private health insurers are responsible for purchasing and remunerating all curative health services that are covered by basic health insurance. Most health insurers operate nationally, but some have their clients primarily in a particular region. This results from their previous role as a regional sickness fund. Insurers are either public limited companies (naamloze vennootschappen) or mutuals (onderlinge waarborgmaatschappijen). The public limited companies are private for-profit organizations with the shareholder meeting being the highest decision-making structure and daily management delegated to a board of administrators. Mutuals are not-for-profit cooperatives, in which the insured persons are members.
and a board of members control its management.

The Dutch Health Care Authority (NZa) has an important role. The NZa supervises the compliance of actors with the Health Insurance Act (Zvw) and the Health Care Market Regulation Act (Wmg). NZa interferes with restrictions or obligations when an actor, that is a health insurer, health care provider or consumers, together or alone, hinder fair competition in (part of) the health care market. Furthermore, the NZa establishes tariffs and performance directions for those health services that are not subject to free negotiations. Lastly, the NZa monitors health care markets and promotes its transparent operation, both in terms of price and quality.

The Health Care Insurance Board (CVZ) advises the Ministry of Health, Welfare and Sport on the content of the basic health insurance package. Furthermore, it supplies information to insurers (but also consumers and providers) on the nature, content and scope of the basic health insurance. The CVZ also administers the Health Insurance Fund and operates the risk-adjustment scheme (see Section 3.4 Pooling of funds). Furthermore, the CVZ is the advisory body to the Minister of Health regarding the budget for the General Fund for Exceptional Medical Expenses (AFBZ) and the level of the AWBZ contribution to be paid by residents.

Health insurers operate under private law and are thus subject to the same regulations as all Dutch commercial enterprises. If insurers wish to provide basic health insurance under the Health Insurance Act (Zvw), they need to apply for permission to provide indemnity insurance with the Dutch Central Bank (DNB). Furthermore, health insurers have to adhere to the regulations of the Act on the Supervision of Insurance companies (Wet Toezicht Verzekeringsbedrijven) and the regulations of the Dutch Competition Authority (NMa).

According to the Social Support Act (Wmo), certain forms of home care are the responsibility of the municipalities. In general, there are no third-party payers in home care, since the municipalities directly purchase the care. However, some municipalities outsource the settlement of income-dependent cost-sharing requirements to the Central Administration Office (CAK). Municipalities can develop their own regulations on eligibility and needs assessment. Some municipalities have outsourced the needs assessment to the Centre for Needs Assessment (CIZ).

4.1.2 Regulation and governance of providers

4.1.2.1 Regulation of individual health care professionals

According to the Individual Health Care Professions Act (BIG) health care professionals in the Netherlands need to register and hold a licence. After registration and receiving a licence professionals are allowed to practise in the field of individual health care, on condition that specific titles are protected and certain listed actions, such as surgical treatments, are reserved to designated professionals (see Section 5.2.4 Registration/licensing). To protect patients, the Act specifies that bringing harm to someone’s health is illegal. Physicians, pharmacists, midwives and physiotherapists can be summoned to disciplinary tribunals (tuchtrecht) (see Section 2.5.5 Complaints procedures (mediations, claims)). The Health Care Inspectorate (IGZ), based on assessment by the Board of Medical Supervision (Collegie van Medisch Toezicht), can initiate a procedure to expel professionals in case of incapacity due to physical or mental conditions or substance abuse (Ministry of Health, Welfare and Sport 1996).

Licensing of physicians is mainly self-regulated by the profession. The umbrella organization of associations of physicians, the Royal Dutch Medical Association (KNMG, see Section 2.3 Organizational overview), regulates the vocational training and the licensing of physicans. KNMG determines the content of the training for medical specialists, the accreditation of training institutes and trainers, and the requirements for re-registration of medical specialists. Additionally, KNMG aims to promote the quality of the profession and public health in general. It publishes the medical journal Medisch Contact for its 46 000 members (in 2008).

4.1.2.2 Regulation of health care providers

Any organization providing care under the Health Insurance Act (Zvw) or the Exceptional Medical Expenses Act (AWBZ) needs to be licensed according to the Health Care Institutions Admission Act (Wet Toelating Zorginstellingen, WTZi). The Act defines which types of institutions are allowed to make a profit.
Generally, institutions that provide inpatient care are not allowed to make a profit while those providing only ambulatory care (including day care) may do so. To obtain a licence, an institution needs to comply with the budgetary rules provided by the Minister of Health, Welfare and Sport and fulfil the following transparency requirements from the Health Care Institutions Admission Act (WTZi):

- a supervisory board should be installed with members who are not involved in daily management;
- the organizational structure should be laid down in the articles of association;
- decisions of the supervisory board should be open to independent investigation, for instance by client boards;
- responsibilities within the care institute or organization should be laid down in a written document; and
- in reports, revenues from care activities should be easily distinguishable from those from other activities (such as parking, shops, etc.) (Linders 2009).

4.1.2.3 Regulation of public health services

Regulation related to vaccinations and screenings is primarily a governmental task. Which vaccinations are covered by the National Vaccination Programme (Rijksvaccinatieprogramma) is decided by the Minister of Health, Welfare and Sport based on advice from the Health Council of the Netherlands. At operational level, 10 regional Vaccination Administration Bodies (Entadministraties) are responsible for medical supervision and implementation of the National Childhood Vaccination Programme. Side-effects of vaccinations must be reported to the National Institute for Public Health and the Environment (RIVM). For influenza vaccinations, the Minister of Health, Welfare and Sport, again advised by the Health Council, decides which risk groups are eligible for free influenza vaccination.

In pursuance of the Screening Act (Wet op het Bevolkingsonderzoek, WBO), institutions involved in screening activities need permission from the Minister of Health, Welfare and Sport. A permit is necessary for screening on cancer, screenings using ionizing radiation techniques (such as CT scan or radiography) and screening for incurable diseases. The Minister is advised by the Health Council of the Netherlands.

4.1.3 Regulation and governance of the purchasing process

Since 2006, managed competition is being introduced step by step into the Dutch health care purchasing market. Since free negotiations are relatively new, the share of freely negotiable health care is still limited. This incremental approach should enable actors to build up the necessary expertise and experience to assume their enhanced purchaser roles. The purchasing of curative care is covered by the Health Insurance Act (Zvw). Negotiating on the volume, quality and prices of health care services, as well as the option to selectively contract, should result in an efficient health care system. At least theoretically, these mechanisms would lead to the disappearance of low-quality care providers (for more detailed information on the purchasing process see Section 3.5 Purchasing and purchaser–provider relations).

4.1.4 Regulating quality of care

The Dutch government is free to decide how to meet its constitutional responsibility for the quality of health care (Buijsen 2006). The government presumes that market mechanisms will bring about good-quality health care at affordable costs. The legal framework as laid out in the Quality of Health Facilities Act (KZI), the Individual Health Care Professions Act (BIG) and the Medical Treatment Agreement Act (WGBO) provides instruments for quality assurance. Furthermore, patients are expected to act as informed consumers and critically assess which providers to visit. By doing so, they play a critical role in optimizing the quality of health care (Boot and Knapen 2005). The role of patients is supported by several pieces of legislation and regulation. For more information see Section 2.5.3 Patients’ rights.

As a main advisory body to the Minister of Health, Welfare and Sport, the Health Care Inspectorate (IGZ) plays an important role in regulating the quality of care. The Inspectorate enforces statutory regulations on public health; investigates complaints and irregularities in health care; and takes measures if deemed necessary and appropriate. Quality indicators, provided by providers and institutions, are powerful tools for the Health Care Inspectorate (IGZ). Values on the indicators may give rise to a practice visit or an investigation to check whether guidelines and procedures are observed (Groenewegen, Hansen and Ter
Bekke 2007). More information on the Health Care Inspectorate (IGZ) can be found in Section 2.3 Organizational overview, while more details on the disciplinary system and complaint procedures can be found in Section 2.5.5 Complaints procedures (mediation, claims).

4.1.4.1 Health care facilities

The 1996 Quality of Health Facilities Act (KZi) replaced many detailed quality norms with broadly defined requirements applicable to all health care institutions (Buijsen 2006). For example, institutions are required to systematically collect data on the effectiveness, patient centredness and efficiency of the provided care, to set up a quality assurance system and to produce publicly available quality reports annually. The Act transfers the responsibility for quality to health care institutions and gives them the freedom to fulfil the general requirements in a way that results in “responsible care” (for a definition see Section 2.5.3 Patients’ rights) (Oosterlee 2006). The requirements are monitored by the Health Care Inspectorate (IGZ) (Buijsen 2006).

An evaluation of the Quality of Health Facilities Act (KZi) in 2001 showed that stakeholders, with the exception of the health insurers, were generally satisfied with the framework provided by the Act. However, policies on quality in institutions turned out to be focused mainly on procedures. There was no transparent system of standardization and the perspective of the patient was not included systematically (Casparie et al. 2001).

4.1.4.2 Individual professionals

Quality of care provided by individual health care workers is regulated through the Individual Health Care Professions Act (BIG) (see Section 4.1.2 Regulation and governance of providers). The BIG aims to safeguard the quality of the practice of professions and to protect patients from incompetent health care practitioners. Similar to the Quality of Health Facilities Act (KZi), this Act provides a framework for health care providers while details have to be worked out in lower-level regulation (Buijsen 2006). The BIG contains requirements with regard to (1) competence (requirements for registration and title protection), (2) expertise (the practitioner has to be an expert in the professional domain) and (3) proficiency (stipulated restrictions and functional autonomy) (see also Section 5.2.4 Registration/licensing).

Furthermore, the Individual Health Care Professions Act (BIG) regulates professional secrecy and, analogous to institutions, individual practitioners are bound to provide “responsible care” (Hendriks 2006). By way of sanctions, the Act contains disciplinary rules. The BIG is enforced by the Health Care Inspectorate (IGZ). A 2002 evaluation of the BIG showed that professional organizations were making an effort to comply with the Act regarding quality measures. Although the BIG was seen as an important instrument for the protection of patients and governing quality, its effectiveness was felt to be limited because of the limited use made of the instruments related to the Act (Cuperus-Bosma et al. 2002).

4.1.4.3 Quality regulation by medical professions

As a result of Dutch policy on quality assurance, which has promoted professional self-regulation since the early 1990s, professional guidelines have been developed and are in use by the medical professions (Boot and Knapen 2005). Guidelines provide rules of best practice for certain complaints or treatments and thus their application should improve quality of care. Examples are guidelines for GPs, developed by the Dutch College of GPs (NHG). Research in 2007 found that guidelines tend to be developed more often by multidisciplinary teams, which may include nurses and representatives of patient organizations (Groenewegen, Hansen and Ter Bekke 2007). Although the use of guidelines is generally perceived positively, there is criticism as well. The lengthy process of developing guidelines is sometimes felt as a limitation to their use, particularly in areas where there is a great deal of medical innovation (Hukkelhoven et al. 2006). Furthermore, guidelines are not always seen as consistent with daily practice and some perceive guidelines as a threat to their professional autonomy (Van Everdingen 2003). The Health Care Inspectorate (IGZ) may use professional guidelines. Providers may be invited, for instance, to explain why, in particular cases, they have not complied with the guidelines (Baan, Smits and Limburg 2001).

For quality improvement through integrated care and cooperation between primary health care professionals, Regional Support Structures (Regionale Ondersteuningsstructuren, ROS) have been established. These structures support primary care workers, such as GPs, physiotherapists, midwives, speech therapists and mental care workers in developing mono- and multidisciplinary teamwork,
implementing quality-of-care policies and improving the continuity of care. The ROS are partly financed by health insurers and municipalities and provinces. Municipalities are interested in the integration of primary care with services for which they are responsible, such as prevention, social support and youth care.