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:** German
- **Link:** [http://www.gesetze-im-internet.de](http://www.gesetze-im-internet.de)
- **Nature:** Official federal law database
- **Organisation responsible for the website:** Federal ministry of justice and consumer protection of Germany

**Health law database**

- **Language:** German and English
- **Link:** [www.bmg.bund.de](http://www.bmg.bund.de)
- **Nature:** Official website of the federal ministry of health
- **Organisation responsible for the website:** German federal ministry of health

**Legal UHC start date**

1883

**Source:** [http://www.country-data.com/cgi-bin/query/r-4924.html](http://www.country-data.com/cgi-bin/query/r-4924.html)

**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 Germany ..................................................................... 3
Regulation

Germany
HIT: 2013 – Busse R, Blümel M
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Germany: Regulation

2.8 Regulation

2.8.1 Regulation and governance of third-party payers (including SHI benefit package)

The corporatist institutions on the payer side are the sickness funds, which have a key position within the SHI system, as defined by SGB V. They have the right and the responsibility to collect contributions from their members. However, from January 2009 the sickness funds no longer have the authority to determine their own contribution rates; instead, a uniform contribution rate is set by federal law (SGB V). Other responsibilities of the sickness funds include negotiating prices, quantities and quality assurance measures with providers of health care services. The services covered by the resulting contracts are usually accessible to everyone with SHI and do not require prior authorization from an individual’s sickness fund. Prior authorization is necessary, however, for preventive spa treatments, rehabilitative services and short-term nursing care at home. If there is any doubt, the sickness funds must obtain an expert opinion on the medical necessity of a given treatment from the SHI Medical Review Board, which is a joint institution of all sickness funds (see section 5.8).

Independent of the status, the amount of contribution paid or the duration of insurance, members and their dependants are entitled to the same benefits. The following types of benefit are currently included in the benefit package, usually in generic terms through Chapter 3 of SGB V:

- prevention of disease, health promotion at the workplace (§§ 20–24b);
- disease screening (§§ 25 and 26);
- treatment of disease (ambulatory medical care, dental care, drugs, care provided by allied health professionals, medical devices, inpatient/hospital care, nursing care at home, and certain areas of rehabilitative care, sociotherapy) (§§ 27-43b);
- dental prostheses and orthodontics (§§ 55-58);
- emergency and rescue care (§ 60); and
- certain other benefits such as patient information and supporting self-help groups.

While the SGB regulates preventive services and screening in considerable detail (e.g. concerning diseases to be screened for and screening intervals), it leaves further regulations to the Federal Joint Committee.

The Committee has considerable latitude in defining the benefits package for curative diagnostic and therapeutic procedures. The decision-making process concerning coverage is described in more detail in section 2.7.2. All procedures covered in the ambulatory sector are listed in the Uniform Value Scale together with their relative weights for reimbursement (see section 3.7.2). The range of covered procedures is wide, from basic physical examinations in the office to home visits, antenatal care, terminal care, surgical procedures, laboratory tests and imaging procedures including magnetic resonance imaging (MRI).

While benefits for ambulatory physician services are legally defined in generic terms only, one can observe more details in the description of dental – especially prosthetic – benefits in SGB V. One reason was the dysfunction of the Federal Committee of Dentists and Sickness Funds, until 2003 in charge of decision-making on ambulatory dental care concerning benefits, accreditation and quality. The regulation of the Health Insurance Contribution Rate Exoneration Act (Krankenversicherungsbeitragsentlastungsgesetz) to remove crown/denture treatment from the benefits package for people born after 1978 (even though they still had to pay the full sickness fund contribution rate) was politically contentious. The Act to Strengthen Solidarity in SHI reintroduced these benefits from 1999. A new legal initiative to exclude dentures from the SHI basket in favour of mandatory co-insurance was modified in 2004 in favour of a “special contribution” of 0.9% to be paid only by employees from July 2005. Dentures thus continue to be part of the benefit basket.

Another sector comprises the therapeutic services of allied health professionals other than physicians,
such as physiotherapists, speech and language therapists and occupational therapists. Insured patients are entitled to such services unless they are explicitly excluded by the Federal Ministry of Health, which is currently not the case (§§ 32 and 34 SGB V). According to § 138 SGB V, services provided by allied health professionals may be delivered to the insured only if their therapeutic use following quality assurance guidelines is recognized by the Federal Joint Committee. In the Committee's directive for care provided by allied health professionals, the conditions for the prescription of these services have been reformed in consultation and cooperation with professional bodies of the respective professional associations, which however have no right to take part in the Federal Joint Committee's final decision-making. The list of services provided by allied health professionals reimbursable by SHI is now linked to indications and therapeutic targets. Non-physician care may be ordered only if a disorder can be recognized, healed or mitigated or if aggravation, health damage, endangerment of children or the risk of long-term care can be avoided or decreased.

As in care provided by allied health professionals, insured are entitled to medical aids, such as prostheses, glasses, hearing aids, wheelchairs or respirators, unless they are explicitly excluded from the benefits package through a negative list issued by the Federal Ministry of Health (see section 2.8.5). In late 1989, the Federal Ministry of Labour and Social Affairs (responsible for SHI at that time) explicitly excluded aids with small or disputed therapeutic benefit or low selling price (e.g. wrist bands), an exclusion that still applies in 2014. Since 2004, visual aids have been excluded from the SHI benefits package for people above the age of 18.

Home nursing care is regulated separately. Mandated by the 2nd SHI Restructuring Act (2. GKV-Neuordnungsgesetz), the Federal Joint Committee passed a directive to clarify responsibilities and improve cooperation among the sickness funds responsible for acute home nursing care and the long-term care funds. However, organizational responsibilities and financing obligations are still subject to debate; for example, the Federal Social Court decided that medical aids for recipients of statutory long-term care insurance have to be paid by their statutory sickness fund.

The range of services provided in the hospital sector has traditionally been determined by two factors: the hospital requirement plan of the Länder governments and the negotiations between the sickness funds and each hospital. In 2004, DRGs were gradually introduced as the dominant form of payment in hospital care. The transitional phase ended in 2009. Access to and financing of innovative interventions is subject to especially intense debate (see sections 2.7.2 and 3.7.1).

In addition to these benefits in-kind, sickness funds give sick pay to their employed members as 70% of the last gross salary (maximum 90% of net salary) (§§ 44–51) from week 7 up to week 78 of certified illness, while employers continue to pay 100% of the salary during the first six weeks of sickness.

Until 2003, licensing of drugs meant SHI (see section 2.8.4). Further benefits that have been legally excluded from SHI coverage since 2004 include lifestyle medications and all OTC medications with few exceptions, which are defined by the Federal Joint Committee. Since 2004, visual aids (e.g. eye glasses) are no longer subsidized by the sickness funds, with the exception of those for people who are 18 years of age or younger, or for people with severe visual impairment. Transport to ambulatory care is also excluded unless the therapy is necessary and the person in question (1) has a severe physical impairment that limits personal mobility, (2) has been assessed as having a grade II or III need for long-term nursing care, (3) is blind or helpless, or (4) needs transport to and from oncological radiation/chemotherapy, or ambulatory dialysis.

2.8.2 Regulation and governance of providers

Organization

The corporatist institutions on the provider side are required by law to ensure that the geographic distribution and volume of acute medical care services are sufficient to meet the health needs of the population. The clearest examples of such institutions are the regional associations of SHI physicians and dentists, which must guarantee the availability of ambulatory services, ensuring that physicians from all specialties are available according to community needs and are located within a reasonable distance of each individual's home. To meet this service availability requirement, a regional association must negotiate with the sickness funds operating in its particular Land and set a prospective budget, which is
ultimately allocated between its SHI-accredited members according to nationwide rules that have been adapted to regional circumstances (Fig2.1) (see section 3.7.2).

SGB V sets the framework for these negotiations, specifying general categories of benefits and the scope of the areas to be negotiated between the sickness funds and the regional associations of SHI physicians and dentists. These negotiations determine the conditions of remuneration and the specific items in the ambulatory benefits package. As a general rule, both areas are regulated in great detail in the German ambulatory sector, whether through legislation or through negotiations between providers and the sickness funds.

The regional associations of SHI physicians and dentists must deliver the health services that have been defined by law and in contracts with the sickness funds. In doing so, the regional associations guarantee the sickness funds and the insured population that these services meet all legal and contractual requirements. Due to their supervisory and regulatory role, the regional associations were established as self-governing, quasi-public corporations. This status enhances their ability to influence decisions that generally fall within the clinical freedom of physicians, while at the same time supporting the principles of internal democratic legitimization and self-government. In return for these obligations, the regional associations enjoy a monopoly over the provision of ambulatory care. This monopoly means that hospitals, municipalities, sickness funds and non-physician health professionals are not permitted to provide ambulatory medical care outside the collective contracting agreements, except for purposes mandated by legislation or by joint commissions of payers and providers. Although ambulatory medical care is the classic sector in which the corporatist institutions have the greatest power, these exceptions to the regional associations’ monopoly have gradually been expanded in recent years (see section 5.4).

Although the regional associations are obliged to guarantee the availability of ambulatory care services both during and outside normal working hours, since 1997 the responsibility for ensuring the availability of emergency services has been with the Länder governments, which have delegated this task primarily to hospitals (see section 5.5).

Because of the absence of corporatist institutions in the hospital sector, hospitals contract individually with representatives of the sickness funds at the regional level, such as the regional associations of sickness funds. Usually, sickness funds participate in the collective negotiations with a hospital if their insured members account for more than 5% of the patients treated there. The conditions regarding the number and scope of services and the remuneration rates are the same for all sickness funds, however.

Quality

In Germany until the end of the 1980s, monitoring of technical and hygienic safety and professional self-regulation (see section 4.2.3) were regarded as sufficient measures to ensure quality of health care. Basic quality requirements as set out in the SGB, the regulatory framework for the German social health insurance system, were limited to hospitals only and served as a means to qualify for reimbursement and to incorporation into the regional hospital requirement plan. However, since the Health Care Reform Act (Gesundheitsreformgesetz) of 1989, quality assurance measures are a legal obligation. Through the SHI Reform Act (GKV-Änderungsgesetz) of 2000 and the SHI Modernization Act of 2004, the demands placed on quality assurance in hospitals and the ambulatory sector have been fundamentally revised. All of these regulations are based on the concept that the legal directives within SGB V constitute the framework within which the respective contractual partners have the freedom to make appropriate formal arrangements. In 2007, the Act to Strengthen Competition in SHI increased the competences of the Federal Joint Committee again by including the mandate to pass directives for quality assurance across sectors, that is, for services provided by both inpatient and ambulatory care providers as well as those where the service is provided in one sector and follow-up in the other.

Quality assurance in the hospital sector

Quality assurance in hospitals has changed substantially since the 1990s, shifting from voluntary activities to obligatory tasks. Requirements for safeguarding quality of processes, and recently of outcomes, have gradually been increased as outlined in the SGB. Quality assurance of processes based on documentation was first introduced in the form of registries in the early 1970s.

In 1996, quality-relevant documentation of case fee (Fallpauschale) procedures, associated with the introduction of prospective case fees, became a task to be negotiated by the associations of sickness
funds and hospital associations at the state level. Since the Länder Chambers of Physicians, previously involved in registry quality measures, were initially not involved, negotiations were delayed and implementation was weak. A federal working group for quality assurance, consisting of sickness funds, regional associations of SHI physicians, the German Hospital Federation, the Federal Chamber of Physicians and the German Nursing Council, sought to improve communication and cooperation in quality initiatives across professional groups and sectors. The working group built an information system on quality projects and organized various meetings but was dissolved in 2004. Its tasks were delegated to the Federal Joint Committee, where decisions on quality assurance can be linked more closely to more powerful instruments of contracts, regulations and reimbursement.

Since 2000, hospitals have been obliged to run internal management programmes and to negotiate contracts with sickness funds on external quality assurance measures that allow for quality comparisons through the standardized documentation of quality indicators. For this purpose, the Federal Office for Quality Assurance (Bundesgeschäftsstelle für Qualitätssicherung (BQS)) was established to assist the contract partners in choosing and developing the quality indicators to be monitored, to collect, compile and analyse the data, and to make the findings available to individual hospitals in the form of reports and recommendations. In addition, BQS started to publish annual quality reports on hospitals, which are also available to the public.

The last BQS report for 2008, which was based on data from 1730 hospitals, covered a total of 26 areas, such as obstetrics, transplantation, cardiac surgery, hip and knee replacement, pacemaker implantation, and prevention of pressure ulcers (nursing), assessing these using a total of 206 quality indicators. The evaluation of the findings for the individual areas was performed by the individual expert groups, whose members are appointed by the contract partners in the SHI scheme’s system of joint self-government. Hospitals identified as underperforming are required to explain and, if deemed necessary, take appropriate action to improve performance (Bundesgeschäftsstelle Qualitätssicherung, 2009b).

In 2007, the Act to Strengthen Competition in SHI mandated the Federal Joint Committee to commission an institute to support the Committee regarding technical support in developing and carrying out quality assurance measures across sectors. After an EU-wide tendering process, the AQUA Institute was commissioned in 2009 (for initially five years). It took over from BQS, starting with analysing data from 2010 and publishing annual quality reports based on data from 2009 onwards.

Minimum services volumes were legally enacted for selected hospital services in 2002. Contract partners (i.e. the former federal associations of sickness funds, the German Hospital Federation and the Federal Chamber of Physicians) were required by law to develop a list of elective services in which there is a clear positive relationship between the volume of services provided and the quality of health outcome. For those services, delivery of a predefined minimum volume during the previous year is the condition to become (or to stay) “contractible” and for reimbursement.

In addition, as of 2005, legislation requires hospitals to biyearly publish standardized quality reports. These include structure and process data of the hospital such as number of beds, staffing, type and volume of services provided and medical equipment, as well as documentation of the internal quality management system specific to the individual hospital. The reports are accessible online, enabling the public to search for information on quality by hospital and/or location, although direct comparison is not possible. Since 2007, all hospitals have been required to publish results on 27 selected indicators collected by BQS, thus allowing for a targeted comparison of hospitals (Busse, Nimptsch & Mansky, 2009). In 2011, the Federal Joint Committee decided to enlarge the number of quality indicators on which the hospitals are required to report publicly to 182 from 2012 onwards.

Besides these legally required quality assurance measures, several additional measures have been developed in recent years. For example, the Scientific Institute of the General Regional Funds and Helios Clinics have developed methods allowing them to measure routine data-based quality of hospitals (Quality Assurance Based on Routine Data). Sets of indicators for measuring routine data-based quality (e.g. the German Inpatient Quality Indicators; Mansky et al., 2011) offer the advantage of access to existing data concerning diagnoses, procedures or demographics and thus avoid extra expenses for data collection.

Hospitals may also participate in voluntary quality inspections and certification procedures. The Federal Association of Sickness Funds, Federal Chamber of Physicians, the German Hospital Federation and the
German Nursing Council established the Organization for Transparency and Quality in Health Care (Koordination für Transparenz und Qualität im Gesundheitswesen), which since 2002 has served to evaluate quality management in hospitals and improve process and outcomes quality. As part of this procedure, information is gathered on 63 criteria in the areas of patient orientation, staff orientation, hospital safety, information technology, hospital management and quality management. An initiation self-assessment performed by the hospitals themselves is followed by an external assessment. As in previous years, quality requirements have been expanding to other health care sectors and institutions: the Organization for Transparency and Quality in Health Care procedure has been offered to physicians’ offices, ambulatory health care centres, rehabilitation institutions, long-term care facilities and hospices since 2011.

**Quality assurance in the ambulatory sector**

Quality assurance in the ambulatory sector has also progressively been transformed from an initially voluntary task to a legal obligation. This was, in part, prompted by a report in 2000/01 by the Advisory Council for the “Concerted Action in Health Care” Round Table Committee, revealing considerable shortcomings in the quality of health care in the German system, as documented by inappropriate provision of services for those with chronic conditions (Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen, 2002). From 2000, successive measures to improve the quality of care were introduced, including DMPs, which facilitate the structured treatment of patients with chronic diseases (see section 5.3).

Another measure is the obligation embodied in SGB V to ensure and refine the quality of services in the ambulatory sector. It obliges providers to take part in external quality assurance measures spanning multiple practices in order to improve the quality of outcomes, and to introduce and refine internal quality management (§ 135a SGB V). The Federal Joint Committee determines the criteria regarding the necessity and quality of medical services, as well as the minimum standards for structural, process and outcome quality. The Committee is also able to define penalties (e.g. reduced remuneration) in cases where providers do not fulfill their quality assurance obligations.

Quality assurance in the ambulatory sector is also characterized by a range of actors at various political levels. In 2006, a directive of Federal Joint Committee came into effect that set requirements for internal quality management in the practices of SHI-accredited physicians, psychotherapists and ambulatory medical treatment centres.

In order to offer special services, mostly invasive procedures or medical imaging, SHI physicians need to fulfill certification requirements, in addition to being licensed as specialists. This is the case for about 30% of services listed in the Uniform Value Scale. Certification is obtained when the surgeries fulfill minimal technical requirements and the physicians have undergone additional training, defined as a minimal number of patients treated under supervision. Organizational requirements are also considered for certification. For example, a binding cooperation agreement with a heart surgery unit within a certain area (measured as time to access) is required to obtain certification for ambulatory percutaneous transluminal coronary angioplasty. Specific certificates are required for arthroscopy, dialysis, pacemaker supervision, ultrasound and laboratory testing, for example. The performance of other services not only requires a specific qualification but also evidence of sufficient experience, indicated as a minimum number of services in the preceding year, for example 200 colonoscopies or 350 percutaneous transluminal coronary angioplasties (Kassenärztliche Bundesvereinigung, 2011).

Recertification is needed in order to remain eligible for sickness fund reimbursement for providing special services within the contracts. Recertification requirements are fixed in the contracts and vary depending on the service in question. The different approaches include minimum volumes of procedures done in a year, or case verification and evaluation of skills (with thresholds for sensitivity, for example). Furthermore, the contracts also include agreements that physicians involve themselves in quality improvement interventions, such as auditing or supervision with significant event reviews. These requirements are defined by the Federal Association of SHI Physicians and are contract items between the sickness funds and the regional associations of SHI physicians.

The regional chambers of physicians are responsible for accreditation and continuing education, and for setting professional standards. Their activities and functions are coordinated at the federal level by the Federal Chamber of Physicians. Maintaining eligibility for reimbursement requires recertification;
(re)certification criteria are defined by the Federal Association of SHI Physicians and form part of the contractual arrangements between sickness funds and regional associations of physicians. In 1995, the Federal Chamber of Physicians together with the Federal Association of SHI Physicians founded the Centre for Quality in Medicine (Ärztliches Zentrum für Qualität in der Medizin), which is charged with advising and supporting the Federal Association of SHI Physicians in questions related to quality assurance in physician training.

The Federal Association of SHI Physicians has developed a special programme, “Quality and Development in Physician Practices” (Qualität und Entwicklung in Praxen) to assist physicians in private practice in the implementation of internal quality management and self-assessment procedures. In 2009, a total of 24 000 physicians and other practice staff took part in the programme. In addition the Federal Association of SHI Physicians offers so-called quality circles, which serves as a forum in which SHI-accredited physicians can exchange experiences with colleagues and engage in reciprocal evaluation. In late 2009, there were 8900 quality circles with a total of 75 000 participating physicians.

The Federal Association of General Regional Sickness Funds (AOK-Bundesverband) developed a system of quality indicators for ambulatory care (QISA) in collaboration with the AQUA Institute. These are 130 indicators that are meant to support quality assurance in physician practices and are particularly relevant for GPs.

The federal government, the federated Länder governments and the organizations of various health professions have the competences for regulating training and continuous professional development and medical education. The Federal Medical Code regulates basic questions for the practice of physicians in Germany. The Physicians’ Approbation Ordinance (Ärztliche Approbationsordnung) also regulates the basic principles of medical education on a federal level. The federated Länder governments set the general rules for medical education. Details are regulated by the medical associations of the Länder (see section 4.2.3).

Regulation and needs-based planning of health care providers also follow the federal structure. The chambers of physicians, dentists and pharmacists are required by law to publish statistics on their (mandatory) members (Bundesärztekammer, 2014). The structure of, and trends in, employment within the health care sector have been documented annually by the Federal Statistical Office since 2003. These data are broken down according to occupational qualifications, place of work, occupational position, gender, and part-time or full-time work (Statistisches Bundesamt, 2013b). The regional associations for physicians and dentists document the structure and qualifications of physicians and dentists who have been accredited to provide care to people covered by SHI (Kassenärztliche Bundesvereinigung, 2014). These data serve as the basis for requirements planning.
Organizational relationships of the key actors in the German health care system, 2014

2.8.3 Registration and planning of human resources

SHI physicians
According to §§ 99–105 SGB V needs-based plans have to be developed to regulate the number of SHI-accredited physicians in private practice. Originally, the intention was to guarantee that the less common specialties would also be available in rural areas. Since the 1980s, however, the focus has been on avoiding oversupply. Since 1993, the SGB has stipulated that new practices may not be opened in areas where supply exceeds 110% of the average number for a given specialty; exceptions may only be made in cases where a physician is taking over a registered practice that is “essential” to the provision of care in a particular area. Since the mid-2000s, the discussion about underprovision in rural areas, particularly of GPs, has reoccurred.

The Federal Committee of Physicians and Sickness Funds (now the Federal Joint Committee) developed a directive defining such limits. The directive, in its version up to the end of 2012, classified all planning areas into 1 of 10 groups – ranging from large metropolitan areas to rural counties – and defined the need per group as the actual number of physicians of that group working on average in all counties in 1990, divided by the population. Oversupply was then defined as 110% of that figure. For groups of specialists numbering fewer than 1000, no ratios were defined, meaning that new practices could be opened up freely. Factors such as age, gender, morbidity or socioeconomic status of the population or the supply of hospital beds were not taken into account (only the age structure of the population could be taken into account as a modifying factor since 2010). Based on this definition, the “need” for certain specialties varied widely – up to a factor of nine in the case of psychotherapists – since differences were frozen (for more details, see Busse & Riesberg, 2004).

In early 2010, out of a total of 395 planning areas, none was open for new specialist internist practices, and only four or five (1%) for new radiology, orthopaedic and urology practices. A total of 9 planning areas (2%) were open for new anaesthesiology practices; 15 (4%) for new psychotherapy practices, 17 (4%) for new gynaecology practices, 23 (6%) for new neurology practices, 29 (7%) for new ear, nose and throat (ENT) practices, 30 (8%) for new dermatology practices and 58 (15%) for new ophthalmology practices. However, 204 planning areas were open for family physician practices, meaning that the 100% threshold had not been reached in 52% of all planning areas (Kassenärztliche Bundesvereinigung, 2014). In fact, the density of SHI-accredited physicians varies between metropolitan areas and rural areas. Of the 16 Länder, Hamburg has the highest and Brandenburg – a largely rural Land surrounding Berlin – has the lowest rate of family physicians and specialists alike.

The SHI Care Structures Act has changed the conditions for needs-based planning considerably (see section 6.1.6). The Federal Joint Committee developed a new directive which came into force in 2013 (Gemeinsamer Bundesausschuss, 2013). In order to better meet the needs of ambulatory care, the basis for calculating needs-based population ratios was restructured according to the level of care and spatial differences. The level of care was differentiated into four categories: (1) family physician care, (2) specialist care, (3) highly specialized care, and (4) separate specialized care. Since it could be assumed that physicians with a higher level of specialization are able to provide services to a larger catchment area, the size of the planning area increased with the level of care. Only population ratios for “normal” specialists were further split into five types that reflected the effects of care in the surrounding areas, while the needs-based ratios for both family physicians and highly and “separate” specialized physicians were assumed as equal across the country (Table 2.6).

Furthermore, the new directive provided a demographic factor that involves differences in population ageing. The needs of people aged 65 and older in a planning area would be determined separately from those under 65. As a result of the new needs-based plans, 3000 family physician practices and 1400 psychotherapy practices can additionally be established.

Allied health professionals

The conditions for independent health care professionals other than physicians – such as physiotherapists or speech and language therapists – to be reimbursed for treating SHI-covered patients are regulated by the SGB and details are delegated to the Federal Joint Committee (see section 2.5.3); § 124 SGB V regulates the accreditation of SHI providers, who must fulfil certain prerequisites (training, practical experience, practice equipment, contractual agreements) if they want to participate in the care of the insured.

Hospital personnel
To better plan nurse staffing in hospitals (see section 5.4.1) an interesting instrument was included in the Health Care Structure Act of 1992, namely the introduction of nursing time standards, through which a daily documentation of nursing activities put every patient in one of nine categories with a standardized required nursing time between 52 and 215 minutes per day. The total number of minutes per ward and per hospital could be calculated into the nursing staff needed by the unit. Nursing time standards were introduced to end a period of perceived nursing shortages, on the assumption that new jobs would be created. However, the 2nd SHI Restructuring Act abolished the regulation for the official reason that the standard had led to almost 21 000 new nursing positions between 1993 and 1995, when the law-makers had anticipated only 13 000. The Hospital Financing Reform Act (Krankenhausfinanzierungsreformgesetz) of 2009 introduced a programme for improving inpatient nursing in hospitals. A total of 21 000 additional nursing positions were to be created between 2009 and 2011, 70% of which would be financed by the sickness funds.

Table 26:

Needs-based population ratios, defined as covering 100% of need per specialty, since 2013

| Family physician* | 1 671 |
| Specialties         |       |
| Ophthalmologists   | 13 399| 22 229| 24 729| 22 151| 20 664 |
| Surgeons           | 26 230| 39 160| 47 479| 42 318| 39 711 |
| Gynaecologists#    | 3 733 | 5 619 | 6 066 | 6 571 | 6 042 |
| Dermatologists     | 21 703| 35 704| 42 820| 41 924| 40 042 |
| ENT physicians     | 17 675| 28 921| 33 102| 31 638| 31 183 |
| Neurologists/psychiatrists | 13 745| 28 921| 33 102| 31 638| 31 183 |
| Orthopaedists      | 14 101| 22 298| 26 712| 26 281| 23 813 |
| Psychotherapists   | 3 079 | 7 496 | 9 103 | 8 587 | 5 953 |
| Urologists         | 28 476| 45 200| 52 845| 49 573| 47 189 |
| Paediatricians*    | 2 405 | 3 587 | 4 372 | 3 900 | 3 850 |

*Highly specialized physicians

Anaesthetists      | 46 917 |
Specialized internists (e.g. in cardiology, endocrinology) | 21 508 |
Child and youth psychiatrists | 16 909 |
Radiologists       | 49 005 |
Separate specialized physicians

Physicians for human genetics | 606 384 |
Laboratory physicians | 102 001 |
Neurosurgeons      | 161 207 |
Nuclear medicine   | 118 468 |
Pathologists       | 120 910 |
Rehabilitation medicine | 170 542 |
Radiotherapists    | 173 576 |
Transfusion physicians | 1 322 452 |

Source: Based on data from Gemeinsamer Bundesausschuss, 2014.
Notes: *Includes general practitioners, practitioners, physicians without any specialist qualification, and family internists; #Ratio refers to female population; *Includes family paediatricians and specialist paediatricians and the ratio refers to population under age 18.

2.8.4 Regulation and governance of pharmaceuticals
When looking at the regulation of pharmaceuticals, two steps have to be clearly separated: (1) licensing (i.e. market access), which is determined to a large degree by EU regulation transposed into national law, and (2) the national decision about coverage (i.e. reimbursement by the SHI scheme).

**Licensing of pharmaceuticals**

Licensing for new drugs became mandatory only with the Pharmaceutical Act (Arzneimittelgesetz) of 1976 (effective from 1978), after it became clear that a significant proportion of drugs were of unproved effectiveness, and is the most regulated area of medicine in Germany. The admission of pharmaceuticals for humans on to the market is the responsibility of the Paul Ehrlich Institute (blood, blood products, sera and vaccines) and the Federal Institute for Pharmaceuticals and Medical Devices (all other drugs). This national regulation applies provided that the medication has not yet been approved by the central authorization procedure of the European Medicines Agency (formerly the European Agency for the Evaluation of Medicinal Products), which allows approval in all Member States of the EU.

In Germany, approvals are awarded separately for different doses and modes of application, as a result of which in 2010 there were nearly 60 000 preparations in the market (Fig2.3). In 2010, the “Rote Liste” contained 8500 preparations, of which 2000 preparations represent 90% of the SHI prescriptions. In 2010, 80% of the preparations on the “Rote Liste” were chemically defined substances, 8% herbal medicinal products, 8% homoeopaths and 4% other drugs (Verband der forschenden Pharma-Unternehmen, 2011).

The criteria for licensing pharmaceuticals are scientifically proven safety and efficacy. This includes a stepwise testing in studies with healthy humans (phase I and II) and controlled clinical trials in people affected by the target disease (phase III). Based on the EU-wide standard on “good clinical practice” (directive 2001/20/EG of the European Parliament and Council and directive 2005/28/EG of the European Commission), an extensive formalization and documentation of study procedures is required. However, only a marginal beneficial effect needs to be demonstrated with a small sample in order to fulfill the efficacy criteria, and cost-effectiveness is of no importance. This has led to the admission of active substances that are merely minor modifications rather than real product innovations. Licensing is, in any case, limited to five years, after which an application for an extension is required.

Besides regular admission, an accelerated admission process is also possible, intended for drugs that generate considerable public interest on the basis of their potential therapeutic value but lack sufficient data to judge their therapeutic efficacy. In such cases, it can be decreed that within a certain period data should be systematically collected on the drug’s efficacy in order to reappraise its therapeutic value. However, this procedure is very rarely adopted.

The accelerated licensing procedure for orphan drugs (those used to treat very rare diseases) is more often used, and since 2000 may only be initiated at the European Medicines Agency. The mutual recognition procedure is an increasingly used strategy for approval, in accordance with EC directive 75/319, which came into effect in Germany on 1 January 1995. Based on this directive, a manufacturer whose drug has been admitted in another country may also apply for the drug’s admission to Germany, which may only be refused by the Federal Institute for Pharmaceuticals and Medical Devices if a public danger exists. In this case, the European Medicines Agency enforced arbitration would be initiated, and eventually the situation would be adjudicated by the European Commission.

Homoeopathic and anthroposophic drugs are exempted from the licensing procedure under the Pharmaceutical Act and are subject to registration only. Registration requirements refer mainly to the quality of the basic products and the manufacturing process as well as to the durability of the final products. Registered homoeopathic drugs do not need to prove their therapeutic efficacy unless they are to be licensed for a specific purpose. In this case, a manufacturer has to apply through the regular admission procedure. The characteristics of the admission of homoeopathic and anthroposophic drugs, and fixed combinations of phytotherapeutics, are regulated explicitly by the Ministry of Health. Exceptions to this are prescription drugs produced and sold in pharmacies in quantities of up to 100 units per day and homoeopathic drugs produced in quantities of less than 1000 units per year.

Market admission is not linked to obligatory comprehensive and systematic postmarketing surveillance. However, physicians and other professionals are requested to report problems they or their patients encounter with drugs and medical devices to the Federal Institute, which is required to maintain a
database of all side-effects, contraindications and other drug problems. Records are assessed by medical, pharmacological and toxicological experts and forwarded to the European Medicines Agency and other international pharmaceutical authorities. There is a phased plan according to which appropriate actions are taken depending on the seriousness of the problem. In the most serious case, the market licence can be withdrawn.

Coverage/SHI reimbursement of pharmaceuticals

Unlike many other countries, Germany does not have a “positive list” of SHI-covered (i.e. reimbursable) pharmaceuticals. The Health Care Structure Act of 1992 had included a mandate for a positive list to be developed by the Federal Ministry of Health. This regulation, however, was dropped only weeks before it was supposed to be put into effect on 1 January 1996. The Federal Minister of Health decided not to pursue the idea of a positive list and justified this by citing the successful cost-containment measures in the pharmaceuticals sector, the otherwise rising costs for patients with chronic conditions making OTC purchases and, most importantly, the threat to smaller pharmaceutical companies. While this decision was welcomed by the pharmaceutical industry, it was criticized by both the sickness funds and the Social Democratic Party. The SHI Reform Act of 2000 again introduced the mandate for a positive list, which the Federal Ministry of Health, supported by an expert commission, consequentially submitted to the Federal Council (Bundesrat) at the end of 2002. However, the opposition, with a majority in the Federal Council, threatened to reject the proposal. Following opposition and government negotiations for the SHI Modernization Act, the Ministry’s mandate for compiling a positive list was withdrawn again.

Until 2003, market entry for most drugs meant SHI coverage, but there were a few important exceptions that were gaining attention.

- Drugs for “trivial” diseases (common colds, drugs for the oral cavity with the exception of antifungals, laxatives and drugs for motion sickness) are legally excluded from the benefits’ package for insured over 18 years (§ 34(1) SGB V).
- Inefficient drugs, that is, those not effective for the desired purpose or combined more than three drugs the effect of which cannot be evaluated with certainty, could be excluded by the Minister of Health under SGB V rules. The evaluation of these drugs takes into account the peculiarities of homoeopathic, anthroposophic and phytotherapeutic drugs. A negative list according to these principles came into effect on 1 October 1991, has been revised several times and as of October 2003 contained about 2400 drugs.
- Coverage of drugs was also regulated in the pharmaceutical directive of the Federal Committee of Physicians and Sickness Funds (replaced as of 1 January 2004 by the Federal Joint Committee), which is legally binding and limits the prescription of some drugs to certain indications (e.g. anabolics to cancer patients), specifies that they may only be used after failed non-pharmaceutical treatments or, in a few cases, disallows any prescription on the account of sickness funds (e.g. drugs to stop smoking).

Since 2004, the SHI Modernization Act has brought substantial changes to the coverage by adding two other groups of excluded drugs.

- So-called lifestyle drugs have been legally excluded from the benefit basket. The Federal Joint Committee is responsible for defining the exact extent of this regulation in its pharmaceutical directive.
- OTC drugs may no longer be reimbursed by sickness funds except for children below the age of 12. The task to define exceptions to this general exclusion has also been delegated to the Federal Joint Committee, which lists OTC drugs and the indications for which they may be prescribed in its pharmaceutical directive.

Another issue that has received increased attention is the prescription and SHI coverage of drugs for off-label use, raising concerns about access to innovations as well as pharmacovigilance and liability. Generally, drugs not licensed at all for the German pharmaceutical market or not licensed for the respective indication may not be prescribed by any physician except under clinical trial conditions. Sickness funds may not fund clinical research and may basically not cover prescriptions of unlicensed drugs or for unlicensed indications. Since 2007, the Act to Strengthen Competition in SHI has allowed off-label use for patients with serious illnesses in cases where the therapy can be expected to lead to an improvement, the benefits reasonably justify the additional costs, the treatment is conducted by an SHI-accredited provider and the Federal Joint Committee does not object to the treatment (see section 5.6.4).
2.8.5 Regulation of medical devices and aids

When looking at the regulation of medical devices, two steps again have to be clearly separated: (1) licensing (i.e. market access), which is determined to a large degree by European regulation transposed into national law, and (2) the national decision about coverage (i.e. reimbursement) by the SHI scheme.

Registration (licensing) of medical devices

Since 1 January 1995, the Medical Devices Act (Medizinproduktgesetz), transposing EU directives into German law, has been in effect. In compliance with EU directives 90/385 (concerning active implant devices such as pacemakers), 98/79 (in vitro diagnostic devices), and 93/42 (medical products other than those active implant devices), devices marketed in Germany must meet the requirements of the Medical Devices Act. In contrast to drugs, medical devices are defined as instruments, appliances, materials and other products that do not produce their main effect in a pharmacological, immunological or metabolic way.

The licensing of medical devices is the responsibility of authorized institutions ("notified bodies"), which require accreditation through the Federal Ministry of Health. The safety and of technical suitability of a device are the primary criteria for their market admission. In contrast to drugs, medical devices do not need to prove that they are beneficial in terms of potential health gain in order to be marketed. Devices marketed in Germany are reviewed for safety and for whether they technically perform as the manufacturer claims (Wörz et al., 2002).

The EU Medical Devices Directive 93/42 established a four-part classification system for medical devices. The rules for classification take into account the risk associated with the device, its degree of invasiveness and the length of time it is in contact with the body. A device’s classification determines the type of assessment the manufacturer must undertake to demonstrate conformance to the relevant directive’s requirements. Coverage decisions about medical devices and mechanisms to steer their diffusion and usage differ depending on whether they are used directly by patients ("medical aids") or as part of medical or surgical procedures in the ambulatory or hospital sector.
Coverage/SHI reimbursement of medical devices and medical aids

Decisions concerning the reimbursement of medical aids under SHI differ depending on the purpose and the sector of the utilization, that is whether (1) it is utilized by the patient him- or herself as a prescribed medical aid; (2) it is utilized as part of a medical or surgical procedure (e.g. implants), with differences in inpatient and ambulatory care; or (3) it concerns medical devices that can provide various services (see section 2.7.2).

Diffusion and usage of medical aids and prostheses is regulated by the Federal Joint Committee, which issues directives that limit the prescription of medical aids to the following cases: assuring the success of medical treatment, prevention of threatened health damage, preventing the health endangerment of a child, and avoidance or reduction of the risk of long-term care.

Medical devices can only be reimbursed by SHI if they are included in the Catalogue of Medical Aids (Hilfsmittelverzeichnis) of the Federal Association of Sickness Funds, which also regulates the quality requirements for these products in particular. Manufacturers can file a request for inclusion of a medical aid in the Catalogue of Medical Aids at the Federal Association of Sickness Funds with proof of the necessary quality requirements and, when indicated, its benefit. The Federal Association of Sickness Funds finally decides on the inclusion of the medical aid in the Catalogue. Although the Catalogue of Medical Aids has a regulating effect, the sickness funds have no legal obligation to reimburse the cost for listed medical aids.

Since 2004, the Federal Association of Sickness Funds has also been responsible for selecting the medical aid and prosthesis types that could be submitted to reference prices and for defining the price limits. Until the end of 2004, reference prices were set at the Land level and varied accordingly. Sickness funds reimburse the cost of covered medical aids up to the reference price for the specific type of aid, and physicians have to inform patients that they are required to pay costs beyond a reference-price limit for the respective type of medical aid or prosthesis.

In the wake of the Act to Strengthen Competition in SHI, since April 2007 sickness funds and their associations have been able to issue tenders for contracts with manufacturers of medical aids if doing so improves economic efficiency and quality of care. If this does not take place, the contract partners conclude contracts on the details of care related to medical aids and make public their intention to conclude a contract. Sickness funds and the manufacturers of medical aids are permitted to reach individual agreements if a contract for a needed medical aid does not exist according to the above-mentioned criteria, or if care cannot be provided in a reasonable way (§ 127 SGB V). In all three types of agreement, the price of the medical aid may not exceed the reference price set by the Federal Association of Sickness Funds, in so far as a reference price exists.

Expensive medical devices

Agreements upon the diffusion of expensive medical devices ("big ticket technologies") and their distribution between the ambulatory and hospital sector has been called a “never ending story”. This judgement is the result of various attempts of corporatist and legislative bodies to improve planning of expensive medical devices in the light of increasing costs and new device types such as extracorporeal shockwave lithotripsy.

Until 1982, when the Hospital Cost-containment Act (Krankenhaus-Kostendämpfungsgesetz) came into effect, no regulations concerning expensive medical devices existed. With this law, it became mandatory for expensive devices to be subject to hospital planning. Devices that were not part of an agreement could not be considered in the per diem charges and consequently could not be refinanced. In contrast, notification to the relevant regional association of SHI physicians was sufficient for expensive devices in the ambulatory care sector. This unequal situation remained essentially unchanged until the Health Care Reform Act of 1989.

Between 1989 and 1997, regional distribution of expensive medical equipment for the SHI-covered population was controlled intersectorally by Land-level committees consisting of representatives of the hospitals, regional associations of SHI physicians, sickness funds and a Land representative, who negotiated aspects of the joint use of devices by third parties, service requirements, population density and structure, as well as the operators’ qualifications.
After the Health Care Structure Act of 1993, the Minister of Health could determine which devices fell under the auspices of the committees but did not do so, and the committees defined expensive medical equipment on their own. On 30 June 1997, the following devices fell within this definition in almost all Länder: left heart catheterization units, computed tomography scanners, MRI devices, positron emission tomography machines, linear accelerators, tele-cobalt-devices, high-voltage therapy devices and lithotripters. The 2nd SHI Restructuring Act abolished the committees (effective July 1997); the self-governing bodies were then obliged to guarantee the efficient use of expensive equipment via contracting and remuneration regulations. In effect, this has led to even steeper increases in the number of expensive medical devices (at least in the hospital sector for which data are available), since previous site-planning procedures have been annulled (see section 4.1.3).

2.8.6 Regulation of capital investment

Since the Hospital Financing Act (Krankenhausfinanzierungsgesetz) of 1972, hospitals are financed by two different sources: "dual financing" means financing investments through the Länder (see section 4.1.1) and running costs through the sickness funds, plus private health insurers and self-pay patients (see section 3.7.1). In order to be eligible for investment costs, hospitals have to be listed in the hospital requirement plans set by the Land. These plans also list the specialties that are necessary, and even the number of beds per specialty for every hospital. The number of hospitals and beds is planned at a trilateral committee consisting of representatives from Land government, hospitals and sickness funds.

Investments are in principle covered through taxes and are, therefore, not contained in the reimbursement. Investments in long-term assets require a case-by-case grant application and are classified as construction of hospitals and initial procurement or replacement of other assets. In addition, hospitals receive an annual flat-rate grant for short-term assets (3–15 years economic life); the grant amount is determined by the size of the hospital and the development of costs. Hospitals are free to spend these grants as they choose on the purchase of short-term assets and minor construction projects. According to the Hospital Financing Act, a hospital acquires a legal claim to subsidy only as long as it is included in the hospital requirement plan of the Land. The inclusion in the hospital requirement plan means, on the one hand, that there is a claim to the above-mentioned flat-rate grant and, on the other, that the sickness funds have to finance the hospital care provided by the hospital.

It is noteworthy that listed hospitals do not have a right to have the financing of specific investments secured. That depends also on the budgetary situation of the responsible ministry and on political decisions. Should a hospital not be included in the hospital requirement plan, it still has the possibility to contract with sickness funds but no claim to state investment financing. Hospitals not fully publicly subsidized can, within a very narrowly defined framework, refinance investment costs via sickness fund reimbursement (Wörz & Busse, 2004).

The Hospital Financing Reform Act of 2009 stipulates that investments in hospitals included in the hospital requirement plans are to be financed as of 2012 by performance-based flat-rate grants rather than the mix of case-by-case grants and (non-performance-based) flat-rate grants described above. If a Land chooses to remain with the current case-by-case system, however, it may do so. In order to identify the need for investment for inpatient and outpatient care, the lump sum investment promotion is calculated at a national uniform investment valuation ratio and a federal state uniform investment case value (see section 3.7.1).