
ADVISORY COUNCIL
on the Assessment of Developments
in the Health Care System

**Needs-based Health Care:
Opportunities for Rural Regions and
Selected Health Care Sectors**

**Report 2014
Abridged Version**

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Foreword

The Council hereby presents the abridged version of its 2014 Report, “Needs-based Health Care: Opportunities for Rural Regions and Selected Health Care Sectors”. The first part of the Report focuses on the pharmaceuticals, medical devices and rehabilitation sectors, the second on needs-based provision in rural regions. In submitting the unabridged version of this Report, the Council has fulfilled its mandate under Section 142 (2) of Book V of the Social Code (SGB V) to identify ways and means of furthering the development of the health care system.

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All trademarks and trade names used in the Report are the property of the respective owners. Further identification of such trademarks and trade names, when used, has been dispensed with for the sake of greater clarity and better readability.

All references to sources and literature are included only in the unabridged version of the Report, and only that version is suitable for citation. The Council carries the responsibility for any errors in the Report.

Bonn/Berlin, June 2014

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Part I: Needs-based Health Care in Selected Health Care Sectors

1 Introduction: Needs-Based Health Care as a Criterion for Health Care Provision

1. Needs-based health care is a normative concept in which patients receive medical care quantitatively and qualitatively commensurate with their specific needs, which are ideally assessed using objective criteria. Although this 'objective need' is subject to change over time and, to an extent, remains an unmeasurable indicator, a general trend outlining the needs-based health care required by a specific patient can be plotted using positive and negative criteria. Thus, at different levels of this objective need, underprovision, overprovision and misprovision can occur and be largely identified in principle.

Irrespective of the level of the objective need, there is misprovision if health care services are not correctly provided or are not provided in the quality required. Even at a high level of objective need, induced demand can lead to overprovision, while at a lower level of objective need, problems in terms of accessibility for certain patients can lead to underprovision, meaning that even a modest normative benchmark is not attained. In the end, the level of objective need does not allow conclusions to be drawn as to the extent of under, over or misprovision. By way of example, Britain's National Health Service targets a low level of objective need compared with Germany or France, but this normative basis does not necessarily mean more misprovision

Irrespective of the level and structure of the respective objective need, which can vary over time and, as has been seen, even between economically comparable countries, a needs-based health care system should be primarily based on the severity of illness and/or disability and not on a patient's financial status, income, gender, marital status, address, profession, social class or origin. In addition, the criteria of effectiveness and efficiency in needs-based health care call for the availability of health care services that are based both on sufficient evidence from patient-focused studies and affordable service provision. With such optimal conditions, neither misprovision nor under or overprovision would ideally occur.

This objective need has many similarities with and also differs in some instances from the following concepts:

- Subjective need
- Latent need
- Demand for health care
- Use of health care services

2. Subjective need stems from the need or the desire of a patient and thus – in addition to objective morbidity criteria – from personal preferences. Two individuals of the same age and gender with identical morbidity traits and intensity, as well as other exogenous influencing factors (due to diverging needs for security, for example), can have different subjective needs. This is expressed in differing demand for health care provision, i.e. in relation to preventive services, check-up examinations and visits to the doctor. Where this variation remains within a given tolerance range, both cases can be seen as meeting the definition of needs-based provision. This means that neither the one individual receives overprovision nor does the other receive underprovision. A model for needs-based provision which is merely based on objective need and fails to take account of patients' differing needs paternalistically fails to do justice to the postulate of accounting for individual preferences.

3. Having estimated the objective need, the question arises – with a view to equity in health care services in relation to needs-based health care as defined in Germany's statutory health insurance system (SHI) – as to the scope of the catalogue of services and the associated effectiveness and efficiency of the care provided. As regards effectiveness and efficiency, it is not so much the outlined wide range of care on offer under the SHI (including in international comparison) as the non-indication-based, situation-based and over-intensive use of those services that poses a key medical and financial problem. This places health care provision under the SHI under special scrutiny. This applies directly to treatment given within the health care sectors and at their interfaces, and also indirectly to the respective service capacities, which can create supply-induced demand problems of a medical and financial nature. It is evident that, when it comes to the individual health care sectors, different degrees of transparency and thus different degrees of evidence concerning the quality of treatment exist. For example, there is far more data and analysis available about the services and the quality of treatment provided in the hospitals sector than is available for the outpatient sector. Benefit assessments and cost-benefit analyses should not, therefore, be limited to certain health care sectors. Rather they should stretch across the entire SHI care portfolio, and apply verifiable medical and financial criteria.

4. The relationship between objective and subjective need and the associated differences in the use of health care services can also differ from region to region. Only valid information on the determinants of regional disparities and their quantitative effects allow conclusions to be drawn regarding deviations from objective need, meaning under and overprovision within the SHI. Against this backdrop, the question arises as to the measures needed to eliminate or at least reduce such disparities, both in terms of needs-based health care and as regards effective health care services.

5. In contrast to the 2000/2001 Report, this Report does not address the relationship between needs-based health care, cost-effectiveness and under, over or misprovision. Rather, the following focuses in Part I on the pharmaceuticals, medical devices and rehabilitation sectors. The observations and analyses in this Report primarily address issues such as quality assurance and patient safety in the provision of pharmaceuticals and medical devices, while in the case of rehabilitation they take in issues concerning evidence-based treatment, regional differences, remuneration and competition. The more detailed Part II looks at how, in the face of demographic change in structurally weak regions and especially hard-hit rural areas, needs-based health care provision – meaning the availability of high-quality health care nationwide – can be secured.

2 Pharmaceuticals Provision

2.1 The German pharmaceuticals market

2.1.1 Pharmaceuticals expenditure in Germany in international comparison

6. A comparison of Germany's pharmaceuticals expenditure with that of other countries serves primarily to identify an international macro-level benchmark for health care services. According to the health statistics published by the OECD, in a listing of pharmaceuticals expenditure shown in US dollar purchasing power parity, Germany ranked sixth out of 26 countries in 2011. Looking at national pharmaceuticals expenditure relative to the countries' respective GDP, Germany ranks 13 out of 33 countries. Until 2011, Germany's pharmaceuticals expenditure significantly exceeded the average in European countries with comparable economies. In terms of the relationship between national pharmaceuticals expenditure and the associated total health expenditure, Germany's pharmaceuticals expenditure shows no significant difference when compared with other countries. In 2011, Germany took 16th place among 26 countries and with 14.1 percent was also below the OECD average of 16.8 percent.

7. The various national regulation systems can explain, at least in part, the differences between pharmaceuticals expenditure in OECD countries. These systems, which cover pricing, reimbursement via statutory or social health insurance funds, quantities, sales and (only very rarely) the quality of pharmaceuticals and prescriptions, influence to a significant extent the scope and structure of the respective pharmaceutical spend. For example, prior to the introduction in 2011 of the early assessment of the additional benefits of pharmaceuticals with new properties under the Act on the Reform of the Market for Medicinal Products (Arzneimittelmarkt-Neuordnungsgesetz, or AMNOG), the German pharmaceuticals sector had relatively few far-reaching regulatory instruments such as the state-regulated pricing seen in other countries in the EU. As a result, the prices charged by German pharmaceutical companies were significantly higher than the average prices in EU countries with comparable economies. Instead of direct price regulation, the German pharmaceuticals sector is subject to a complex mesh of some 25

regulatory instruments aimed at limiting growth in pharmaceuticals expenditure in the SHI. In contrast to most of the other countries, whose pharmaceuticals regulation primarily targets the producer level, German regulation tends to culminate at the level of prescribing non-hospital physicians. As a result, the German regulatory system has steadily grown with the introduction of 'add-on' regulations and contains an increasing number of components which strengthen or weaken one another, make others unnecessary and in some cases block the legislature's intended effect.

8. In an international comparison of pharmaceuticals expenditure, the most significant finding is the low percentage of contributions paid by private households in relation to per capita pharmaceuticals expenditure. Second only to Luxembourg (12.8 percent), Germany had the smallest share (17.2 percent) among 27 countries. The extremely low co-payment for private households in the overall share of national pharmaceuticals expenditure has its roots in the comprehensive full insurance coverage systems, namely the statutory health insurance funds (SHI) and the private health insurance funds (PKV). This generates a low level of demand elasticity among fund members or patients and thus runs the risk of being a moral hazard in pharmaceuticals consumption.

2.1.2 Pharmaceutical innovation and generic drugs in the pharmaceuticals sector for statutory health insurance funds

9. The vast majority of statutory regulations, which are often no more than cost-containment measures, target the pharmaceuticals sector serving the statutory health insurance funds. It helps to delineate in analysis between generic drugs or patent-free pharmaceuticals which are largely subject to a fixed price rule and non-generic drugs which are mostly patented pharmaceuticals. In the period 1987 to 2012, the share of prescribed generic drugs in the generic-tolerant market for the SHI rose from 45.7 percent to 87.0 percent, or when expressed in sales figures, from 31.4 percent to 73.3 percent. The share of prescribed generic drugs in the entire SHI pharmaceuticals market in the same timeframe rose from 17.2 percent to no less than 74.6 percent. This high percentage of prescribed drugs, however, corresponds to a sales share of only 37.0 percent.

Primarily in the generic drugs market for the SHI, the health insurance funds amassed sales and refunds under discount agreements with pharmaceutical companies worth almost €2.09 billion in 2012. Since 2007, when dispensing a substitute drug with the same or similar properties to the one actually prescribed, dispensing chemists are required to give priority to drugs covered by the discount agreements. This rule boosts competition for generic drugs which are authorised for prescription under the SHI and most certainly for those whose prices fall below the fixed rates.

10. With regard to patented pharmaceutical innovations, analogues are a focus of heated debate. These contain new drug molecules with largely identical pharmacological and very similar clinical effects to drugs already on the market. Where these are substituted as therapeutically equivalent primary compounds, the drug prescription report (Arzneiverordnungs-Report) sees huge savings potential at a level significantly above that with generic drug substances and controversial drugs. Analogues which offer significant savings potential are primarily those where pharmaceutical companies, when the patents for their innovations expire, manage to hold onto large market shares in high-revenue indication areas in competition with upcoming generics by making minor modifications (often of no relevance to therapy) to the original substance. Whether analogues raise or reduce the costs of pharmaceuticals depends on whether they compete against expensive first generation or less expensive generic drugs with the same or similar therapeutic effects (see Report 2006, Item 773).

Together with drug innovations with therapeutic benefits, the prescription of analogues had its biggest impact on the structural component. In the past 25 years, this has been the dominant influencing factor of growth in pharmaceuticals expenditure in the statutory health insurance system. In contrast, the number of prescriptions remained largely constant, while prices have dropped over the past 20 years, both in the generics sector and in the pharmaceuticals market overall – and from 2010 in the non-fixed price sector. The growth seen in SHI expenditure for pharmaceuticals was thus accounted for by the structural component alone, meaning in relation to both the inter-medicinal and the intra-medicinal effect. From the mid-1990s until 2006, the inter-medicinal effect was clearly a stronger factor in expenditure growth, after which the intra-medicinal effect (switching between package size and substance strength) was the dominant influencing factor.

11. This trend with regard to analogue products and the structural component, and also the finding that a prescription share of just 2.5 percent accounts for an expenditure share of some 26 percent in the SHI pharmaceuticals sector, highlights from both a medical and financial perspective that detailed, valid information on the cost-benefit ratio of pharmaceutical innovations is needed to allow adequate reimbursements from the SHI. Because research efforts in pharmaceutical companies tend to focus on future growth markets such as oncology, further growth in cost-intensive drugs can be expected. Against the backdrop of this growing pharmaceuticals trend, it is not a question of ‘whether’ but solely of ‘how’ to perform early assessment of the additional benefits of pharmaceutical innovations compared with those of the existing appropriate therapy. When it comes to patient-relevant outcomes, such early evaluation of patented pharmaceutical innovations should not be based on similarly secured informational sources such as an analysis which, using a multi-year study of health care provision, can identify the effects on patients’ everyday life. This does not, however, detract from the

necessity and potential for early evaluation. Rather, it calls for the two analytical decision-making aids to be used in parallel.

Spotlight: Pharmaceuticals supply shortages

12. Pharmaceuticals supply shortages have increased in recent years in terms of frequency, the range of care affected and not least negative and harmful impact on patients' health. To a great extent, such shortages affect chemotherapy medicines and antibiotics.

These supply shortages have multi-layered, complex causes whose roots lie both in supply and demand, market conditions and state regulation. These involve a) shortfalls in the production of the necessary raw materials, b) concentration of substance production in just a few locations and lack of much-needed investment in what are in some cases out-dated production facilities, c) a reduction in the product range, resulting in fewer alternative products, d) re-imports and parallel imports of pharmaceuticals, e) the removal of some lower-priced generic drugs from the market, f) an increase in demand for drugs, especially in emerging economies, and g) the increasing discovery of quality deficits following state regulation and the resulting delivery delays.

In spring 2013, Germany's Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM) began publishing an overview of current supply shortages in human drugs based on voluntary information provided by producers. In early May 2013, the list contained 13 drugs. Where such shortages occur, treating physicians feel compelled to postpone planned treatments or to prescribe an alternative drug. This can have a negative impact on patients' health.

The discount agreements drawn up between the statutory health insurance funds and pharmaceutical companies provide for default fines and claims for loss and damage should a supply shortage occur. These contractually agreed conditions are not enough, however, which is why additional regulations are needed. The latter should apply for life-saving or medically vital drugs for which no therapeutic alternative is available and whose lack of availability reduces a patient's longevity and/or results in a significant reduction in their quality of life. A list of such drugs should be drawn up in cooperation with scientific medical societies. Pharmaceutical companies should be required by law to report all previous, current and anticipated supply shortages. The names of the drugs in short supply should be published. In addition, legal provisions on the expansion of production and storage capacities at producers' sites should, under the 16th amendment to the German Medicinal Products Act (AMG), be introduced in accordance with the originally planned extension of the security of

supply requirement set out in Section 52 (5) AMG, with default fines applying in the case of serious breaches of the respective provisions. The BfArM should take charge of centralised management of vital drugs where supply shortages occur.

2.2 Regional differences in pharmaceuticals provision

2.2.1 Regional differences in pharmaceuticals expenditure and consumption

13. Annual average pharmaceuticals consumption in Germany amounted to 576 daily doses (defined daily dose, or DDD) in 2012, while average per capita SHI pharmaceuticals expenditure was €384. In a comparison of the Panel Doctor's Association regions, clear differences within a notable range are evident between the German Länder (states). In respect of pharmaceuticals consumption, the difference between the Panel Doctor's Association regions, the highest being in Mecklenburg-Western Pomerania and the lowest in Bavaria, is 245 DDD per capita. In 2012, per capita expenditure for statutory health insurance fund patients in Mecklenburg-Western Pomerania amounted to €151, some 45 percent more than that in Bavaria. These differences are increasing over time. In eastern Germany in particular, and also in the city states of Berlin and Hamburg, per capita expenditure for statutory health insurance patients has been well above average for many years. Due to the expenditure ceiling laid down in the price moratorium and a higher producer discount, per capita expenditure on pharmaceuticals has decreased in many Länder despite a significant increase in consumption in some areas.

What is particularly notable is that doctors in Berlin and Hamburg prescribe disproportionately expensive drugs. And throughout the Länder in eastern Germany, prescription costs of €47.24 are above the German average. In the first quarter of 2013, prescriptions in Westfalen-Lippe region were the cheapest.

14. Regional differences can be explained by influencing factors on both the demand side (for example, demographic, epidemiological and morbidity-related factors) and the supply side (such as the density of doctors' practices in a given region). By adjusting various influencing factors, it is possible to explain, at least in part, and thus understand the differences in expenditure levels. Various explanatory factors can be put forward depending on the Panel Doctor's Association region. In eastern Germany, it is primarily demographic change and the associated morbidity issues that explain the high expenditure on pharmaceuticals. Although available studies highlight across the board the huge role played by age in spending on pharmaceuticals, this is not enough to serve as the sole explanation.

Apart from adjustments for age and gender, analyses should also include adjustments for morbidity as an influencing factor (e.g. morbidity-adjusted risk structure compensation based on disease prevalence) and, where appropriate, social strata. Where it is suspected that the factors involved extend beyond the demand side to include supply-side influences, however, the corresponding adjustments should be conducted in a separate analysis. Issues regarding variations in marketing intensity by the pharmaceuticals industry or varying levels of receptiveness for marketing should also be analysed.

2.2.2 Regional differences for selected indication areas

15. Increasing resistance arising from too frequent or inappropriate use of antibiotics has led to greater sensitivity in recent years regarding the broad use of these drugs. In 2010, almost 22 million patients (31.5 percent of all statutory health insurance patients) received at least one prescription for an antibiotic. The ratio of prescriptions for antibiotics for children was higher again. While Germany lies at the lower end of the scale on an international comparison, there are great regional and age-related differences in the frequency and volume of such prescriptions across Germany.

The prescription of antibiotics for young adults is remarkably high in some parts of Saarland, Thuringia, Saxony-Anhalt and Mecklenburg-Western Pomerania. The frequency in Saarland is some 40 percent higher than in Schleswig-Holstein. In a smaller-scale observation at Landkreis (county or district) level, the differences are significantly greater.

Looking at the prescription of antibiotics for patients as a whole (both children and adults), a somewhat different distribution pattern comes to light which can be described as a clear west-east divide.

16. In 2011, some 750,000 people in Germany were diagnosed with an attention deficit/hyperactivity disorder (ADHD). Of these, almost three-quarters were male and mostly children or teenagers. Thus, some 12 percent of all ten-year-old boys in Germany are diagnosed with ADHD and around seven percent of boys aged 11 are prescribed methylphenidate, which can be seen as an indicator of medication therapy for ADHD.

Prescription figures have risen significantly in the past 15 years. In 2008, some 53 million DDD of methylphenidate were prescribed, although the increase since then has been less pronounced. A slight drop in the number of prescriptions was first seen in 2013. On the whole, the prevalence for diagnosis and prescription in Germany matches the European average. There is, however, evidence of huge differences in the figures for diagnoses made and prescriptions issued. While the figures for Bremen, Mecklenburg-Western Pomerania and Hesse are extremely low, those for the Rhineland-Palatinate and Bavaria are significantly above the German average: in both of these Länder, the

expected rate of prescriptions relative to a patient's age and gender are exceeded by 33 and 24 percent respectively.

Apart from the different health care structures, one possible cause of these great regional differences could lie in the inequitable expansion and availability of alternative approaches. In the Special Report issued in 2009, the Advisory Council highlighted the huge need for multi-modal forms of therapy (behavioural therapy, educational intervention in schools, parental training, family therapy, etc. in combination with medication).

17. Medications which are potentially inadequate in the treatment of older patients include preparations, forms of administration and dosages that should be avoided in old age due to an unfavourable risk-benefit ratio. Lists containing such medications have been drawn up in numerous countries such as the US, Canada and France. Germany has its own list, the PRISCUS List, which contains 83 substances. The use of medicines cited in this list is, for example, associated with a high risk of causing falls. In 2011, some 4.5 million patients aged 65 and over (meaning 25.3 percent of the older population) were prescribed at least one potentially inadequate medication. The German Länder show marked differences, with a west-east divide: The total share of patients given prescribed a potentially inadequate drug on the PRISCUS list ranges from 19.2 percent in Brandenburg and 27.5 percent in Rhineland-Palatinate.

18. In sum, it can be said that for the indication areas outlined above, great regional differences exist in pharmaceuticals provision. It must, however, be remembered, that the comparison does not allow a conclusion to be drawn regarding 'rational' or 'irrational' prescription of drugs. In all three indicators addressed, the issue at hand involves a potential overprovision or misprovision. It is nonetheless to be presumed that there are also indication areas with underprovision of drug therapy; the signs are that this is the situation in Germany with regard to drug therapy for secondary prevention following myocardial infarction. However, there is a lack of studies on the health impacts of regional variation in prescription practices for pharmaceuticals. It would be helpful to see comparisons at administrative district level across Germany, for example with regard to antibiotics resistance or side effects (such as increased prevalence of falls).

Differences due to regional-level agreements

19. Data from the first quarter of 2013 highlight regional differences in the share of prescribed analogue and generic drugs. Particularly when comparing the share of analogues, clear differences can be seen. For example, the analogue share of prescriptions in eastern Germany is relatively high – about twice as high in Mecklenburg-Western Pomerania as in Bremen. The generic share of prescriptions varies to a lesser extent between the Panel Doctor's Association region.

20. Any attempt to interpret the reasons behind these large differences must be viewed with caution. The differences could, at least in part, be a result of the differing approaches taken and recommendations given in the various Panel Doctor's Association regions – for example at information and discussion events – or prescribed quotas.

Between the health insurance funds and the Panel Doctor's Associations, agreements are reached on the prescription of pharmaceuticals to guarantee, by means of budgets, thresholds and controls, the most cost-effective prescription management practices. These drugs agreements mainly lay down an expenditure volume for the total quantity of drugs prescribed by SHI-accredited physicians along with various medical provision and cost-effectiveness targets which include specific measures. Apart from framework requirements at national level and agreements at Länder level, deviating or supplementary agreements may be drawn up at individual level, meaning between individual health insurance funds and doctors.

Performance audits in health care provision by SHI-accredited physicians

21. Monitoring for compliance with the requirement for cost-effectiveness in health care provision by SHI-accredited physicians occurs via the performance audits defined in Section 106 of Book V of the German Social Code (SGB V). The law provides for two different monitoring processes: compliance or prescription target checks, and random sampling. The basis for compliance checks is the physician group-specific volume of medicinal products and dressings prescribed per doctor – known as the prescription target. The random sampling involves physician-related monitoring based on physician and patient-related sampling.

Many drugs, dressings and medicines are recognised as being practice-related. This involves objective, verifiable, structural circumstances in which a practice differs significantly from average practices in specialist groups, because they expend above-average treatment and prescription effort.

Exceeding the prescription target in a given calendar year triggers a performance audit. If a doctor exceeds the target by more than 15 percent and the excess cannot be attributed to practice-related circumstances, they may be invited to an advisory consultation. If the target is exceeded by more than 25 percent, the doctor must reimburse the health insurance fund(s) for the additional expense incurred. With the entry into force of the SHI Health Care Provision Act (GKV-VStG) in 2012, the risk of doctors having to reimburse costs was considerably reduced. Thus, where a doctor exceeds the target by 25 percent for the first time, they receive one-on-one advice. Then, if further budget overruns occur, reimbursement claims can only be made for a specific audit period following the advisory session.

22. The structure and use of performance audits is subject to controversial debate. Critics stress the restrictive effect the audit process has on everyday health care provision. They point in particular to how it deters doctors from setting up their own practices, especially in the prescription-intensive general practitioner sector. It is thought that some doctors face the risk of insolvency should they be required to reimburse large amounts. Management via cost requirements is said to be not suited as a means of controlling practicing physicians because it only provides for limited cost transparency. Given the correlation between the volume of prescriptions written and patient morbidity, the current calculation system used in the prescription target checks is said to be inappropriate.

Advocates of the performance audit process mainly highlight the necessity for state regulation of pharmaceuticals expenditure. Performance audits, it is argued, serve as a management instrument which provides the stakeholders who approve the particular service with an incentive to use available resources responsibly and sparingly.

In the accounting period 2008, reimbursement claims were made against 0.5 percent of medical practitioners who write prescriptions. In 2007, these reimbursement payments amounted to an average €30,000.

The German government's Coalition Agreement states that the current performance audit process will be replaced by regional self-administered agreements between health insurance funds and Panel Doctor's Associations by the end of 2014.

Other ways in which Panel Doctor's Associations influence drugs prescription

23. Apart from the agreement on prescription targets, Panel Doctor's Associations can enter into regional agreements with individual doctors on substances and substance groups. These can be based on expenditure or prescription targets, and quotas covering primary compounds, maximum prescription volumes, minimum prescription volumes, analogues (or drugs with no proven additional benefits), generic drugs, aut-idem (substitute) drugs or special drugs. Although framework requirements exist at national level, it is not possible to agree specific quantities at regional or Länder level. Also, there are numerous other regional-level arrangements in place. Of great importance in effective management of drug prescription practices is timely reporting in the form of prescription data reports. Using indicators extracted from routine data, peculiarities in a doctor's prescription issuance practices are made transparent, discussed in organised quality circles and, using targets, are then steered in a certain direction.

Panel Doctor's Associations survey on management of pharmaceutical prescriptions

24. Because only little publicly accessible information is available on measures to secure needs-based and affordable management of pharmaceutical prescriptions at regional level, in January 2014 the Advisory Council, with support from the National Association of Statutory Health Insurance Physicians (KBV), conducted its own questionnaire-based survey of German Panel Doctor's Associations on how they manage pharmaceuticals prescriptions issued by SHI-accredited physicians in the outpatient sector.

The survey showed that pharmaceuticals therapy consultations are offered by all 17 Panel Doctor's Associations. Relative to the doctors in each Panel Doctor's Association region, between 0.04 and 0.39 pharmaceuticals therapy consultants are available per 100 doctors. At national level, less than one enquiry per doctor per quarter was submitted to a Panel Doctor's Association in 2012 (mainly by telephone). The range spreads, however, from between one and nine enquiries per doctor. The most frequent instruments used in managing pharmaceuticals prescription are targets for primary compounds (15 associations), biosimilars (10 associations) and specialist group-specific agreements on substances and substances groups (nine associations).

All the Panel Doctor's Associations surveyed provide their accredited physicians with prescription reporting forms, and all of the associations offer training courses. Special services are offered for newly authorised doctors opening their own practices, and more than half the associations offer advisory consultations on performance audits. Pharmaceuticals therapy consultations for quality circles are widely offered (by 13 associations), but only one panel organises specially designed/topic-focused quality circles.

Spotlight: Knowledge-sharing to ensure high-quality, evidence-based and needs-based health care

25. The availability of knowledge is a vital prerequisite in the provision of high-quality, evidence-based and thus cost-effective and needs-based medical care. Despite international cooperation efforts such as the Cochrane Collaboration and the numerous other agencies who evaluate studies, conduct health technology assessments (HTAs) and support one another in their work, many questions remain unanswered – some of which are of interest to a specific country or countries (such as complex intervention in the health care system). Added to this is the fact that scientific articles are published in English, thus creating an obstacle for most German doctors. Many countries have responded to these challenges by implementing national institutes for health information. These institutes are financially independent, identify open and relevant research questions, address these questions or

commission studies on them, and, in particular, provide easy-to-understand findings (translated into the local language).

In Germany, such activities have been under-funded to date or have been divided across a range of different institutions. Many arguments speak in favour of establishing an independent 'German Institute for Health Knowledge' in order to provide the most populated country in the EU with health-related information in German. The German Cochrane Centre could form the core of such an establishment. This would, however, call for stable financing which for regulatory policy reasons should be funded via the taxation system.

2.3 Pharmaceutical benefits assessment under the Act on the Reform of the Market for Medicinal Products (AMNOG) as set out in Section 35a of Book V of the German Social Code (SGB)

26. The Act on the Reform of the Market for Medicinal Products (AMNOG), which entered into force at the start of 2011, gave Germany its first instrument with which to evaluate the (additional) benefits of patented medicinal products followed by negotiation of reimbursement agreements between the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and pharmaceutical companies. Previously, Germany was one of the few countries in which pharmaceutical companies were free to set their own prices for their newly patented products on a long-term basis.

As part of the early benefits assessment, an analysis of the additional benefits of all medicinal products placed on the market since 1 January 2011 (or those for which the original scope of use has been extended) is compared with an appropriate comparison treatment. Where a product has multiple uses, a special benefits assessment is performed. One key exception involves 'orphan' drugs for rare diseases where annual sales of a drug of this kind do not exceed a maximum of €50 million. The additional benefit of these drugs is deemed as proven by the fact that they have been approved for sale and use. In such cases, it is only the extent of the additional benefit which is assessed by the Federal Joint Committee (G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany.

27. The benefits assessment process begins when a medical device is placed on the market for the first time. At the time of placing the product on the market, the pharmaceutical company involved is required to submit a benefits dossier which must meet the statutory requirements and serve as the basis for all benefit assessments. The process involving the dossier, the benefits assessment and its findings, the reimbursement

negotiations/fixed amount, the arbitration office (where appropriate) and the relevant deadlines is shown in Figure 1.

The early benefits assessment focuses on patient-related outcomes which are described as an improvement of patient health, shortening the length of illness, extending longevity, reducing side-effects and improving quality of life.

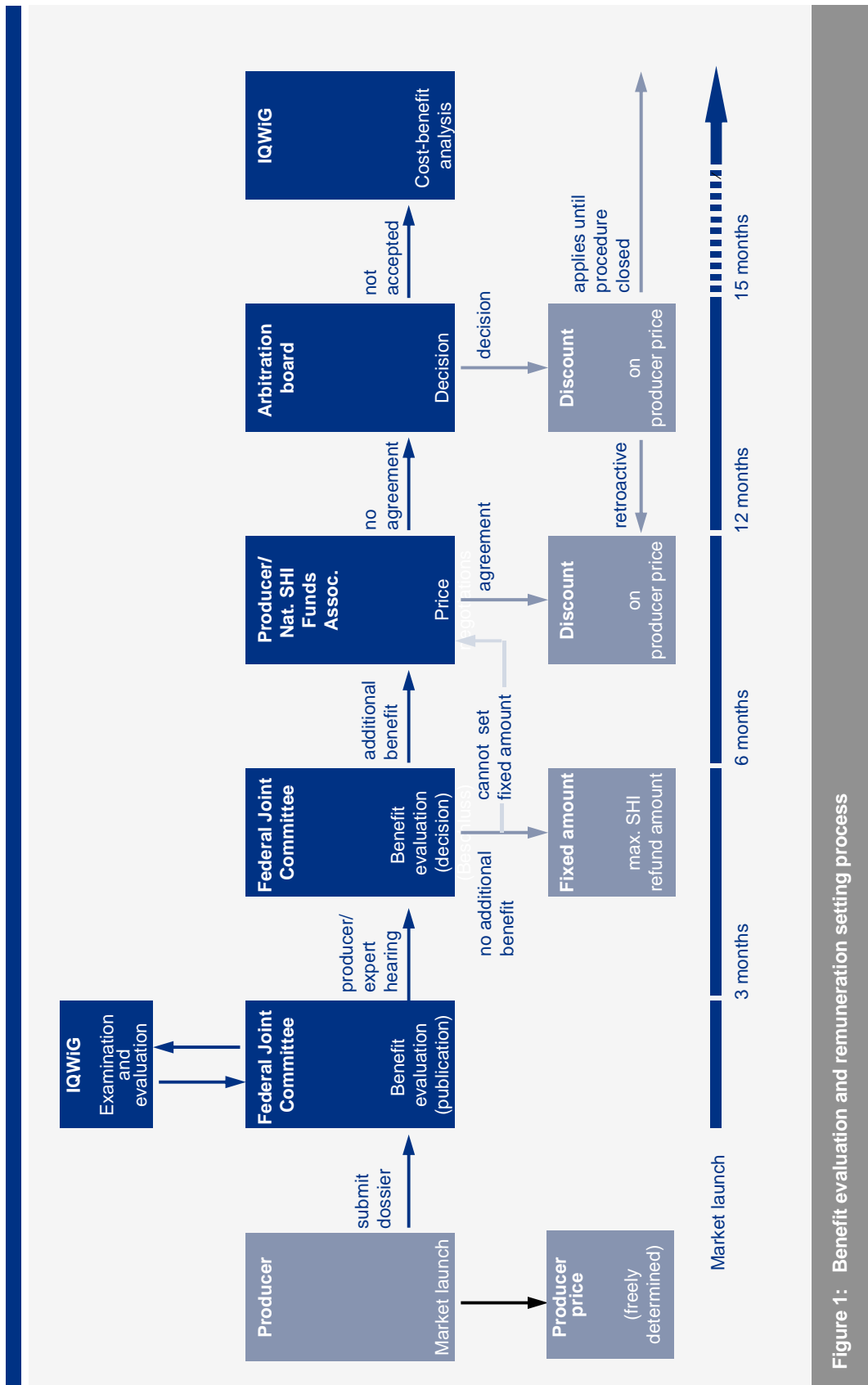


Figure 1: Benefit evaluation and remuneration setting process

Source: Own compilation, based on BMG 2013 (charts illustrating medicinal products reform legislation), www.bmg.bund.de/glossarbegriffe/a/das-gesetz-zur-neuordnung-des-arzneimittelmarktes-ammog.html (as of 7 June 2014)

28. Until 1 April 2014, early benefits assessments as defined in Section 35a of Book V of the German Social Code (SGB V) had been conducted for 63 products, and in 22 cases at least one high-quality, double-blinded RCT's were available which took into account the appropriate comparison treatment required by the Federal Joint Committee and supplied data on patient-related outcomes or measurable surrogate parameters.

For 31 of the 63 products assessed, evidence, an indication or proof (albeit marginal in some cases) of additional benefit was reported. Looking at the individually assessed indications or patient groups, some 101 assessments were conducted of which only 33 provided evidence, indications or proof of marginal or significant additional benefits. For 55 substances and their sub-populations, no additional benefit could be proven. In 12 cases, evidence, indications or proof of a non-quantifiable additional benefit were found, and in one case, evidence of a lesser benefit. Overall, the definition of the appropriate comparison treatment by the Federal Joint Committee plays an important role in early benefit assessment.

29. In 2000, the EU made orphan drugs subject to an accelerated approval process, discounted processing fees and a ten-year market exclusivity status. Currently, some 76 orphan drugs have been approved (as of 1 April 2014) whose use (via expanded indication), including in the off-label sector, will be extended and is of not insignificant financial interest to pharmaceutical companies. In addition, around 65 orphan drugs with this special approval status outside the EU are available on the German market and subject to reimbursements under the statutory health insurance system. The quality of the studies conducted in this sector has been repeatedly criticised, saying that most of the products involved would not stand up to a benefits assessment.

30. Also excluded from the benefit assessment are pharmaceuticals which are used solely in the inpatient sector. If the legislature assumes that the additional benefit for a medicinal product in general is not automatically provided by way of its approval (with the exception of orphan drugs), it does not make sense that, for example, new medicines for the treatment of serious fungal diseases should not be subject to assessment. New medicinal products for inpatient use were exempted from the benefit assessment on the condition that the expected expenditure incurred by the statutory health insurance funds would be marginal. Apart from the quality aspect of an additional benefit, the assumption of minor cost on the part of the statutory health insurance funds is insufficient because, in the end, the additional costs associated with these (unassessed) innovations will be passed on to hospitals and clinics.

31. A key component of the current assessment and pricing process is the proven benefit of a medicinal product in relation to patient-relevant outcomes. Here, proof of effect must be provided to the Federal Joint Committee, largely by means of randomised, controlled clinical studies. Given that the early assessment is timed immediately

following a product's entry onto the market, any assessment of its benefits as regards long-term effectiveness or side-effects is fraught with uncertainty. The legislature has thus provided the Federal Joint Committee with the option of requesting supplementary, treatment-relevant studies whose costs are borne by the pharmaceutical company involved. So far, the Federal Joint Committee has, however, made use of this option on only one occasion.

How the different benefit considerations can vary is shown in comparative studies of benefit assessments conducted at international level. The studies' methodological requirements, scales and assessment methods differ, and the issue of comparative treatments is not uniformly addressed, which means that medicinal products are assessed differently between the EU member states. Savings on the resources used in national assessments appear possible if, in parallel to the approval process, comparable benefit assessment methods were to be used and the responsibilities shared.

32. Where medicinal products do have an additional benefit, the National Association of Statutory Health Insurance Funds and the pharmaceutical manufacturer enter into reimbursement negotiations. Key factors involve the annual treatment costs of the appropriate comparative treatment, the actual sales price in other EU countries and the extent of the additional benefit. A period of six months is allowed for these negotiations. Should the parties fail to reach agreement within the six-month period, the case is referred to the central arbitration office which then has a further three months in which to determine a reimbursement amount. If one or other of the parties objects to the arbitration office decision, the Federal Joint Committee can request a more detailed cost-benefit assessment.

Medicinal products with no additional benefit are classified by the Federal Joint Committee directly into a fixed-contribution group where a suitable group exists. If no such group exists, negotiations are entered into between the National Association of Statutory Health Insurance Funds and the producer, whereby the reimbursement amount is to be negotiated such that the treatment costs do not exceed those of the appropriate comparative treatment.

It appears paradoxical that the cost-benefit assessment information relevant to conduct price negotiations should only be compiled after negotiations have failed. One important reason why the two options available for using cost-benefit analyses have not been used so far is that by law, these are solely conducted by the Institute for Quality and Efficiency in Health Care (IQWiG). This is unusual in other countries and, in the interests of plurality in analysis, is undesirable. The methodological requirements for health expenditure analysis should be compiled by IQWiG and subsequently debated publicly and then issued by the Federal Joint Committee.

The cost dimension is reduced in the dossier to be submitted to the Federal Joint Committee to details on the direct medicinal costs (from a statutory health insurance fund perspective) of the medicinal product to be assessed and the appropriate comparative treatment, and where necessary the costs of additionally required statutory health insurance fund services. This approach goes nowhere near far enough because to evaluate the additional costs, not the gross but the net costs must be taken into account. This applies especially in relation to savings achieved by reducing follow-on treatments or by providing substitute services.

Because licensing approval studies can often be fraught with uncertainty when it comes to long-term treatment results and the treatment actually provided, it appears wise to draw – at least in relation to reimbursement price negotiations – on statistical models based on extrapolated data from the licensing approval studies.

33. The outcome of pricing negotiations is implemented in the form of a discount on the manufacturer's price for a medicinal product. In contrast to the discount agreements under Section 130a (8) SGB V, which are classed as confidential, the newly negotiated discount agreed under Section 130b SGB V is included in the prevailing price lists for medicinal products. This is the subject of criticism, notably from the pharmaceuticals industry. A discount agreed in Germany triggers pricing mechanisms in other countries which (can) in turn lead to a new round of reimbursement negotiations for a given substance and to even larger discounts in Germany. In consequence, this trend can lead, in countries with higher prices, to an increase in re-imports and parallel imports of pharmaceuticals which are subject to a discount in Germany. Non-confidentiality of discounted prices could also result in the market entry of a product being delayed or halted. What speaks against greater confidentiality with regard to discounts most of all is that otherwise, retail mark-ups would have to be added to the higher and ultimately fictitious original price.

Benefit assessments for medicinal products already on the market

34. With the establishment of early benefit assessments under AMNOG, there exist at present – depending on whether the licensing approval for a new medicinal product was issued before or after 1 January 2011 – unequal conditions regarding medicinal product pricing for the pharmaceutical producers involved. To ensure fair competition, it was thus planned that the Federal Joint Committee should be entitled to subject products already on the market to a benefits assessment based on a dossier which the pharmaceuticals producer is required to submit. One of the key challenges involved, however, was the need to define a process which sets out legally sound criteria for selection (and sequence) of the substances to be assessed without triggering any distortion of competition. In June 2012, the Federal Joint Committee took a first step in assessing the existing market by initiating the assessment of gliptins used as an oral anti-

diabetic. The only marginal indication of an additional benefit in monotherapy stands in contrast to the market share for gliptins (18 percent of all prescription costs and around nine percent of prescribed daily doses of anti-diabetic drugs) and underlines the role of benefit assessment, including for products already on the market.

35. On 20 February 2014, the German Bundestag (lower houses of parliament) adopted the 14th amendment to Book V of the German Social Code. With the complete deletion of Section 35a (6), the Federal Joint Committee no longer conducts the systematic assessment of additional benefits of medicinal products already on the market. This is justified with arguments that on experience so far, the process used in benefit assessment and the subsequent reimbursement negotiations for medicinal products already on the market are significantly more complex than expected. Given the difficult legal basis regarding the sequence in which the selected products are to be assessed, a large number of court proceedings can be expected. In addition, it is said, the expenditure-reducing effect of the assessment of products currently on the market is difficult to calculate. An advantage is identified in the fact that the administrative effort involved for the pharmaceutical company and the associated institutions falls away. To achieve the required level of savings on medicinal products, the price moratorium issued under the 14th amendment to Book V of the German Social Code (SGB V) was extended to 31 December 2017 and the general producer discount for patented pharmaceuticals was raised, in the form of a volume discount, from the existing six to seven percent. The Advisory Council believes the pragmatic arguments for stopping the assessment of products already on the market are understandable. However, the line of argument based solely on cost savings means that the qualitative component of benefit assessment is lost. Waiving the benefit assessment of products already on the market hails many more years with a parallel process of transparent evaluation on the one hand and substances which are not assessed for their additional benefits on the other. The Federal Joint Committee can, however, continue to commission benefit assessments for specific medicinal products under Section 139a (3) 5 of SGB V and should make use of this option.

2.4 Pharmaceuticals distribution

36. In 2013, sales at Germany's retail pharmacies amounted to €53.1 billion, including VAT, with pharmaceuticals accounting for some 90.8 percent. Among these pharmacy sales, prescription-only drugs dominate with a share of 80.3 percent compared with non-prescription pharmacy-only medicines. The statutory health insurance funds play a key role, with a share of 72.2 percent of pharmaceuticals expenditure across all payers.

In 2013 there were 20,662 pharmacies in Germany, of which 16,661 were primary or individual pharmacies and 4,001 belonged to pharmacy chains. While the total number of pharmacies in the period 2000 to 2013 dropped marginally by 4.3 percent, the number of those belonging to pharmacy chains rose steadily since their introduction in 2004. The pharmacy density, defined as the number of inhabitants per publicly accessible pharmacy, was 3,880 in 2013 and ranges across the German Länder from 3,160 in Saarland and 3,720 in Saxony-Anhalt, to 4,260 in Brandenburg and 4,280 in Bremen. In western Germany, pharmacy density in 1970 was lower, at 5,000, although this did not result in a pharmaceuticals supply problem. Compared with countries with similar economies, Germany has a relatively high pharmacy density. This goes hand in hand with very limited price competition which is restricted to non-prescription medicines. Apart from Germany's Drug Price Regulation (Arzneimittelpreisverordnung), many other national, competition-restricting regulations in the pharmacy sector hinder efficient and effective distribution of medicinal products.

Steps towards deregulation and greater competition

37. When it comes to regulatory policy, the tightly regulated German pharmacy market is characterised by an atomistic supply structure and low price elasticity of demand, especially for prescription-only drugs. To make supply more efficient and increase demand price elasticity, various deregulation measures are currently being discussed. The following focuses on the introduction of fixed-sum remuneration for services provided in connection with pharmacy-specific retail margins and on the withdrawal of the multi-ownership and third-party ownership ban.

38. In contrast to non-prescription pharmaceuticals, prescription-only medicines are subject to strict pricing rules and extremely low price elasticity. Under the Drug Price Regulation, when selling a proprietary medicinal product, the wholesaler will at first add a mark-up on the pharmaceutical manufacturer's price of no more than 3.15 percent or a maximum of €37.80 excluding VAT, plus a fixed surcharge of €0.70 excluding VAT. The pharmacy retail price comprises the pharmacy wholesale price, which is a kind of list price, a surcharge of three percent on that wholesale price, a surcharge of €8.35 plus €0.16 to fund and secure the availability of the emergency pharmacy service, plus VAT and a mandatory discount stipulated by the statutory health insurance funds of currently €1.80 (2014).

With the currently applicable framework regulation, neither does the insured person/patient have a financial incentive to search for a low-price pharmacy, nor can price or quality competition play a major role in a pharmacist's financial success. Pharmacies that work to implement efficient operating practices are unable to force those of sub-optimal sizes out of the market.

39. Price competition for prescription-only medicines can be achieved with the introduction of pharmacy-specific retail margins. The legislature prescribes an across-the-board fixed margin (AFS) for pharmacies which is made up of the average selling costs, meaning expenditure for storage and customer consultation, and an appropriate proprietor wage for the entire pharmaceuticals distribution service performed, i.e. for wholesale and pharmacy sales. The pharmacies add the AFS to the manufacturer's price which, together with VAT, makes up the price the health insurance funds reimburse.

Independent of the AFS, pharmacies are free to set their own, meaning pharmacy-specific retail margin (AIH) relative to their cost structure, their negotiations with the wholesaler and their targeted profit margin. In contrast to the prevailing framework regulation, this approach gives them a competition parameter with which to generate additional demand by means of a lower selling price. Where a patient's co-payment is involved, a positive (negative) difference between the AFS and the AIH reduces (increases) the surcharge the patient is required to pay for the prescription. Where no co-payment is involved, if $AIH > AFS$ the patient must pay a surcharge on the health insurance fund reimbursement price (KEP), while if $AIH < AFS$, the pharmacist reimburses the patient the difference. This price competition is likely to prove stronger in areas with an over-supply of pharmacies than in less-well developed rural regions and as such will create an incentive for pharmacists to set up in poorly served areas. To prevent over-burdening patients financially, a ceiling is placed on the AIH. The danger of a monopolistically high AIH, particularly in regions with few pharmacies, could be countered by a combination of online retail and a number of other deregulatory measures such as limited dispensation licences for general practitioners.

40. A more radical model that incorporates both remuneration and supply aspects includes pharmacies as an integral component of primary health care provision in an integrated services or cross-sectoral, possibly even population-oriented, network (see Special Report 2009, at 766 ff). Pharmacies contribute in compilation of a network-specific positive list. To improve patient adherence and prevent avoidable drug-related incidents, pharmacies work with medical practices in taking on the responsibilities of targeted medication management. Pharmacists' fees are agreed in network-specific agreements.

41. Germany's pharmacy sector operates a blanket ban on third-party ownership and allows very limited opportunities for pharmacists to own more than one pharmacy. Following the relaxation of the multiple ownership ban under the Act to Modernise the German Health System (Gesetz zur Modernisierung des Gesundheitssystems, or GMG) in 2004, a pharmacist may operate up to four pharmacies but must personally manage one of them as the primary pharmacy. In addition, the primary pharmacy and the others in the chain must be located within the same district, or in neighbouring districts or towns.

From a regulatory policy standpoint, the bans on third-party and multiple pharmacy ownership appear a throwback to medieval guild structures. And from a health care policy perspective, there are no convincing arguments as to why an employed pharmacist should exercise less care in advising patients and dispensing pharmaceuticals or have greater incentive to maximise profit than a proprietor pharmacist. The removal of the third-party ownership ban and the opening or expansion of multiple ownership allow the establishment of financially well-resourced pharmacy chains and thus the transformation of the German pharmacy sector from its atomistic structure in the direction of an oligopolistic structure. Pharmacies can then work more efficiently and effectively by centralising certain responsibilities and activities. The availability of information on a larger number of patients enables earlier detection of drug-related risks and faster response in mitigating them. Also, pharmacy chains offer broader employment opportunities for pharmacists who prefer to work as employees, either in full-time or part-time positions.

A competition policy risk could exist in respect of vertical concentration. Financially well-resourced pharmaceutical companies could also enter the pharmacy market as potential buyers and then have an incentive to influence pharmacies' product selection policies.

Arguments in favour of judicious expansion of existing structures (see Special Report 1995, at 418 and similarly Report 2001/2002, at 68) include issues such as safeguarding the sphere of trust. In conclusion, it would make sense, in conjunction with a lifting of the third-party ownership ban, to open the pharmacy market to allow a significant expansion of multiple pharmacy ownership.

As part of an evaluation which should take in the impact that the introduction of pharmacy-specific retail margins would have on distribution and competition, health care policy would benefit from empirical information on the prevailing competition processes and can use that information in a subsequent reform to allow unlimited multiple pharmacy ownership subject to the checks and balances of competition law.

2.5 Recommendations concerning the pharmaceuticals market

42. Based on the analysis and discussion on pharmaceuticals provision, the following recommendations are inferred in respect of performance audits, benefit assessments, pharmaceuticals supply, the requirement for evidence-based, cost-effective and coordinated drug prescription practices, and the distribution of medicinal products.

The performance audit process used when SHI-accredited physicians have exceeded the prescription target is subject to widespread criticism. In the Advisory Council's survey Panel Doctor's Associations on pharmaceuticals prescription management, the

most frequently cited comment was a call to do away with or modify the performance audit process.

A review of the calculation formula for the prescription targets laid down for the various physician groups is recommended in this connection. One option would be the targeted compilation of a calculation model for a homogenous group of practices which are representative of a specific medical discipline. This could be operationalised for example by stipulating that practices that by predefined criteria are 10 percent above or below the specialist-group average (notably 'atypical' general practices) should no longer be included in the comparison group. The setting of an additional ceiling for potential claims at a sum which does not endanger the physician's livelihood (say, €20,000) should be considered in order to maintain the management effect of the performance audit while both avoiding the risk to medical practices and minimising doctors' hesitation when it comes to setting up their own practices. In any event, claims should be made earlier than four years from the time of the audit.

It is recommended that the management of pharmaceuticals prescription practices focus more on qualitative medical parameters, for example by reference to primary compounds. In this way wholly cost-based and thus substantively non-medical management requirements placed on doctors can be replaced with treatment-based agreements; this can also lead to cost savings.

Very little use is made nationwide of practice-specific circumstances which, since the entry into force of AMNOG, provide the legal basis for the inclusion of medicinal products with additional benefits in the calculation of prescription targets. By adjusting the approval processes, such circumstances could be more easily considered, given a higher status in the performance audit and thus provide for assessments which take better account of the structural circumstances that apply to a particular medical practice. For example, the costs for the medicinal products involved could be automatically deducted from the prescription volume stipulated for an SHI-accredited physician before any overshooting of the prescription target is assessed.

43. Benefit assessment for medicinal products has proven to be an instrument for use in limiting the rise in costs resulting from new pharmaceuticals and in improving the quality of medical care. It is nonetheless recommended that the use of cost-benefit analyses be allowed as an additional decision-making criterion in the price-setting process. Also, in the interests of plurality in analysis, cost-benefit analyses should be conducted by other bodies in addition to IQWiG.

Possible synergies arising from a harmonised EU-wide benefits assessment should be looked into and the steps already taken should be speeded up so that the generation of evidence from a variety of competent institutions in the EU can be conducted jointly. An assessment should be made regarding the extent to which the various national scales

applied in quantifying additional benefit are in any way comparable and allow broader-based quantification. The price negotiations held on the basis of these assessments would continue to be conducted at national level.

On 20 February 2014, the German Bundestag agreed for primarily procedural reasons to end the institutionalised, systematic benefit assessment of patented medicinal products already on the market, i.e. those that entered the market prior to 1 November 2011. The expected disadvantages arising from the procedure are understandable, especially in respect of the number of legal battles that can be expected in relation to the difficulty involved in justifying the order of priority in which the products are to be assessed and the effort involved in producing a dossier. From a substantive perspective, however, it would make sense to continue institutionalised, systematic benefit assessments for medicinal products already on the market. Apart from significant theoretical cost savings, it would be of great advantage from a medical and quality standpoint to have benefit assessments available for at least the most significant products on sale. Section 193a of Book V of the German Social Code (SGB V) provides an option which allows the assessment of products already on sale. This option should be used for the reasons mentioned.

44. New medicinal products for use in the inpatient sector have been excluded from benefit assessment assuming that, for the statutory health insurance funds, the expenditure incurred in relation to proprietary medicinal products is marginal. A benefit assessment would still make sense for such products, however, because the cost increases associated with these unassessed innovations will be passed onto the hospitals and thus cause an indirect rise in fees per case. Assessment of additional benefits would also aid evidence-based therapy and help avoid potential adverse drug effects.

45. Drug supply shortages have increased significantly on a global scale in recent years in terms of frequency, the range of care affected and negative effects on patients' health. The relocation of production capacity to low-wage countries is a contributing factor, but the causes are complex and have their roots in both supply and demand. Contractual fines set out in discount agreements to compensate for the event of a missed delivery can have a preventive effect but are not enough to remedy the problem. There is thus need for further regulation to protect patients' interests. The BfArM list of current shortages of human medicines should be supplemented with a mandatory reporting register. Past, current and anticipated shortfalls, meaning as early as when a quality problem occurs in production, should be reported as part of a mandatory process which leads to a subsequent assessment and notification to hospitals, medical practitioners and pharmacies. In cooperation with scientific medical societies, a list of clinically indispensable medicines should be drawn up for which, on the basis of prevailing legal requirements, pharmaceutical companies should increase their production and storage

capacities. The installation of a prevention-focused, centralised risk management system within the BfArM is recommended.

46. The availability of evidence-based diagnostic and therapy information is indispensable in scientifically founded, modern medical care. It is of fundamental importance that the information be made available independent of any particular financial interest, hence the recommendation for producer-independent training on pharmaceuticals. Structured pharmaco-therapy quality circles could also play a key role.

When developing guidelines as a key component of evidence-based diagnostics and therapy, care must be taken to ensure the greatest possible independence among the stakeholders involved. Also, studies which provide no positive results must be published on a regular basis. In addition to early benefit assessments, and given the fact that systematic assessment of existing products is no longer provided and the deficits inherent of that process, the availability of independent information on pharmaceuticals, medicinal products and therapeutic procedures from a credible, sustainably financed institution is crucial. The institutionalisation of the German Cochrane Centre could serve as the core for this type of information platform.

47. In light of the increasing numbers of older and multi-morbidity patients, and the frequent phenomenon of multi-medication, it would also be wise to take account of these issues in the various sets of guidelines in order to ensure optimal medical treatment for patients and to keep undesired interactions and side-effects to an absolute minimum. More widespread use should be made of standardised instruments such as lists of medications that pose potential problems for or are to be preferred for older patients. Also, structured medication check-ups, for example when prescribing more than five types of medication or after a patient has been discharged from hospital, should be further developed and regularly put to use. Regular, up-to-date feedback on treating physicians, say from the Panel Doctor's Associations or in the form of comparative prescription reports as part of a structured pharmaco-therapy quality circle programme, can help increase drugs-based therapy safety. Management of the ever-more complex medical treatment of multi-morbidity patients also needs to be reflected in reimbursement arrangements operated by health payers (e.g. fixed sums for multi-medication checks performed by doctors or pharmacists).

48. The aim of needs-based and cost-effective pharmaceuticals provision should also result in a coordinated process in relation to individual substance classes. Thus, when it comes to preventing resistance, care should be taken to ensure appropriate prescription practices when prescribing antibiotics for which serious regional differences are evident in prescription volumes. Also, with a view to the regionally very heterogeneous prescription rates for methylphenidate, multi-disciplinary medical care models are

needed for ADHD patients, with cooperation activities between paediatric, general practitioner and child psychiatrist and psychotherapist practices.

49. The tightly regulated German pharmacy market is characterised by an atomistic supply structure with a comparatively very high pharmacy density and extremely narrow price competition, which is limited to non-prescription only drugs. In the interests of efficient and effective pharmaceuticals distribution, a lifting of the ban on third-party ownership and multiple ownership of pharmacies is recommended. Such a ban can be justified neither on regulatory policy nor on health policy grounds.

In addition, a reform of pharmacist remuneration is suggested which could be achieved through the introduction of pharmacy-specific retail margins. Pharmacist remuneration would then be provided via a standardised fixed pharmacy margin which covers average operating costs and proprietor wages for the entire pharmaceuticals distribution service. The pharmacy-specific retail margin could be freely calculated by the pharmacists themselves relative to their cost structures and profit targets. This would give them a competition parameter with which to generate additional demand via cheaper prices. The pricing competition that would ensue would develop in areas with heavy pharmacy density, thus providing an incentive for pharmacists to open up premises in poorly served regions.

A broader-based model includes pharmacies as a component of primary health care in an integrated health care service in which they, for example, take on responsibility for targeted medication management.

3 Medical Device Provision

3.1 Definition and classification of medical devices

50. Medical devices comprise a very broad and heterogeneous range of objects. Under Section 3 of the German Medical Devices Act (MPG), medical devices can among other things take in individual or related instruments, apparatus, equipment, substances and preparations made up of substances. Their functions contain many similarities with medicinal products, but they differ from them in their intended primary effects. Medical devices achieve their effect on the human body neither through pharmacological or immunological substances nor through metabolism, although they can support them. In-vitro diagnostics (IVD) are also medical devices, but these are not addressed in this report, nor has an analysis of medical aids and large-scale equipment been included.

This brief definition reflects the scope and heterogeneity of medical devices available. The spectrum ranges from swabs and plasters to medical aids like wheelchairs and hearing aids, surgical instruments and implants such as joint prostheses, pacemakers and larger-scale equipment such as lithotripters and positron-emission tomography (PET) scanners. The number of product groups is estimated at about 10,000, while the number of actual medical devices is thought to be somewhere between 400,000 and 500,000.

51. According to prevailing law governing medical devices, manufacturers categorise their products in line with certain classes. Article 9 of the Medical Device Directive (MDD) (Council Directive 93/42 EEC) places medical devices into four risk classes which set out the respective minimum requirements for market access. These risk classes involve various criteria including duration and invasiveness of use, place of use and whether a product is an active or an inactive device. Active, implantable medical devices belong to Class III. Table 1 provides a synoptic overview of the four risk classes with examples. This classification system can be subject to amendment or alignment when new, relevant information becomes available. Thus member states in which the MDD is binding, for example when undesired events arise in connection with the

specific medical device group, can apply for classification in a different risk class. By way of example, breast implants were switched from Class IIb to Class III in 2003.

Risk class	Description	Examples
Class I	Low risk potential	Spectacles, stethoscopes, mouth spatulas, urine bottles; also many dressings, collars, wheelchairs, incontinence pads and anti-decubitus mattresses
Class IIa	Medium risk potential	External hearing aids, contact lenses, urinary catheters, cannulas, surgical gloves, diagnostic ultrasound, MRI, PET, and TENS equipment
Class IIb	Enhanced risk potential	Peripheral vascular grafts or stents, brachytherapy equipment, dialysers, surgical lasers, pins and plates, external pacemakers and defibrillators, lithotripters, X-ray equipment, and condoms
Class III	High risk potential	Pacemakers, heart valves, heart and ablation catheters, hip, shoulder and knee prostheses, breast implants, intracranial stents, and coronary stents

Table 1: Risk classes of medical devices with examples

MRI: magnetic resonance imaging; PET: positron emission tomography; TENS: transcutaneous electrical nerve stimulation

Source: Modified after Leigemann et al. 2013

3.2 Medical device market overview

52. Data on the number of people employed in Germany's medical device sector vary depending on source and definition from 120,000 to 190,000. Independent of this estimation range, the medical device sector in Germany largely comprises small and medium-sized enterprises (SMEs), with more than 90 percent of companies employing fewer than 250 people. These businesses generated sales of €22.3 billion in 2012. In a global market with overall sales of €220 billion, this makes Germany the third largest producer of medical devices, ranking only behind the US with sales of €90 billion and Japan with €25 billion. Among German manufacturers, more than 50 percent of production falls to imaging equipment, dentistry and replacement joints or prostheses. The German medical device industry accrues more than two-thirds of its sales overseas. With a global market share of 14.6 percent it is the second biggest exporter, ranking behind the US with 30.9 percent. A large portion of those exports (40 percent) go to EU member states, from which almost 50 percent of the medical devices imported into Germany also originate. One peculiarity of the medical device sector involves the short lifecycle of certain products – producers generate approximately one-third of their sales with products that have been on the market for less than three years.

53. The share of medical device companies conducting research amounts to 17 percent, with research employees accounting for 15 percent of the workforce and research and development expenditure equivalent to nine percent of sales. To highlight the innovativeness of the German medical device sector, in 2012 some 623 patents were

awarded to companies domiciled in Germany. Hence, with around 14 percent of all patents awarded in the medical devices industry, Germany ranks only second to the US (41 percent or 1,889 patents). No information is available regarding the risk classes for medical devices listed in Table 1. The same applies regarding the total number of medical devices currently on the market and their distribution across the respective risk classes.

When it comes to the quantitative importance of medical devices in overall health expenditure in Germany or that of the statutory health insurance system, only very sparse data is available. Statistics on health care expenditure, which are primarily structured according to health payers and their spending on different categories of services and institutions, contain no separate health care services category for medical devices. Inferring indirectly from the various categories, which take in things like medical aids, implants, medical and nursing consumables, and anaesthetic, laboratory and other medical supplies, expenditure on medical devices (with the exception of investment items and denture replacements) amounted to an estimated €28 billion in 2011, consisting of €14.7 billion for medical aids and €12.6 billion for other medical needs. The SHI share of this expenditure is estimated at €17.6 billion or 63 percent. Publicly accessible data does not, however, allow any valid conclusions to be drawn regarding expenditure for medical devices overall and for each of the health payers, including the SHI.

3.3 Regulation of medical devices: Current situation

3.3.1 Regulation of market access for medical devices in the EU

54. The great heterogeneity among medical devices combined with changes in the product range brought about by medical advancement poses huge challenges in terms of regulation – challenges which make it extremely difficult to take account of all product-specific requirements. In accordance with the EU Council resolution of 1985 (85/C 136/01 – the ‘new approach’), in the interest of ensuring free movement of goods, legislative harmonisation is limited to the adoption, by means of directives, of essential requirements for medical devices. Only a small number of directives should be used to govern a large number of products and without the need for constant modification to keep up with technological advancement.

Regulation at EU level and its implementation in Germany: An overview

55. In line with the above approach, the following three over-arching directives were issued to regulate market entry of medical devices:

- Directive 90/385/EEC on active implantable medical devices (AIMDD)
- Council Directive 93/42/EEC concerning medical devices (Medical Device Directive, or MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

These directives address both technical and economic considerations, and are designed to provide a high degree of health protection. In general, all medical devices placed on the market and/or taken into operation must, in line with the producer's intended purpose, meet the provisions laid down in the AIMDD or the MDD. Also, in contrast to other technical equipment for which all other prevailing requirements apply, a clinical assessment must be performed to provide proof that the fundamental requirements have been met. This proof must be provided by the producer as part of the conformity assessment.

56. The MPG and other secondary legislation (shown in an overview provided in Table 2) are intended to implement the EU directives at national level. Implementation of the MPG falls in many areas of responsibility. While the German Federal Ministry of Health (BMG) is responsible for issues concerning national and international legislation, and also for supervision of subordinate bodies, general supervision of the market and monitoring of operators and users of medical devices falls to the German Länder. The Federal Institute for Drugs and Medical Devices (BfArM) is largely responsible for approving clinical assessments of medical devices and for centralised identification and evaluation of the risks involved in their use.

Legislation	Effective date	Abbreviation
Medicinal Devices Act (Medizinproduktegesetz)	Enacted 2 August, 1994; most recently amended by Article 13 of the Act of 8 November 2011	MPG
Medicinal Devices Ordinance (Verordnung über Medizinprodukte)	Enacted 20 December 2001; most recently amended by Article 2 of the Ordinance of 10 May 2010	MPV
Medical Devices Operator Ordinance (Verordnung über das Einrichten, Betreiben und Anwenden von Medizinprodukten)	Enacted 29 June 1998; as amended by notice of 21 August 2002; most recently amended by Article 4 of the Act of 29 July 2009	MPBetreibV
Ordinance on Clinical Trials with Medical Devices (Verordnung über klinische Prüfungen von Medizinprodukten)	Enacted 10 May 2010	MPKPV
Ordinance on Medical Devices Vigilance (Verordnung über die Erfassung, Bewertung und Abwehr von Risiken bei Medizinprodukten)	Enacted 24 June 2002; most recently amended by Article 3 of the Ordinance of 5 May 2010	MPSV
Ordinance on the Database-supported Information System on Medical Devices of the German Institute for Medical Documentation and Information (Verordnung über das datenbankgestützte Informationssystem über Medizinprodukte des Deutschen Instituts für Medizinische Dokumentation und Information)	Enacted 4 December 2002; most recently amended by Ordinance of 10 May 2010	DIMDIV
Ordinance on Distribution Channels for Medical Devices (Verordnung über Vertriebswege für Medizinprodukte)	Enacted 17 December 1997; most recently amended by Article 382 of the Ordinance of 31 October 2006	MPVertrV
Ordinance on the Mandatory Prescription of Medical Devices (Verordnung über die Verschreibungspflicht von Medizinprodukten)	Enacted 17 December 1997; as amended by notice of 21 August 2002; amended by Article 1a of the Ordinance of 23 June 2005	MPVerschrV
Federal Fees Ordinance (Gebührenverordnung zum Medizinproduktegesetz) and implementing ordinances	Enacted 27 March 2002; most recently amended by Article 4 of the Ordinance of 10 May 2010	BGebV-MPG
General implementing regulations on the Medicinal Products Act	Enacted 18 May 2012	MPGVwV

Table 2: Legal basis for the regulation of medical devices in Germany (as of January 2014)

Source: Own compilation

57. The conformity assessment and issuance of the respective certification are performed by Notified Bodies such as DEKRA and TÜV. To be designated, such organisations must fulfil criteria concerning their independence, technical and staffing resources, expertise and confidentiality. These are all criteria which until recently were poorly defined. Designation and monitoring of these organisations falls for active medical devices within the responsibility of the Zentralstelle der Länder für Sicherheitstechnik (ZLS) or for inactive devices and IVD the Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG). The accredited Notified Bodies are notified to the European Commission and receive from the Commission a four-digit number which is published in the EU Official Journal. The NANDO (New Approach Notified and Designated Organisations) database operated by

the Directorate-General Enterprise and Industry lists all Notified Bodies to which producers may turn to request certification of conformity for their medical devices. Producers can choose from a total of 73 Notified Bodies (as of 31 January 2014) providing that the one they choose has the appropriate accreditation. Of these 73 Notified Bodies, only 18 are accredited for assessments set out in both the MDD and the AIMDD (including six of the 14 Notified Bodies located in Germany). Direct access to the lists of Notified Bodies is provided by the German Institute of Medical Documentation and Information (DIMDI), which publishes the lists on its website. DIMDI is also responsible for establishing the medical devices information system to support enforcement of the MPG and for providing information needed by the Federal and Länder authorities responsible for medical devices (Section 33 (1) MPG).

Conformity assessment for medical devices

58. In conformity assessment, producers aim to obtain permission to use the CE label which allows them to place their products on the European market comprising over 30 countries. The conformity declaration states that a product meets prevailing requirements laid down in harmonisation regulations. Under Section 9 (3) MPG, the CE label must bear the identification number of the Notified Body involved in the conformity assessment process. An EU Commission Implementing Regulation from September 2013 sets out the criteria for accreditation and monitoring of Notified Bodies. In contrast to the centralised processes applied in the approval of drugs, producers may choose from a pool of Notified Bodies. This in turn establishes a customer relationship between the producer and the assessing institute, which creates a risk of financial considerations playing a role in assessment – in some cases to the detriment of medical device safety.

In the course of the conformity assessment, the producer must prove that the product performs as required and meets the fundamental requirements regarding quality, safety and compliance. The producer may choose one or a combination of the modules listed in Table 3, depending on the risk class assigned to the product. For example, for medical devices in Risk Class III, the conformity assessment process requires (in Annex II MDD or Annex 2 AIMDD) documentation on all aspects of the medical device, from design to production, from clinical assessment to delivery, and subsequent monitoring. The Notified Body must assess the documentation provided based on a representative example of the medical device in question and conduct an on-site assessment of the production process involved in the manufacture of the medical device. For medical devices in Classes IIb and IIa, however, a closed conformity assessment procedure can be used which does not require the Notified Body to assess the design documentation. For products in Risk Class I, the producer declares and documents without involving a Notified Body that their medical device meets the Directive's requirements – provided

that the product is not in a sterile condition or sold with a measurement function. The certification issued by the Notified Body is valid for a maximum of five years and may be extended upon request for a further maximum period of five years. No publicly accessible information exists regarding which conformity assessment process is used for specific medical devices or how often such assessments have been conducted/are conducted for products in specific risk classes.

Procedure	I	Ila	Ilb	III ^{a)}
EC declaration of conformity (full quality assurance) as set out in Annex II ^{b)} /Annex 2 ^{c)}	(X)	X ^{d)}	X ^{d)}	X
EC type-examination as set out in Annex III ^{b)} /Annex 3 ^{c)} in conjunction with (see choices under 'OR')			X	X
EC verification as set out in Annex IV ^{b)} /Annex 4 ^{c)}	(X)	X	X	X
EC declaration of conformity (production quality assurance) as set out in Annex V ^{b)} /Annex 5 ^{c)}	(X)	X	X	X
EC declaration of conformity (product quality assurance) as set out in Annex VI	(X)	(X)	X	
EC declaration of conformity as set out in Annex VII (see choices under 'OR')	X ^{e)}	X		

Table 3: Simplified representation of possible conformity assessment procedures in relation to the risk class of a medical device

a): Applies for Class III medical devices under MDD and all medical devices under AIMDD; b): MDD; c): AIMDD; d): in this case, Section 4, i.e. examination of the product design dossier, does not apply; e): producer issues EC declaration of conformity; (X): see text

Source: Own compilation

Clinical assessment of medical devices

59. The need for a clinical assessment distinguishes medical devices from non-medical technical products such as televisions when it comes to establishing conformity. The producer must provide proof that the product performs as stated under normal conditions and must declare the extent of any undesired side-effects. In providing such proof, producers have the option of referring to data on clinical assessments for similar products instead of producing the data themselves, providing, that is, that they can provide evidence that the products subject of the assessments are equivalent to their own. In the assessment of product performance and safety, however, there are no minimum requirements regarding the completeness of the required data or the way in which equivalency should be demonstrated. In the case of a clinical assessment, the applicable directives contain no specific indication or requirements regarding the design of the study, the aspects to be analysed or the duration of the monitoring period. Also, in contrast to the approval of pharmaceuticals, the clinical assessment process contains no explicit requirement for proof of a product's efficacy or benefit.

In exceptional cases, there is a possibility to submit the conformity declaration, with a statement containing a reasonable justification, without an assessment based on clinical data. A questionable aspect here is that this exception rule is also contained in the AIMDD, which exclusively refers to medical devices in Risk Class III.

The MPG and its associated regulations and ordinances contain what are largely clear provisions on the formalities and procedural requirements involved in clinical assessments. Preconditions for the commencement of a clinical assessment of medical devices under Section 20 MPG call for the approval of the Ethics Commission and for authorisation from the BfArM. Because no publicly accessible information is available regarding the approval process, it is uncertain how many applications for clinical assessments have been submitted or approved, or on what grounds they were rejected.

3.3.2 Market monitoring of medical devices

Market monitoring and vigilance system

60. The competent authorities at Länder level have the task of monitoring the market and must thus play a key role in protecting patients, users and third parties from the potential risks to their health and safety arising from the use of medical devices. Their authority to act includes the ability to stop a product being placed on the market and/or to order its withdrawal. It was only with the entry into force of the German Medical Device Implementation Act (MPGVwV) at the start of 2013 that the conditions were created for a nationwide, standardised procedure, e.g. with regard to monitoring intervals and measures, and the associated quality assurance requirements. Also, those responsible for the devices (usually the producers or their authorised representatives) and the users are required to take specific protective measures. The German Ordinance on the Installation, Operation and Use of Medical Devices (MPBetriebV) provides, for example, for regular, documented metrological checks, and also the issuance of written patient information containing details of the product, the producer and those responsible for performing the implant where an active medical device is involved. There is no equivalent regulation on non-active implants. Operators and users are required to provide documentation, however, for certain specifically named non-active medical devices (heart valves, vascular prostheses/supports, hip prostheses and breast implants). This does not apply to other medical devices with high risk potential, such as other joint prostheses or implants, such as pins and plates.

To further minimise the risks arising from medical devices, BfArM centrally records, assesses and evaluates incidents and coordinates the necessary response measures in a medical device monitoring and reporting system. Decision-making regarding the measures to be taken falls to the competent authorities at Länder level. An incident is an

occurrence which could have directly or indirectly led to the death of a patient, user or other individual, or to a serious deterioration in their health, or could do so in the future (Section 2 of the German Medical Devices Safety Plan Ordinance, or MPSV). In contrast to this, pharmacovigilance is not restricted to serious incidents, but additionally takes account of suspected cases involving side-effects regardless of the degree of severity. Incidents that occur in Germany must be reported to BfArM by the producer, operator or user and by those who supply the medical device to the end user. It is noteworthy that comparatively fewer incident reports (15 percent) stem from professional users or operators. This is remarkable in that the (Model) Professional Code for Physicians in Germany (MBO) contains a mandatory obligation to report incidents to the competent authorities.

61. In contrast to Germany's Medicinal Products Act (AMG), the MPG contains no specific liability provisions. Liability for medical devices is thus based on general liability law, which means that liability can arise under contract, in relation to an unlawful act as defined in Section 823 (1) and (2) of the German Civil Code (BGB) in conjunction with a protective law, under Section 831 BGB, or under Section 1 of the Product Liability Act (ProdHaftG). Producers are thus liable in particular for design defects, production defects and misinstruction, and for breach of product monitoring and recall obligations. The burden of proof regarding non-contractual liability lies with the patient, who must provide proof of the product-related defect and the damage resulting from it. By way of contrast, the law on drug-related liability contained in Section 84 AMG provides for a lesser burden of proof for affected patients who, to support their claim, have the right to receive information from the pharmaceutical company involved. On the whole, patients who incur medical device-related loss or damage face considerable problems in enforcing their claims. In addition, the law on medical devices differs from that on medicinal products in that it provides no financial safeguarding mechanisms in the event of producer insolvency.

Medical device information systems

62. With the information system on medical devices of the German Institute for Medical Documentation and Information (DIMDI) and the EU Database on Medical Devices (EUDAMED), two information systems exist for the identification and transfer of data on medical devices. DIMDI lists defined, centrally received information via an automated process, assigns it to the responsible authority and notifies that authority when such information is received. The data is used in five DIMDI databases, one of which also lists incident reports along with information about the completion of and outcomes from the associated risk assessment. This particular database is also used to store information on corrective measures taken in relation to medical devices which other member states have notified to BfArM and have assessed for plausibility. Because

these five databases, with the exception of the one concerning medical device reports, are solely available to the institutions responsible for regulating medical devices, there is no publicly accessible information source for use by patients, their representatives or other institutions. Irrespective of the fact that the informational content of each of the databases is difficult to assess, it must be assumed that the databases cover only some of the medical devices operated or used in Germany.

The EU Commission decision of 19 April 2010 requires the parties involved to submit data to EUDAMED, which is also not available to the general public. Because information on the regulation of medical devices placed on the market prior to 1 May 2011 must only be reported retroactively for products in Risk Class I, EUDAMED fails to provide a complete picture of the medical devices currently on the market in the EU. It is also questionable whether specific medical devices belonging to higher risk classes can be clearly identified, because neither the MDD nor the AIMDD contains a reporting requirement prior to the date the devices entered the market. Also, when it comes to entering data into EUDAMED, there is no obligation to use a standardised nomenclature, which can lead to problems regarding data collection, especially in relation to incidents.

3.3.3 EU-US comparison of medical device regulation

63. In contrast to the EU, the US operates stricter, more transparent and centralised regulation/approval of medicinal products in the interests of patient safety by the Food and Drug Administration (FDA) and its executive body, the Center for Devices and Radiological Health (CDRH). The CDRH is responsible for regulating companies which produce medical devices, re-pack or label them and/or import them into the US. The US has three classes of medical devices, each with low, medium and high risk classifications and differing regulatory requirements. The approval process comprises two options: premarket notification (PMN 510k) and premarket approval (PMA). The PMN 510k process is mandatory for all medical devices as soon as they enter the US market. This includes ones that have been modified or have a new intended use. Products in Class I and II may be exempt from this rule, and this exemption is largely used for Class I products. Under the PMN 510k process, applications must provide proof that the product is at least as safe and as effective as a similar product already on the US market.

Medical devices in Class III are subject to the PMA process during which the FDA checks whether, for a specific indication, sufficient, valid evidence is available to allow the product to be approved in respect of its safety and effectiveness. The FDA requests comprehensive, detailed data on the clinical assessment of the respective medical device, including risk-benefit analyses. Compared with EU practices, this process stands out for the following reasons or differences:

- There is an explicit requirement for proof of safety and efficacy in human-health studies.
- These studies and their results must be published in a freely accessible (study) register.
- Studies on the assessment of medical devices with high risk potential require approval from the Ethics Commission and a license from the FDA, and – in contrast to EU provisions – these medical devices must be used solely for the purposes of clinical studies.
- Medical devices for which proof of safety and efficacy is (still) lacking, must be clearly labelled as excepted products.
- All PMA decisions, including justifications and descriptions of the data used are published for general access on the Internet once the process has been completed.
- A freely accessible database operated by the FDA provides information on all reported incidents and withdrawal of medical devices.

On the whole, compared with the EU, US regulation of medical devices via a centralised approval process is characterised by the fact that proof of safety and efficacy is explicitly required for approval and also by a considerably greater degree of transparency.

3.3.4 Recommendations for future regulation of medical devices

64. In response to the situation regarding PIP breast implants, the European Parliament asked the European Commission in summer 2012 to develop a proposal for “an adequate legal framework to guarantee the safety of medical technology”. On 26 September 2012, the Commission presented its draft for an EU regulation on medical devices covered by the MDD and AIMDD up to that point in time. Since then, in parallel with consultations within the EU Council, a number of hearings have been held before the European Parliament and these have resulted in a report by the Committee on the Environment, Public Health and Food Safety (ENVI). On the basis of this report, the first reading of the framework regulation took place before the European Parliament on 22 October 2013 and the EU Council met for initial consultations on the regulation in December 2013. Prior to the re-election of the European Parliament in May of this year, no final agreement had been reached regarding a new regulation so that it remains unclear as to whether and to what extent a reformed regulation approach might ensure the safety and efficacy of medical devices.

Approval and clinical assessment of medical devices

65. Against the backdrop of the identified deficits, the comparison of drugs regulation and the differences between the EU and US systems, the following reform measures are recommended in terms of the approval and clinical assessment of medical devices:

- A Europe-wide central, independent approval system (including differentiation between IIa and IIb) at least for medical devices in Classes IIb and III in accordance with the division of responsibilities in the approval of drugs under the local centralised process.
- Location of this approval body within the European Medicines Agency (EMA) and the establishment of both a central and an independent body at national level for the evaluation of applications.
- Prior to approving market entry, confirmation of clinical efficacy and investigation into potential adverse events – at minimum for medical devices in Classes IIb and III.
- Provision of proof, usually by means of random controlled studies, for clearly defined indications with patient-relevant endpoints such as mortality, morbidity and health-related quality of life.
- Use for the same indication as a prerequisite for reduced requirements for generic products and criteria for use in defining a medical device as a generic product.
- Registration of all clinical trials involving medical devices, prior to commencement of the study, in a publicly accessible (study) register and publication of the results reports according to clearly defined and appropriate standards.

Market monitoring of medical devices

66. Market monitoring should focus both on production and use of medical devices and take in regular safety and quality controls performed by qualified staff in accordance with pre-defined standards. Identification of patients who have received medical devices with known defects could be ensured by a EU-wide central register located with the yet-to-be established approval body at EU level. In the interest of data privacy and protection, the documented information would contain detail to a degree prescribed at local or EU-level. To identify those actually affected, a mandatory system for harmonised product labelling is needed. The identification number should also be stated on implant certificates or passes which, in contrast to former practices, should be handed out to patients.

In the interest of patient safety, the term ‘incident’ should be extended to match that of ‘adverse reactions’ in AMG and refer to all functional defects irrespective of the

degree of severity involved and of the direct relationship with the medical device where suspected cases are involved. The assessment of such incidents should also occur via a central approval body in accordance with standardised benchmarks and take account of the expertise available within national central and independent bodies. It should also allow the necessary authority to implement or call for timely action according to uniform principles.

Producer liability

67. When it comes to medical device-related liability, to prevent placing the patient in a less favourable position to that provided for under German medicinal products law, it would appear appropriate to require producers to provide risk coverage, e.g. by means of obligatory liability insurance cover. Should this not be possible under current EU legislation, an appropriate national legal arrangement should be found to protect patients' interests.

Access to information

68. As comparison with the US regulation system shows, transparency in the medical device sector can be achieved. Transparency calls for the provision of a freely accessible and easily searchable online platform containing data on all medical devices irrespective of risk class and also on their approval, including the period of validity of that approval, product-related information including the reasons behind the approval decision allowing the device to enter the market, all reported incidents and the findings of the investigations and measures prescribed as a result.

3.4 Medical device-related reimbursement under Germany's statutory health insurance system

69. While the market access framework for medical devices is laid down at EU level and then implemented at national level, the right to take "measures ... to manage the funding of public health and sickness insurance schemes" remains with the member states "provided Community law is complied with" (MDD). In Germany, this applies in that the health insurance funds are required to provide services to their members in accordance with the dictates of cost-efficiency (Section 12) and that the "quality and effectiveness of their service ... must correspond to the generally recognised state of medical knowledge and take medical progress into account" (Section 2 (1) of the Book V of the German Social Code). In Section 12 (1) of Book V of the German Social Code, it is also stated that therapy must not go beyond what is medically necessary. This principle is also set out in Section 70 of Book V of the German Social Code. Actual

practice in the provision of care that largely involves the use of medical devices falls short of this requirement in many instances.

70. The Federal Joint Committee has the decision-making authority to restrict or prohibit service provision or prescription “if by the recognised state of medical knowledge the diagnostic or therapeutic benefit, medical necessity or cost-effectiveness has not been demonstrated” (Section 92 (1) SGB V).

71. While consultations on the respective assessments in the preparatory committees, including the associated notes and records, are not made public, the publication of Federal Joint Committee directive decisions, including the underlying reasoning, allows interested parties an opportunity to inform themselves about the reasons behind a given decision. Worthy of note in relation to the process used by the Federal Joint Committee are the participation options afforded to scientific medical societies, medical device producer representatives and medical device producers. In terms of patient safety, however, the significant influence that the service providers (especially the German Hospital Federation (DKG) and health payers (National Association of Statutory Health Insurance Funds) have on the objects to be assessed and the associated expansion or limitation of the range of services provided by statutory health insurance funds (GKV) should be subjected to critical assessment.

A conflict of interest cannot be ruled out on either side given the financial considerations involved. What could also prove problematic is the lack of transparency regarding the type and number of applications that have been submitted but have not yet been discussed or will not be discussed because the subject of the application has been rejected. This denies both doctors and patients the opportunity to inform themselves about services which should be discussed.

3.4.1 Services prohibited unless expressly approved, under Section 135 (1) of Book V of the German Social Code

72. Problems arise from the different rules governing decision-making on approved provision of health care services relative to the respective health care sectors. Section 135 SGB V prohibits certain services from use in health care provision by SHI-accredited physicians unless expressly approved. This relates to services that have not yet been included in the uniform assessment standard (EBM) to date or are included but have been either modified significantly or expanded in scope relative to the indication or type of service performed (Federal Joint Committee Code of Procedure, Chapter 2, Section 2 (1)). Based on this definition of ‘new’, newly introduced medical devices cannot be used if they do not also constitute a new method that meets these criteria.

73. As the EBM is designed as the main billing system for health care provision by SHI-accredited physicians, it is conceivable that, in line with the specifications for items listed in the fee schedule, the EBM could allow new examination and treatment methods to be billed for the services to be provided without the need for prior assessment by the Federal Joint Committee.

74. Independently of the above points of criticism, given the comparably low-level requirements regarding clinical assessment of medical devices under the conformity assessment process and the prevailing lack of transparency regarding medical devices already on the market, identifying new examination and treatment methods that are directly related to medical devices and proving that they meet the criteria for inclusion would appear to pose a major challenge. In the assessment of examination and treatment methods, the Federal Joint Committee – irrespective of the health care sector involved – rightly applies the principles of evidence-based medicine. When it comes to benefit assessment, documentation on Evidence Level I with patient-related outcomes should be used wherever possible (Federal Joint Committee Code of Procedure, Chapter 2, Section 13 (2)) and in the interests of patient safety departures from this requirement should only occur in exceptional cases. Such data is rarely available, meaning that assessment applications cannot be submitted or cannot be accepted for inclusion in medical services performed by SHI-accredited physicians due to the lack of benefit assessment documentation. It was not possible to identify any systematically structured early-warning systems to identify promising methods for medical care provided by SHI-accredited physicians in the course of the research conducted by the parties represented in the Federal Joint Committee as part of this study.

3.4.2 Services approved unless expressly prohibited, under Section 137c SGB V, including selected aspects relating to Section 137e SGV V

75. In contrast to medical care provided by SHI-accredited physicians and notwithstanding the absence of sector-specific provisions in the principles set out in Sections 2 and 12 SGB V, medical services provided in the inpatient sector are allowed unless expressly prohibited. With these provisions, medical services involved in hospital examinations and treatments may be provided without prior assessment as long as they have not been explicitly banned by the Federal Joint Committee (Section 137c SGV B). The underlying principle guiding the legislature here is that of securing fast access to medical innovations for patients. These potential benefits do not appear to have been weighed against possible harmful effects or such effects would appear to be assigned lesser importance.

76. There is no systematic assessment of examination and treatment methods for the inpatient sector. Instead, applications based on Section 137c SGB V appear to be

submitted in the main if there are justified grounds for an unfavourable risk-benefit ratio concerning a method in a specific indication, meaning that a large number of patients have been treated using a particular method and may have been harmed in the process. Added to this unsatisfactory patient safety situation are further problems which range from the length of the process involved until a regulatory decision regarding the restriction or exclusion of a method and the possible use of the method in question as part of hospital treatment while the application process is underway.

77. With the entry into force of the SHI Health Care Provision Act (GKV-VStG), the requirements for method exclusion became more stringent. This is reflected in the two-thirds majority required for a decision under Section 91 (7) SGB V, while a simple majority in the decision-making body suffices for inclusion of a new examination or treatment method in medical services provided by SHI-accredited physicians.

78. An even more pronounced instance of barrier-raising is to be seen in the amendment to Section 137c SGB V, under which a method can only be directly excluded if, on the basis of available evidence, the Federal Joint Committee expressly determines that the method is ineffective or even harmful. This requirement can be considered a reversal of the burden of proof and stands in clear contradiction to comparable rules governing medicinal products. Apart from the fact that proof of efficacy and safety must already be provided for medicinal products in the approval process, the Federal Joint Committee may also request studies from pharmaceutical producers on a case-by-case basis (see Section 9 (2a) SGB V). The burden of proof thus lies with the pharmaceuticals producer, including in instances where the evidence provided does not meet the Federal Joint Committee's criteria. The additional requirement that, where the benefits of a method cannot be adequately proven but a necessary alternative treatment exists, the Joint Committee issues a directive to allow its investigation, would appear to mean – in light of the broad interpretation given to the term 'necessary alternative treatment' – that a method can no longer be excluded if it comes under the investigation rule.

79. In the case of the examination and treatment methods in question here, whose application is largely based on the use of a medical device, an investigation directive may only be issued if the producer of the required medical device, or a company which as the supplier of the method has another financial interest in investigation performed at the SHI's expense, enters into a cost-transfer agreement. Only in cases where such agreements are not signed can the Federal Joint Committee issue a directive decision based on the previous criteria (Section 173c (1) sentence 5, and also sentence 4 SGB V) and thus exclude, where appropriate, a method whose benefit has not been sufficiently proven. Given the necessary procedural steps, it can be assumed that such decisions can only be made after an even longer period than under the previous rules, while hospitals continue to be permitted to apply the method in question. Also, even if an investigation directive is issued and put into action, the method concerned (whose benefits and

possible harmful effects are uncertain) may continue to be applied in hospitals outside of the required study and thus without the patient safety precautions applied in a study context. It would appear that the legislature, in accordance with the Coalition Agreement on mandatory participation of hospitals, would like to strengthen this significant weakness in the chain and the associated additional potential difficulties involved in conducting the study.

80. Neither such an amendment nor the opportunity afforded with the entry into force of the GKV-VStG for producers of a medical device to apply to the Federal Joint Committee for issuance of an investigation directive (Section 137e (7) SGB V) allows for the systematic assessment of methods whose application is largely based on the use of a medical device. While in the interests of patient safety, the new provision set out in the GKV-VStG (and this also applies to the amendment of Section 137c SGB V) is seen as a chance to ease the conflict between providing for faster, nationwide introduction and financing of new examination and treatment methods on the one hand and the frequently lack of scientific evidence on the other, it must be remembered that the procedure is voluntary and non-binding.

81. One big problem with this new procedure is lack of transparency regarding applications. Although it is already known that the benefits of a method are not yet sufficiently proven, it can still be used in hospital treatment. Apart from the economic requirement for effective and efficient use of resources, this framework has shortcomings especially as regards the safety of patients receiving the treatment. This is the case because harm to patients can result not only from potential adverse events of a method's application, but also from the application of methods that have no positive effect on patient health. Such treatment is unnecessary and thus results in a delay in the application of effective treatment.

3.4.3 Conditions for reimbursement in the inpatient sector

82. In inpatient care especially, problems remain regarding strict separation of the rules on remuneration from the rules on assessing the benefits of methods whose application is largely based on the use of a medical device. In the general construction of the DRG fees per case system, and also in the conditions concerning its revision, financial issues are the primary focus. The same applies for the procedure on new examination and treatment methods¹ and must be assumed to apply for the per-case fees listed in both nationwide and hospital-specific additional fee agreements. This is explicitly stated regarding the review of the surgical and procedural classification code

¹ New examination and treatment methods which, through the use of diagnosis-related fixed fee payments and additional fees, cannot yet be properly remunerated.

list. Most of the services contained in the list can be performed without restriction and can be invoiced without the need for prior systematic assessment of their efficacy or benefit. Because revisions of the rules are linked to the inclusion of new, higher-remunerated services, this provides an incentive for increased use of new, less-well tested medical devices. Apart from the possible risks to the safety of patients receiving the treatment, this could also run contrary to the necessity and cost-effectiveness criteria. It can also be assumed that this system fails to recognise examination and treatment methods whose application is largely based on the use of a medical device but which do not directly result in higher costs.

83. The situation in the inpatient sector has, at least where the rules regarding procedure for new examination and treatment methods are concerned, resulted in a welcome decision by the German Federal Social Court (BSG). In meeting its obligations under Sections 2, 12 and 70 SGB V, the German Association of Statutory Health Insurance Funds, in preparing for hospital-SHI negotiations on examination and treatment methods, requests expert reports on the majority of such methods from its Medical Advisory Service. With reference to such expert reports, negotiations on fees for new examination and treatment methods are often rejected due to a lack of evidence and the question thus arises as to the admissibility of this practice. According to its recent decision, the BSG believes that the precondition for permission under Section 137c SGB V is that a new examination or treatment method must also meet the generally recognised state of medical knowledge and that there is no blanket permission for new methods; instead, they are only permitted if they meet the quality requirement criteria set out in Section 2 (1) sentence 3 of SGB V. The BSG interpretation suggests that the health insurance funds will receive the right to assess whether a method corresponds to the generally recognised state of medical knowledge before concluding any negotiation on remuneration. The authority to assess the quality and efficacy of a method is thus transferred to the health insurance funds. Because such an advance assessment is deemed necessary, the legislature should enact corresponding provisions for the inpatient sector to provide consistency with Section 135 SGB V.

3.4.4 Further critical aspects regarding reimbursement for medical devices under the statutory health insurance system

84. Ceasing the existing practice where methods of uncertain benefit and capable of causing harm are used outside the safeguards of a study context (in some cases even without patients being appropriately informed) and paid for could lead to significant improvements in patient safety. The aim should be for examination and treatment methods only to be included in general health care provision if they have a positive risk-benefit ratio for a specific indication and if ancillary requirements are stipulated (such as

physicians' qualifications other preconditions). Bringing the use of new methods under a regime of this kind would doubtless have resulted in a situation different from that which can be seen today, in which the use of such methods is increasing – as with transcatheter aortic valve implantation (TAVI) (see full Report) – together with the associated risk to patients. Further risks have been identified in the use of Robodoc and most recently in the use of the Wingspan stent system (see full Report).

85. Assessment of examination and treatment methods is not, however, sufficient on its own. A medical device-specific assessment is needed because, as the drug-coated CoStar stent and the Aptu stent show (see full Report), a not insignificant threat to patient safety and health can otherwise arise.

86. This also highlights the potential knock-on effects of the current situation in which the medical devices to be used are not stipulated in billing systems, leaving hospitals free to choose. Hospitals can bill the same per-case fee regardless of the risk-benefit ratio for a given medical device in a given application. This can create a false economic incentive to use products that, though cheaper, may carry greater risk to patient safety.

87. Also, the comparatively generous requirements for market access, the frequent associated uncertainty regarding quality, safety and efficacy of the medical device in question (particularly in relation to a specific indication, because producers basically determine this themselves when stating the intended purpose of a device – as exemplified by the Wingspan case study in the full Report), the rules on funding medical services, especially in the inpatient sector, and the fact of services in that sector being allowed unless expressly prohibited all go together to form a regulatory framework that from a producer standpoint gives little incentive to subject medical device to systematic assessment in meaningful, conclusive studies.

88. The case studies set out in the full Report show yet other circumstances in the health care sector that favour the adoption of poorly-evaluated methods and medical devices without them having been subjected to critical assessment. The Robodoc case highlights the danger of medical devices being acquired solely for marketing strategy reasons, i.e. in order to be in a position to offer an innovative examination or treatment method. Physicians, scientific medical societies and patients have no means of questioning the method's efficacy in such cases. With other processes, such as TAVI, the availability of RCTs has resulted in guidelines similar to the strictly formulated approval requirements applied in the US. This required RCTs, however, that met the approval criteria applied by the FDA. In the same vein, where a device has been approved on the basis of appropriate evidence, it remains the responsibility of guideline developers to issue separate recommendations on the use of diagnostic or therapeutic measures. Following the negative experience with hip-joint prostheses, the German Trauma

Society (DGU) introduced a register to close regulatory loopholes. This all underscores the need, in addition to regulatory and health policy measures, for an independent institution that processes studies and data and makes them available to the general public (see the Pharmaceuticals chapter).

89. A regulatory framework is needed that protects patients from ineffective or harmful medical devices. This includes conducting and completing the necessary systematic assessments within acceptable timelines so that patients receive the fastest possible access to medical devices/examination and treatment methods and so that producers of such products are afforded planning certainty.

This calls for a reform of the assessment of examination and treatment methods whose application is largely based on the use of a medical device.

3.4.5 Patient safety first: Recommendations for future reimbursement concerning medical devices under Germany's statutory health insurance system

90. Medical devices in Risk Class IIb and III and examination and treatment methods whose application is largely based on the use of such medical devices should in future be made available to patients covered by the statutory health insurance system as quickly as possible. Given that patient safety is the highest priority, the underlying principle here must be that the health-related benefit of a specific medical device must be proven in the indication-specific assessment of the respective examination and treatment method. This applies both for outpatient and inpatient care.

To meet this need, the assessment process must be revised for examination and treatment methods whose application largely involves the use of medical devices in Risk Classes IIb and III (hereafter E&T risk).

91. In future, E&T risk should be assessed on the basis of proof provided by those responsible as required under Section 5 MPG. This must occur no later than at the time a medical device is placed on the market for the first time or four weeks following 'approval' for extended purpose and use of a medical device, by means of the responsible party providing the Federal Joint Committee with conclusive documentation which the latter then uses to assess the level of E&T risk. The responsible party may choose one of three paths to go about this.

Technical equivalence path

92. The responsible party refers to a medical device (reference medical device) for which the health-related benefit for the indication targeted by their own medical device has been proven, provides that proof, and documents the technical equivalence of the

respective medical device. The documentation to be provided must contain the following:

- The ‘approved’ purpose of the medical device placed on the market by the responsible party.
- Documentation showing the technical equivalence with the reference medical device.
- Proof of the health-related benefit of the examination and treatment method using the reference medical device.
- The examination and treatment-related costs incurred by the statutory health insurance funds.
- Requirements to ensure quality-assured use of the medical device.

Clinical equivalence path

93. The responsible party documents the health-related benefit of the examination and treatment method using the medical device concerned, on the basis of clinical studies on the medical device. Comparisons with appropriate comparative treatments must be made. These need not necessarily be examination or treatment methods whose application largely involves the use of a medical device. The idea is to prove that the examination and treatment method using the new medical device is equivalent to that of the comparative treatment. The required documentation must contain:

- The ‘approved’ purpose of the medical device placed on the market by the responsible party.
- Proof of the health-related benefit of the examination and treatment method using the medical device placed on the market by the party.
- The examination and treatment-related costs incurred by the statutory health insurance funds.
- Requirements to ensure quality-assured use of the medical device.

Clinical superiority path

94. The responsible party documents the health-related additional benefit of the examination and treatment method using their medical device based on clinical studies conducted with the device. The required documentation must contain:

- The ‘approved’ purpose of the medical device placed on the market by the responsible party.

- Proof of the health-related additional benefit of the examination and treatment method using the medical device placed on the market by the party in relation to the appropriate comparative treatment.
- The examination and treatment-related costs incurred by the statutory health insurance funds.
- Requirements to ensure quality-assured use of the medical device.

95. Proof of (additional) benefit must be provided through the assessment of clinical studies conducted according to international standards on evidence-based medicine. The Federal Joint Committee sets out the detailed requirements in its Code of Procedure. Using the documentation provided, the Federal Joint Committee is responsible for assessing the benefit of the specific medical device relative to E&T risk. The benefit assessment could be conducted in the same way as the early benefit assessment on medicinal products conducted by the Institute for Quality and Efficiency in Health Care (IQWiG) and would be concluded within a reasonable timeframe, but not in a period of less than three months. Depending on the path chosen by the responsible party, the assessment of technical equivalence should also be performed within the same period. In terms of the latter, appropriate resources must be established and a decision made as to who should bear the responsibility for doing so. The respective assessments must be published on the Internet irrespective of the results.

96. Within another period to be specified, which should not exceed that for the benefit and technical equivalence assessments, the Federal Joint Committee decides on the respective benefit assessment in a directive decision. This decision must be published online together with the documentation submitted by the responsible party, without revealing trade secrets. The responsible party must ensure that all information regarding the study methodology and results are published in full. Depending on the path chosen by the responsible party, the decision and its consequences for the provision of the services involved as well as any reimbursement for those services under the statutory health insurance system could involve one of the following scenarios.

Technical equivalence

97. Technical equivalence and the benefit of the examination and treatment method using the reference medical device are demonstrated. The new medical device may be used in the examination and treatment method for the indication concerned. Remuneration is in accordance with the prevailing reimbursement amounts. If the service is not listed under the medical services provided by SHI-accredited physicians, but could be provided by them, it is listed in the EBM in line with the existing procedure.

The benefit of the examination and treatment method using the reference medical device has been demonstrated, but not the technical equivalence of the new medical device when compared with the reference device. The new medical device is excluded from reimbursement for the provision of the examination and treatment method irrespective of the health care sector involved and may not be used.

Technical equivalence with the reference device has been demonstrated, but neither the benefit of the examination and treatment method using the reference device nor the technical equivalence or benefit of the examination and treatment method using the reference device have been demonstrated. The new medical device is excluded from reimbursement for the provision of the examination and treatment method irrespective of the health care sector involved and may not be used. A check must be made as to whether in such cases the Federal Joint Committee may request the responsible party for the reference device to submit documentation as described above or whether some other form of regulatory steps are needed to clarify the situation.

Clinical equivalence

98. The health-related benefit of the examination and treatment method using the medical device marketed by the responsible party has been demonstrated. The new medical device may be used in the examination and treatment method for the indication concerned. Remuneration is in accordance with the prevailing reimbursement amounts. Where the service is not yet listed as a medical service to be performed by SHI-accredited physicians, but could be performed by them, it is listed in the EBM in line with the existing procedure.

The health-related benefit of the examination and treatment method using the medical device marketed by the responsible party has not been confirmed. The new medical device is excluded from reimbursement for the provision of examination and treatment methods irrespective of the health care segment involved and may not be used.

Clinical superiority

99. The health-related benefit of the examination and treatment method using the medical device marketed by the responsible party has been confirmed. The new medical device may be used in examinations and treatment methods for the indication concerned. This also applies for medical care provided by SHI-accredited physicians where they are able to provide the service. A stipulation is needed regarding remuneration to take account of the additional benefit. A reasonable timeframe should be set for this purpose. In addition, the producer should be granted data exclusivity for a yet-to-be defined period similar to that afforded in the pharmaceuticals sector. This rules out the possibility of other producers being able to take the clinical data used to prove superi-

ority and use it in the technical equivalence assessment process. The clinical equivalence option remains unaffected.

The health-related benefit of the examination and treatment method using the medical device marketed by the responsible party has not been demonstrated, but there is no doubt that benefit exists. The new medical device may be used in the examination and treatment method for the indication concerned. Remuneration is in accordance with the prevailing reimbursement amount. If it is not yet possible to remunerate the service in the inpatient sector, any agreement on reimbursement payments must ensure that the amount agreed does not exceed that for the appropriate comparative treatment. If the service in question is not one provided by SHI-accredited physicians, but could be provided by them, it is listed in the EBM in line with the existing procedure.

The health-related (additional) benefit of the examination and treatment method using the medical device marketed by the responsible party has not been demonstrated. The new medical device is excluded from reimbursement for the provision of examination and treatment methods irrespective of the health care segment involved and may not be used.

100. Figure 2 shows a summary overview of the new process to ensure patient safety in decision-making on reimbursement for examination and treatment methods whose application largely involves the use of medical devices in Risk Classes IIb and III.

101. Like the early benefit assessment for pharmaceuticals, a responsible party should be given the opportunity to obtain a re-assessment of the benefit of the examination and treatment method involved in the use of a medical device if they provide proof of its necessity based on new scientific evidence. This should be possible no earlier than one year following the publication of the Federal Joint Committee's decision. Decisions concerning prohibition of the use of specific medical devices remain unaffected in line with the Federal Constitutional Court's 'Nikolaus' ruling. Use of those devices remains possible in justified cases.

Further aspects of a revised E&T risk assessment

102. It is possible that a responsible party may be exempted from one or other of the obligations outlined above. This could occur, for example, with medical devices used in the treatment or diagnosis of rare diseases. The same applies in cases where the responsible party declares that their medical device will not be marketed in Germany. In such cases, provision must be made to ensure patient safety – at minimum, a public announcement concerning the respective medical device and the examination and/or treatment method involved.

103. A way must be found to allow the Federal Joint Committee to gain knowledge of medical devices for which responsible parties are required to submit documentation

(see the requirements in Section 3.3.4). If, despite a request from the Federal Joint Committee, a responsible party fails to meet their obligation as described above, the Federal Joint Committee would issue a decision excluding the medical device used in the examination and treatment method (irrespective of the health care segment) from reimbursement and the device could not be used as a result.

104. The power of the state to request information on medical devices put into service (see Article 14 (1) MDD) could possibly be used as a means of monitoring compliance with Federal Joint Committee decisions. An appraisal should be conducted into how far this is feasible.

105. The recommended future reimbursement regime for medical devices under the statutory health insurance system calls for extensive ground work, certainly on the part of the legislature and especially the Federal Joint Committee, but also on that of producers of medical devices in high risk classes. Implementation appears realistic for medical devices that enter the market or receive ‘approval’ for an extended purpose on or after 1 January 2018.

106. Given the requirements involved in this reform proposal, patients covered by the statutory health insurance system could be ensured the necessary degree of treatment safety to a far greater extent regardless of future medical device developments at market-access level. Producers of medical devices would need to take the necessary action during the phase in which they apply for approval to place their product on the market. In return, they would receive a high degree of planning certainty by means of clearly defined assessment deadlines and greater transparency regarding the requirements to be met. Added to this is an international competitive advantage over competitors in other health care systems where proof of health-related benefit is likewise required for inclusion in a catalogue of reimbursable services. Given the scarcity of available resources, it can be assumed that this will increasingly be the case in future.

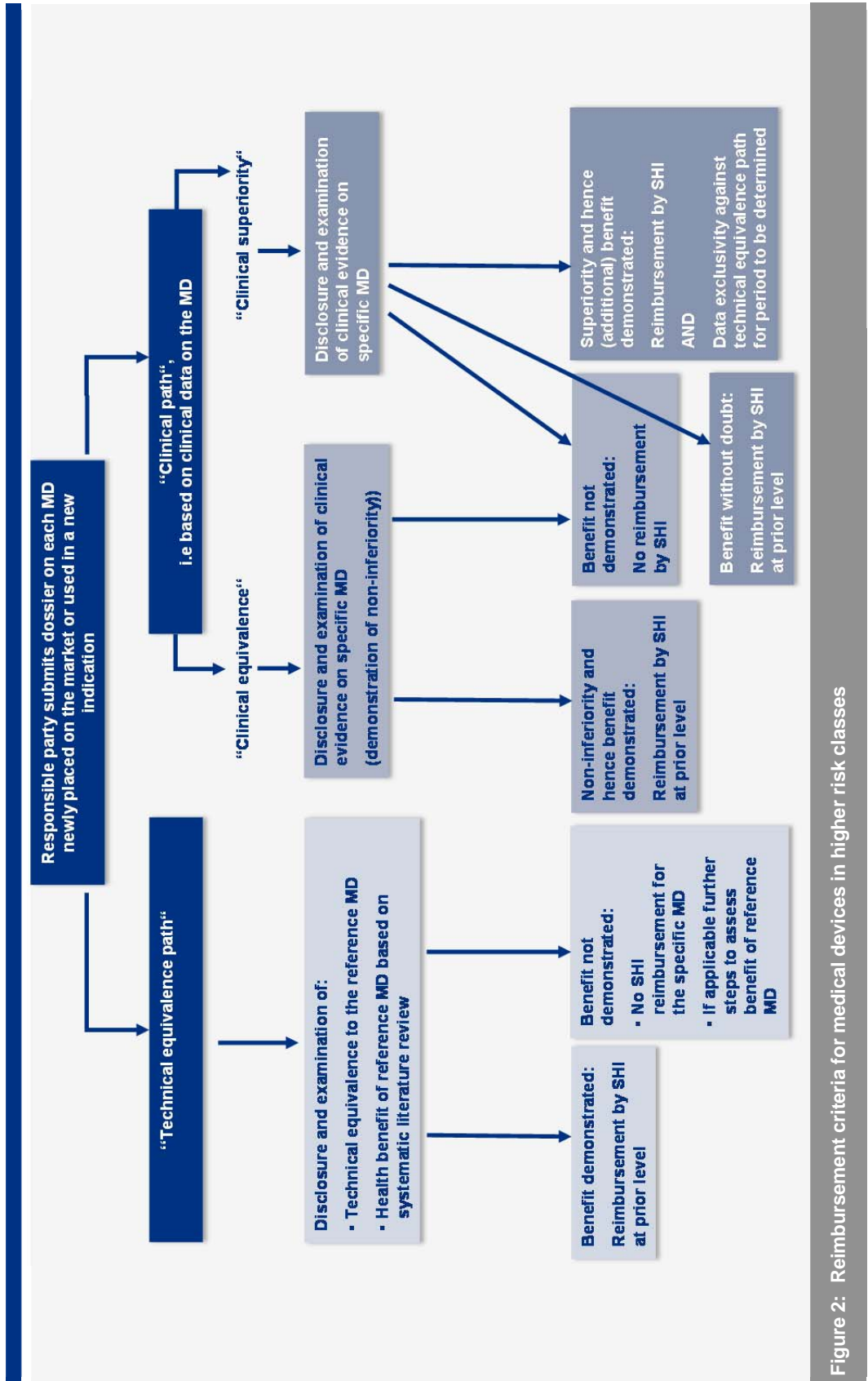


Figure 2: Reimbursement criteria for medical devices in higher risk classes

Source: Own compilation

4 Rehabilitation

4.1 The German rehabilitation market

107. The term rehabilitation takes in the three service sectors of medical, educational/vocational and social rehabilitation. This chapter largely relates to medical rehabilitation. Along with medical treatment and nursing care, medical rehabilitation primarily involves physiotherapy, physical therapy, occupational therapy, speech therapy, psychological and psycho-therapy services, diatetics, nutrition advice, health education and welfare advice and support services. Follow-up rehabilitation is a special procedure which continues (as seamlessly as possible) the treatment provided in inpatient care. Rehabilitation serves to restore a patient's own abilities and skills, and in the case of (threatened) disability helps them to lead as independent a life as possible. To enable equal participation as set out in the UN Convention on the Rights of Persons with Disabilities, conditions must be put in place to secure access to rehab services.

108. In Germany, medical rehabilitation is provided primarily in inpatient care. In 2012, the market share for inpatient care and day-care and rehabilitation centres amounted to €8.71 billion (2.9 percent of total health care expenditure across all health funders). There is evidence of an ongoing, slightly downward trend over the longer term. In 2012, there were 1,212 inpatient care and day-care and rehabilitation centres in Germany, with some 170,000 beds and almost two million cases annually. Of these, 54.4 percent are privately operated, 19.1 percent are state-run and 26.5 percent are in the hands of voluntary, non-profit making organisations. In line with their above-average share of the market, privately operated centres account for 66.4 percent of rehabilitation beds.

The biggest share of expenditure falls to statutory pension insurance and statutory health insurance (SHI), with more than two-thirds of total expenditure (€3.45 billion or 39.6 percent in 2012) falling to pension insurance and €2.62 billion or 30.0 percent to the SHI. Statutory pension insurance is responsible for employed persons and has the primary task of restoring their ability to work or of securing their employability. The SHI, by way of comparison, plays only a subsidiary role in cases where a person's

employability is not at risk and is primarily responsible for non-employed persons. In addition, statutory accident insurance (GUV) is responsible in cases where the need for rehabilitation arises from a work-related situation such as a workplace accident or work-related stress. Despite relatively high awareness, the GUV only accounts for around two percent (€0.14 billion) of all expenditure and cases, most of which are treated in GUV-operated hospitals.

Expenditure on rehabilitation is largely dependent on decisions by the legislature. For example, the introduction of the German Growth and Employment Promotion Act (WFG) in 1996 led to a drop in expenditure in 1997 of around 19 percent or almost €1.5 billion. As a result, statutory pension fund expenditure on rehabilitation was cut, patient surcharges rose, standard treatment times were reduced and the intervals between treatments were extended. This led to a significant drop in the number of rehabilitation cases, length of stay and the number of beds occupied at any given time. It was only in 2007 that levels regained those of 1996.

In 2012 some 119,000 people (approximately 90,500 fulltime equivalents) were employed in inpatient rehabilitation and care centres. These are thus a key economic factor and a key employer in some rural regions. In some areas, over seven percent of the local workforce is employed in medical rehabilitation.

Irrespective of this, this importance of follow-on rehabilitation has grown in recent years: in the SHI, the share of cases directly following hospitalisation currently lies at around 80 percent. This compares with about one-third of cases under statutory pension insurance due to the differing patient group. These figures were significantly lower several years previously.

109. On average, rehabilitation patients covered by statutory pension insurance (excluding juvenile rehabilitation) are aged 51.6 (men)/51.8 (women); those receiving outpatient rehabilitation treatment tend to be younger. An analysis of cases treated in 2012 shows that at 31.9 percent, orthopaedic rehab (meaning diagnoses involving muscular, bone and tissue injuries or diseases) is the most frequent type of treatment. This is followed by mental illness (15.1 percent, with increasing importance), cardiovascular disease, including strokes (14.7 percent with a downward trend) and neoplasms (11.2 percent with increasing importance). All other diagnosis categories account for only a marginal share of cases.

The illnesses and injuries treated differed significantly between outpatient and inpatient rehabilitation, as data provided by the German statutory pension insurance fund shows. While around a third of inpatient cases involved the musculoskeletal system and connective tissue, outpatient cases requiring such treatments were significantly higher, at two-thirds. Looking at all orthopaedic rehabilitation measures in 2012, the share of outpatient rehab was only about 23 percent. Especially low figures for outpatient

treatment are also seen in cases involving metabolism/digestion, neoplasms and mental illnesses.

The average length of stay in a rehabilitation centre was 25.5 days in 2012. For outpatient rehab, the duration of treatments was significantly shorter, ranging from 18.3 to 22.7 days in the SHI, and 21 to 30 days under statutory pension insurance.

110. A Länder comparison of cases involving rehabilitation services shows some marked regional differences. The field is led by Mecklenburg-Western Pomerania and Schleswig-Holstein. At the lower end of the scale come the city states of Berlin, Hamburg and Bremen, and also North Rhine-Westphalia and Saxony-Anhalt. This is due to a combination of hospitals with different specialisms and regional conditions (such as climate) leading to differences that have evolved over several decades. Unlike in other countries, rehabilitation in Germany often takes place away from the patient's home town, but in climatically more favourable inpatient rehab clinics.

When comparing the use of rehabilitation services according to patients' address (data is only available for patients covered by statutory pension insurance), the regional differences are less pronounced. There are, nonetheless, some interesting factors: the five top places are all taken by Länder in eastern Germany. This is possibly explained, among other things, by age structures and differing patient groups in the Länder concerned – employed persons in eastern Germany are somewhat older on average. Further research is needed to identify medical and/or economic reasons for these regional differences.

111. On the whole, it can be said that many rehab funders store and process data in their own way and for their own use. Added to this come problems regarding transparency in some statistics – for example, it is almost impossible to segregate SHI rehab data by Länder. Delays on the part of individual health insurance funds in providing statistics on application and approval patterns, and on the outcome of claims, also prove problematic.

It is thus recommended that statistics be harmonised across all rehab funders, with standardised definitions and delineations between rehab cases, diagnosis groups and expenditure components. Greater differentiation between the reported diagnosis groups (e.g. rehab following a stroke rather than subsuming such cases under cardio-vascular disease) would also be helpful. In addition, the socio-economic reasons behind the need for and use of rehabilitation services should be looked at in greater depth.

The Federal Statistical Office could perform this task, but is reliant on having a supply of high-quality data from all rehabilitation payers. Scientifically usable data is currently primarily available from statutory pension insurance. Any other data used should be made to equal or exceed this in terms of detail level.

4.2 Rehabilitation funding and remuneration

4.2.1 Medical rehabilitation and the need for long-term care: Disincentives for rehab funders

Funders of medical rehabilitation in Germany

112. In Germany, responsibility for rehabilitation falls to various social services funders. Under Section 6 SGB IX, these are the statutory pension insurance funds, the statutory health insurance funds (SHI), the statutory accident insurance funds (GUV), the Federal Employment Agency, the war veterans service, the war victims compensation funds, and the youth welfare and social welfare services. Different funders are responsible depending on a person's age, employment status and the cause of their health impairment.

The SHI is responsible for medical rehabilitation, the statutory pension insurance funds for both medical and occupational rehab, and the GUV for medical, occupational and social services. This makes for a complex division of responsibilities, often with parallel assignment of responsibility. The SHI is by far the key funder of rehabilitation for people in need of long-term care.

According to SGB IX, the social long-term care insurance funds do not pay for rehabilitation. This lack of status provides little incentive for the SHI to fund services to prevent the need for long-term care. Health insurance funds are, in accordance with SGB V, in competition with one another, although in their capacities as long-term care insurance funds they act as a single long-term care insurance scheme under SGB XI. The health insurance funds would have to spend more on rehabilitation measures to prevent the need for long-term care (covering this expenditure from their own budgets) even though expenditure for long-term care is shared across all health insurance funds. There is also the risk that once a need for long-term care arises, rehab services might not be offered in full or automatically although such services should be made available as set out in Section (2) SGB XI.

113. Given the overlapping assignments and responsibilities among the social services funders, uncertainties can often arise where specific cases are concerned. The legislature must ensure that responsibility-related disputes are avoided wherever possible, are not fought out at patients' costs and that patients receive the services they need in a timely and uniform manner. Under Sections 12 to 14 SGB IX, rehabilitation funders are required to cooperate more closely with one another. They must agree joint recommendations and are under obligation to forward applications to the responsible funder within a given timeframe.

The agreements signed between rehabilitation funders show that good inroads have been made. This approach should be continued. The assignment of clear areas of responsibility is desirable in juvenile rehabilitation and oncology. The exception regarding 'equal responsibility' (Section 31 (1) SGB VI) should be abolished and responsibility for these areas clearly assigned to one or the other of the rehabilitation funders. This would turn discretionary services into mandatory services to be provided by health insurance or pension insurance.

Preventing false incentives through the assignment of financial responsibility

114. To solve the incentive problem concerning long-term care, responsibility for associated rehabilitation should lie in the area with the rehabilitation risk. The institution which would be responsible for the financial impact of a need for long-term care should thus be responsible for preventing the need for such care and bear the associated costs.

One pragmatic approach would be to divide the costs of rehabilitation to prevent the need for long-term care between the long-term care insurance and health insurance funds. This joint financial responsibility would also take account of the fact that the need for long-term care is usually coupled with chronic disease or multimorbidity (and thus subject to provisions laid down in both SGB XI and SGB V). Also, in line with the 2013 Coalition Agreement between the governing parties, CDU/CSU and SPD, a check should be made as to whether the principle of 'prevention before rehabilitation before long-term care' can be enforced through the involvement of long-term care insurance.

Irrespective of the compensation mechanism used, difficulties would arise concerning where to draw the line between the health insurance funds and long-term care insurance funds. To prevent an over-burdening of the long-term care insurance system, it is very important for rehabilitation aiming to prevent the need for long-term care to be distinguished from rehabilitation not aiming to prevent the need for long-term care. A general age limit (say, 70) would appear a practicable solution in this regard.

A simpler solution which could, however, only be implemented in the longer term would be full integration of long-term care insurance into health insurance. It would still be necessary to ensure that long-term care insurance is not overburdened. Full consideration of rehabilitation and long-term care services as part of a morbidity-related risk compensation system would be particularly important in order to avoid potential risk selection. With (risk-adjusted) average long-term care costs, the health insurance funds would have an incentive to use both rehabilitative and preventive measures to bring down the actual cost of a patient's long-term care below the average calculated costs.

115. Another important step in integrating rehabilitation and long-term care involves the identification and communication of individual rehab needs as part of the assessment of the need for long-term care performed by the Health Insurance Medical Service (MDK). However, there is evidence that existing rehab potential has not been fully exploited: tests with new forms of assessment have tripled the number of recommendations made. Further research is needed and one specific evaluation measure could be that rejections must be justified.

For long-term care funders it is also difficult to obtain information on whether prevention and rehabilitation services are meaningful. Greater sensitisation and targeted training of health care professionals (especially general practitioners and hospital and care-centre staff) could help in identifying rehabilitation potential.

116. Care must be taken to ensure that any reduction in the need for long-term care achieved through successful rehabilitative measures does not automatically and rapidly lead to financial disadvantages for patients, their dependents and thus, albeit indirectly, the service provider. It would be wise, therefore, to wait until the stability that goes with an attained improvement has been demonstrated over a longer period and the assigned classification retained during that time.

Cost efficiency impacts, for example of geriatric rehab, should be looked at in the course of financial assessments. There is evidence that rehabilitative measures pay for themselves if the need for long-term care can be postponed for just a few months.

4.2.2 Rehabilitation expenditure ceiling

The rehabilitation budget and rehabilitation demand

117. Since the entry into force of the Growth and Employment Promotion Act in 1997, the ‘rehabilitation budget’ has set the ceiling for approved expenditure on participation services funded out of statutory pension insurance. The incremental increases in this budget are based on the projected trends in gross wages and salaries for an average employee in Germany. Since the Act was introduced, expenditure may only increase within this ratio. With the trend towards more employees in low-wage groups and more part-time workers, however, the rehabilitation budget has increased at a lesser rate than gross wages and salaries. In addition, the number of insured persons entitled to rehabilitation increased during the same period. In the meantime, new and altered conditions (such as the establishment of rehabilitation structures in eastern Germany) have been created using funds from the rehabilitation budget. Demographic change was not taken into account until the introduction of a demographic component under the Act to Improve Statutory Retirement Pension Services (RV-LvG) adopted in May 2014. Other changes in rehabilitation needs – which could, for example, arise due to changes

in the length of working lives, the range of illnesses to be treated and available treatments – still go unconsidered for the time being.

118. The degree to which the rehabilitation budget was utilised grew considerably over a short period starting in 2006. Until 2010, there was still scope for increased rehabilitation expenditure, but this has since been used up. The budget ceiling of €5.67 billion in 2013 was completely exhausted (100.2 percent), with actual net expenditure amounting to €5.68 billion. This compares with 99.0 percent in the previous year.

In 2012 some 1,004,617 medical rehabilitation measures were carried out and 1.69 million applications for medical rehabilitation were submitted. This is 30.6 percent more than in 2005. And in 2012, 65 percent of all applications processed via the statutory pension insurance fund were approved. More than three-quarters of all rehabilitation expenditure via pension insurance goes to medical rehabilitation; spending in 2012 amounted to €4.39 billion (77.6 percent).

Forecasts indicate that this trend will continue: assuming that rehabilitation prevalence rates for age and gender remain unchanged, demographic change alone will lead to an increase in the number of rehabilitation cases between 2009 and 2020. Added to this are factors such as the altered morbidity spectrum, shorter lengths of stay, longer working lives and the already emerging lack of workforce potential – all of which can increase the role of medical rehabilitation.

Adjusting to changing needs

119. There have been repeated calls for the rehabilitation budget to be aligned with demographic change. Critics believe that the current formula cannot adequately reflect actual demand. The baby-boomers born in the 1950s and 1960s currently make up a large portion of the employed population. And they are now of an age, or are approaching an age, in which their need for rehabilitation is more likely and the rehab treatments they receive could secure their employability for many more years.

Almost three-quarters of rehab treatments covered by statutory pension insurance fall to people aged between 45 and 65. This is closely linked to the altered range of illnesses, increased multimorbidity, chronic disease and psychological problems. In addition, the increase in pensionable age and thus in the length of working life results in an increased need for rehabilitation because people need to retain their employability for longer. Medical advancement is also cited as a factor driving increased demand for rehabilitation. New treatment methods tend to expand the group of potential rehab patients (even though compressed morbidity can have the opposite effect). It is also recommended that the various guidelines and regulations provide for the integration of rehabilitation measures into the treatment chain as a matter of routine.

120. In sum, a temporary rise in rehabilitation expenditure can be expected that cannot be met from the existing budget. This could mean that both necessary and medically and economically promising measures could be withheld, causing harm to society as a whole.

According to statutory pension insurance calculations, successful medical rehabilitation treatment usually pays for itself from the fourth month after the patient returns to work or if the inception of a reduced earning capacity pension can be postponed for at least four months. A study conducted by Prognos assumes that the German economy currently receives €5 for every €1 invested in medical rehabilitation.

What must be remembered, however, is that the expected effects cited in the studies mentioned cannot be expanded at will. And in many cases, there is a lack of scientifically founded efficacy and cost-benefit analyses. This is why a general call for expanded rehabilitation measures is not enough. Hence, further research is needed in order to determine the size of an appropriate rehabilitation budget.

121. A limited-term increase in the rehabilitation budget (particularly in the near future up to, say, 2020) would allow the rehabilitation potential in the German workforce to be exploited. On 23 May 2014, the German Bundestag adopted the Act to Improve Statutory Retirement Pension Services (RV-LvG), providing for an alignment of the rehabilitation budget and the introduction of a demographic component. The budget for 2014 has been increased retroactively by €100 million, that for subsequent years by €200 million a year, and each annual budget now has a demographic component. Consideration of a demographic component is easy to implement and the same applies regarding any increases in pensionable age and working life. In addition, it would also be possible to include a specific morbidity component and a factor to reflect medical advancement. These would be more difficult to achieve, but having said that, calculation of a morbidity component is already standard practice in other parts of the health care system.

Ideally, funding would be made available relative to the success of a specific treatment. This would, however, pose a range of methodological problems regarding issues such as measurability and attribution, and appropriate adjustment for the health status of the respective group.

As a rule, the rehabilitation budget must be adjusted in the amount that cannot be met by exploiting the scope for efficiency improvements. Too great an increase in the rehab ceiling would negate efforts towards achieving targeted selection of rehabilitation patients and cost-effective management of available funds.

122. The discussion in this section focuses exclusively on the rehabilitation budget managed by the statutory pension insurance funds because no statutory budget is

provided for rehab treatment provided by the SHI. However, despite the increasing number of people in the rehabilitation-relevant age groups, there has been a steady decrease in the SHI share of rehabilitation expenditure. The long-term decline in demand for rehabilitation under the statutory pension insurance system is expected to be paralleled by an increase in demand for rehabilitation under the statutory health insurance system.

4.2.3 Classification models and remuneration of rehabilitation measures

Existing approval and remuneration arrangements

123. Under Section 21 SGB IX, rehabilitation funders enter into agreements with individual rehabilitation centres on the performance of services, in that the Länder-level health insurance fund associations enter into a joint and uniform care agreement (a kind of licence) which is then finalised by the individual health insurance funds – and more recently by multiple health insurance funds acting in an alliance – by means of selective remuneration agreements with the various rehab institutions. There is no obligation to enter into an agreement and no central or state-regulated needs planning takes place.

At the moment, rehabilitation services are remunerated via rehab centre-specific, fixed daily rates (largely for treatment funded by state pension insurance funds, although length-of-stay stipulations mean that the daily rates approximate in many cases to a per-case fee) or per-case fees (generally under the SHI). These generally differ only as regards the department providing the treatment and thus very broadly by indication or severity. Empirically proven fluctuations in the resources needed relative to the degree of illness document the need for better-defined diagnosis groups. In the existing remuneration system, the risk regarding case severity falls almost exclusively with the service provider. What has also attracted criticism is that the current system offers few incentives for cost-effective provision of services and that, rather than focusing on the services provided or the results achieved, remuneration tends to be based on structural characteristics (such as staffing).

The remuneration system for medical rehabilitation is thus of a far less finely classified nature than the DRG system in the acute care sector. In a unitary funding system, the fixed fee payments cover all operating and investment costs. There is little representative data available on remuneration levels. However, analyses show that the increase in remuneration payments, at least in recent years, has been below the growth rate of the input prices, thus putting financial pressure on service providers. Representatives on the service provider side also criticise the strong position of the rehab funders in the negotiation process, casting doubt on the wisdom behind the

creation of Länder-level arbitration offices given that there is no obligation for service providers and rehab funders to enter into contractual agreements.

Access paths

124. The assessment and approval of rehabilitation measures and the subsequent management of admission to selected rehabilitation centres lies (subject to statutory provisions) in the hands of the rehabilitation funder or payer. This allows for relatively tight control of rehab care, but repeatedly attracts criticism regarding the lack of transparency in the approval of rehab services and selection of rehab institutions.

In the case of follow-on rehabilitation, hospitals play a special role in their capacity as referrers. This can pose problems if, when selecting the rehab centre, the referrer acts in their own business interests (such as using up capacity at associated rehab centres or at those owned/operated by the same funder) instead of focusing on rehab quality criteria. The dangers of risk selection must be weighed against the desire for an integrated care chain.

The access paths from outpatient care appear considerably more complex than directly following hospitalisation. This could perhaps explain the years-long decline seen in curative treatments. A fundamental standardisation of the application and assessment processes across the various funders, and, in particular, simplification of the application and approval process for rehab measures funded by the SHI and prescribed during the course of outpatient treatment, are thus recommended.

If patients are able to exercise their own preferences and options in the choice of a rehab centre, then the decision-making criteria are in many ways defined by location and convenience in relation to the centre involved. Medically relevant aspects are secondary. There is a need for better information regarding the existence and limits of patients' rights to exercise preferences and options, together with guidance regarding potentially relevant criteria in the selection decision. Data based on the various quality assurance measures operated by the rehab funders could be provided, for example, in the form of easy-to-understand information published on comparison websites. This would place patients' choice of rehab centre on a better footing. Mandatory requirements on the publication of quality data would serve this purpose.

Alternative classification approaches

125. More finely divided patient classification can, especially with increased transparency regarding the services provided, serve as an incentive to differentiate services on a more patient-related basis, to perform quality and efficiency comparisons between departments and institutions (benchmarking) and, finally, to provide greater equity in the remuneration amounts agreed for specific services. Also, with more finely divided

classification within the case group system, morbidity risk is transferred from the service provider to the funder or bearer of the cost. When looked at from a regulatory standpoint, this is to be welcomed.

The aim in developing a patient classification system is to achieve maximum medical and/or cost homogeneity within groups and maximum heterogeneity between groups. Examples from Germany include the cost-homogenous rehabilitation treatment groups and medically homogenous treatment groups in rehab case management categories. The latter primarily serves quantitative and qualitative specification of needs-based treatment standards, but may also be used in cost assessment and for remuneration. In this connection, it is important to maintain the separation between grouping cases into homogeneous classes and performing cost assessment on those classes.

The Council is in favour of introducing a case classification system that takes account of the above-mentioned group characteristics and allows the integration of outcome-based remuneration components. Integration with the DRG classification system for the acute inpatient care sector is thinkable, although for the rehab sector there are no plans to create a similarly large number of classified groups to the DRG system. A compatible case grouping system would provide incentives for greater integration of care provision and players. On the other hand, neither rehab patient classification system is methodologically mature. Up to now, assessments have focused on cardiology, orthopaedics and addiction. Further research is needed to prepare case groups for additional indications. The proportion of variance explained by the existing approaches also needs to be investigated. The introduction of a complex case classification system is only worth the effort and expense if the system actually identifies greater cost and thus remuneration variances between the different degrees of severity. Analyses using representative data for Germany as a whole are needed before such a system can be introduced on a nationwide basis.

Alternative remuneration models

126. The only real alternative remuneration models based on a more finely divided patient group classification systems would be an enhanced daily fixed fee, more closely classification-based per-case fees and cross-sectoral mixed fixed fees.

There is much in favour of primarily daily rate-based remuneration, which includes stipulating maximum and minimum marginal lengths of stay. Of importance in this regard are a practicable level of classification and the inclusion of investment costs on a unitary funding basis. The German Institute for the Hospital Remuneration System (InEK) could define relative weightings based on real costs in benchmark rehab centres. Negotiating a daily per-case base rate for multiplication of the relative weighting would remain part of the independent agreement process between rehab funders and service

providers. In the course of these negotiations, the parties should strive to agree on more results-based remuneration – an approach that steps have already been taken towards. A bonus/penalty system could serve in this regard, with the focus on verifiable treatment results or patient satisfaction assessments. The use of a tender system for this purpose is highly promising in that it offers greater cost-effectiveness and transparency. This collective agreement-based alternative would be that each hospital would automatically be entitled to bill the agreed fixed fee. Desirable control effects (in terms of volume and quantity) would be lost.

Mixed fixed fees appear useful for some indications that lend themselves particularly well to this approach. This applies in particular with a view to opportunities for implementing the model, set out in the Council's Special Report 2009, for a population-based, cross-sectoral, integrated health care system. One example is knee and hip replacements. Particularly where follow-on rehabilitation is concerned, it should be quickly possible to link remuneration to the hospital discharge diagnosis. There is, however, a need for further research as to whether hospital discharge diagnoses are sufficient in classifying rehab cases. The rehabilitation treatment groups classification model is most probably suited to rehab following acute inpatient care under the DRG system and thus as a catalyst for greater sectoral integration.

4.3 Evidence-based rehabilitation

Study analysis from a medical perspective

127. Studies on the objective benefits of alternative care options in the rehabilitation sector are urgently needed. While special research consortiums and research priorities have been established, there is still only limited knowledge available on the (additional) benefits and the cost-benefit ratio of specific innovations compared with alternative treatments.

Many studies fail to meet all of the strict quality criteria applied in evidence-based medicine. They are largely prospective cohort studies (without control groups) with before-after comparisons. These are not sufficient to prove efficacy because, among other things, the natural healing process overlaps with effects of rehabilitation and changes cannot be apportioned 100 percent to the intervention. Use is seldom made of the 'usual care' comparison often elected in other countries (meaning usual or slightly intensified general medical or specialised care). The same applies regarding comparisons with a modified form of the standard rehabilitation treatment. Cost assessments tend to focus on preventing illness-related absences from the workplace.

The international literature contains studies whose findings show the efficacy of isolated therapy elements. Their findings are worthy of note but, given the different

conditions under which the studies were conducted, cannot be directly transferred to the situation in Germany. In addition, proof of efficacy for a particular therapy element does not provide enough evidence to support the treatment as a whole.

128. From a methodological standpoint, it would make more sense to establish a control group. A treatment comparison could look at the situation versus no provision of rehabilitation or ‘usual care’, or outpatient versus day-care rehab models or modified/improved/expanded inpatient rehab models. With regard to the first option, artificial creation of a control group by statistical means or the use of waiting-list control groups would be the best approach for both social policy and ethical reasons. In the case of comparison with an alternative therapy, problems arise regarding blinding, but in many cases blinding endpoint assessors would be possible. Where establishing a control group proves impossible, the results of the waiting-list control group should be compared with control group results from properly randomised international studies.

As a general rule, studies report on positive outcomes from rehabilitation measures. They provide no insight, however, into how the healing process might have continued without rehab or if an alternative treatment has been used. Also, a publication bias in favour of positive evaluation outcomes cannot be ruled out. There is little evidence regarding medium and long-term outlook, even though some positive indications exist.

Many benchmarks for evidence-based medicine can be transferred or adapted for use in prospective efficacy studies in the rehabilitation sector. Thus, checks should be made as to how the principles of randomisation, reasonable comparison treatment, control group definition, long-term follow-up monitoring with as many follow-up examinations as possible and a sufficiently large number of rehab patients can be achieved with the appropriate level of statistical significance.

Evidence-based medical rehabilitation: Systematic literature review

129. The question of the extent to which medical rehabilitation measures are evidence-based is of fundamental significance both medically and financially. The following literature review is designed to show how the evidence-based aspect of such measures should be assessed in Germany, whether the methodological standard meets the criteria for a Health Technology Assessment (HTA), what weaknesses the studies reveal and what recommendations can be concluded from those findings. By way of example, the indication ‘chronic back pain’ was selected, which accounts for 17 percent of all rehabilitative services covered by statutory pension insurance (for a detailed report see the Advisory Council website: www.svr-gesundheit.de).

According to systematic research of available literature, a total of 28 German and English-language primary publications were evaluated between January 2000 and October 2013.

Almost all of the studies focus on services funded by the statutory pension insurance fund. Only one compared the effects of standard rehabilitation treatment with non-rehabilitation and was thus relevant in respect of the 'absolute efficacy' criterion. The other 27 studies compared various forms of rehabilitation with one another and looked at their differential or additional effects.

Looking at the quality of the studies based on the criteria published by the Cochrane Back Review Group, an average of four out of twelve points were scored, with the best study receiving nine points. Six out of twelve RCTs scored higher on validity (≥ 6 points). None of the non-randomised studies exceeded this threshold. Considerable validity difficulties resulted from what were in many cases high cohort losses – 36 percent among the studies with a twelve-month subsequent monitoring period. With only one exception, where the loss amounted to six percent over twelve months, there was no evidence of approaches towards more intensive cohort care and study adherence.

An aspect that raises problems is that the process quality of the intervention in question was not systematically assessed and evaluated. Only two studies expressly provided information on this point and only four had evaluated their data based on the intention-to-treat principle. Cost aspects were looked at in five studies, with the funder perspective the dominant focus. Dividing the studies into three periods (study commenced prior to 2000, between 2000 and 2005, and after 2005), there were no significant changes in respect of study design and quality. In particular, there was no increase in the number of RCTs, no change in the average risk of bias and no time trend in the number of study arms, size of the net samples, length of the follow-up period and the cohort losses.

Looking at methodological quality and outcome certainty, the entire evidence base (on a six-level grading scale) can only be considered 'satisfactory' (a 'C' grade). Study findings on absolute efficacy are 'unsatisfactory' (a 'D' grade). With regard to the necessary standards for a rehabilitation-specific HTA, problems arise with the low number of studies on a specific topic. Convincing signs of cumulative research with methodologically evolving studies are rare. Only a few studies appear to be based on a HTA-typical policy question, and seem to have contributed little towards any restructuring of the rehabilitation funders' administrative and management routines. Studies on cost-effectiveness, as should be taken into account in a typical HTA, are few and far between; those that were found are descriptive and consider only the funders' perspective. Interventional studies on increasing efficiency are lacking altogether.

Economic perspective

130. The need for economic analysis in rehabilitation research arises from the limited availability of resources, which in turn calls for their most efficient and effective

use. From an economic standpoint, innovations are only advantageous if they improve the cost-benefit ratio. Transferring this to the rehabilitation sector, it can be assumed that most measures have greater than zero benefit. Yet there is frequently uncertainty regarding comparison of a new measure with an existing treatment option and regarding the cost-benefit ratio.

Economic analysis should cover the various types of benefit. It would also be wise to perform a holistic, i.e. societal, cost-benefit assessment over a longer period of time that takes in all cost components, which are put into relation with the effects they trigger. Apart from expenditure on rehabilitation proper, the costs of follow-on measures in outpatient and acute inpatient treatment, and on things like medication should also be considered on the cost side. On the benefit side, medical outcomes such as mortality, morbidity and quality of life must also be taken into account.

As early as in 1999, guidelines were developed for the evaluation of health-related costs in Germany's rehabilitation sector. These could serve as recommendations in the design of the studies required today.

In sum, there are few health economics analyses conducted from a societal standpoint that also take a holistic, long-term perspective. Also, rehabilitation is generally evaluated as a whole. Only in rare cases are the differing treatment approaches or measures compared and assessed for cost-effectiveness. This poses problems in that it is generally assumed that each measure has the same efficacy and the same level of appropriateness. This gives rise to underprovision in Germany and thus to the need to expand the rehabilitation sector and provide for better definition of priority target groups.

Rehabilitation efficacy: Outlook concerning statutory pension insurance

131. As well as routine data on social-medical history, statutory pension insurance holds a wide range of other information which is used for in-house comparisons and for rehabilitation quality assurance. In most cases, however, this comparative analysis is not made available to the public or to rehabilitation patients (at least not at the level of rehabilitation centres). The situation is similar with regard to the rehabilitation quality assurance process operated by the SHI: comprehensive data on the structure, process and quality of the results is held on each individual rehab centre. This is mostly made available to service providers and to funders.

Publication of the data on hospital comparison platforms or in scientific evaluations could significantly increase transparency and strengthen the position of rehab patients in selecting suitable institutions and treatment approaches. In particular, a highly promising application would be to use the data to highlight differences between treatment approaches and service providers, and in combination with the results data.

132. Guidelines usually focus the medical treatment process, but rarely give recommendations on structuring rehabilitation therapy. Only a small number of German directives on acute medical care contain an express reference to rehabilitation. Also, only a small number of targeted rehabilitation guidelines have been registered with the Association of the Scientific Medical Societies in Germany (AWMF). The development status regarding guidelines on medical rehabilitation in Germany is thus less than satisfactory from both a quantitative and qualitative standpoint. There is much to do in this regard. It is recommended that funders, medical societies and research institutes work more closely together on guideline development, both to avoid potential conflicts of interest and to increase acceptance among rehab stakeholders.

133. In sum, the lack of evidence-based medicine is the core problem in the rehabilitation sector as a whole. Studies are needed on the absolute efficacy of existing rehabilitation measures. This touches on issues such as increasing the rehab ceiling, the assumed benefits of geriatric rehab, the expansion of outpatient and mobile care models, and a revised (results-based) remuneration system.

In this regard, prospective, randomised, controlled studies are seen as the Gold Standard. Although in rehabilitation sector, many of the associated requirements cannot always be met for many reasons, future studies should at least focus on these criteria.

134. In addition, rehabilitation should receive greater attention in research projects on health care provision. For example, studies should look at which target groups benefit from specific services. Also, long-term monitoring is needed to assess the lasting effects of successful rehab outcomes.

The necessary studies on provision and/or cost-effectiveness could help in achieving resource-efficient management. Greater transparency regarding results and quality could help service providers overcome the current narrow pricing focus in agreements with rehab funders. Building on this, pay-for-performance approaches could be integrated into the remuneration system, thus switching the focus more in the direction of verifiable quality aspects.

One additional challenge involves transferring results into everyday practice. The establishment of guidelines and their transfer to vocational and further education and training is a key prerequisite. To a broader extent, this includes the provision of information. Rehab funders possess a wide range of information and knowledge which can be of great value to patients and advisory agencies in selecting suitable rehabilitation centres.

4.4 Innovative care approaches and regional differences in rehabilitation

Demographic change and an ever-changing treatment spectrum combined with the altered needs of potential rehab patients and changing general conditions pose huge challenges in the rehabilitation sector. Care approaches are needed which have been adapted to these needs.

4.4.1 Local networks: Including rehabilitation in integrated networks

135. For a long time, the rehabilitation sector resembled an island, both substantively and geographically. While the local aspect can only be changed over time, a cross-sectoral approach is already starting to emerge. This includes a coordinated transition from acute care into rehab and follow-on outpatient treatment. The aim is to achieve ongoing, integrated care processes with needs-based services, short transition times, comprehensive advance and follow-up information, and the cementing of newly-learned lifestyle changes. One approach already adopted by some institutes involves integrated care as defined under Section 140 a – d SGB V, which allows participation by rehab service providers.

No overview is currently available regarding participation of rehab institutions in integrated care. Data available for 2008 shows that participation mostly involves rehabilitation centres with hospital agreements (716/6,407) and less so those with practice-based physicians (180/6,407) or with hospitals and practice-based physicians (182/6,407).

Indication-specific models are well represented. Case and/or care managers are used in some cases. Only in rare cases are coordination services provided at the interface with the nursing care sector. Agreements are mostly limited to a specific region and are extended to include new service providers. For billing and organisational purposes, providers tend to use agreements with multiple service providers.

136. In the main, cross-sectoral mixed remuneration could promote vertical integration and thus cooperation between the acute care and rehab segments. Ideally, this kind of cooperation agreement would include the funder (such as pension insurance or long-term care insurance). At the moment, a mixed fixed fee would be almost impossible in under pension insurance because this assumes none of the costs for medication in preparatory or follow-up treatment (such as that provided in hospitals).

Networks and integration would also allow pooling of expertise, sharing of fixed costs and thus increase profitability. This would reduce the transaction costs arising from the fact that every rehab centre must enter into separate agreements with the various

fundes. It would also prevent interface problems. These advantages should at least compensate for the disadvantages of limited rights of preference and selection. There are basically two ways of achieving sectoral integration:

1. Care is organised for the most part by an acute-care inpatient centre. This can include suppliers of inpatient and outpatient rehab and the hospital may reallocate available resources to rehab capacities. Possibilities include own rehab wards or centres, mergers, letting arrangements and association via networks or integrated care models. This option is best suited to follow-on rehabilitation.
2. Care is largely organised by a (rural) rehab centre in its capacity as a local health centre (LHC). This poses a major challenge in that at the moment such centres are rarely part of a local network and patients sometimes have to travel considerable distances for treatment. To establish a local network, service providers would need to change their practices accordingly.

While the second option would mostly be considered for rural areas, the first is likely to attract acute care hospitals or hospital partnerships in towns and cities. This could promote the expansion of outpatient services in the urban sector.

137. In many cases, there is a need for altered, better-defined treatment models. These include:

1. Expanding outpatient rehab structures. These should be mobile, meaning that they should go to the patient. The most suitable patient groups would be less serious cases that do not need constant monitoring in hospital and for whom night-time care is secured (through family members). Groups that would normally do without rehab could also be reached in this way.
2. Coordinated, integrated care given in the same place that the acute care was administered. This means treatment in local networks, such as acute inpatient units with an integrated rehab department. Coordination with treating physicians, involvement of providers of preparatory and follow-on outpatient treatment, and the integration of family members or employers would be made easier with this approach.
3. Specialised treatment of very seriously ill patients or for selected diagnoses. This can involve subjecting rehab patients to travel further for treatment. The choice of service provider should, however, focus on the quality of the treatment and not on the attractiveness of the centre's location.

4.4.2 Value of outpatient rehabilitation

138. Outpatient rehabilitation measures offer a flexible way of adjusting to the needs of a specific case. Under Section 19 (2) SGB IX, outpatient services can be provided as long as the treatment aims can be achieved with similar efficacy. In the SHI, where the objectives are the same and taking account of individual circumstances, outpatient rehab may even take priority under Section 40 SGB V.

Outpatient rehab is especially suited for patients who due to personal or work-related commitments are unable to travel for treatment. Although the desire for rehabilitation alongside work can increase their potential, the growing number of single people is a problem. Also, rehab patients must be sufficiently stable to do without full-day care. For this reason, only some of the current inpatient services could be provided in outpatient care.

Since 2000, the number of outpatient treatments has quadrupled, but their share of all medical rehabilitation cases remains low (2012: 12.7 percent for statutory pension insurance and 10.7 percent for the SHI). Some 527 outpatient centres were reported to exist in 2011. In the interests of integrated care, this is to be welcomed in principle, but more must be done to achieve wider coverage with such centres.

Given the shorter treatment periods, it would appear that outpatient rehab centres are linked to lower direct treatment costs (according to statutory pension insurance data for 2012, €1,761 versus €2,621). The main cause is the lack of hotel costs, which more than makes up for daily travel costs.

Literature review on efficiency and effectiveness

139. Based on an in-house review of the literature, an analysis was conducted of 21 German and English-language studies conducted in the period 2000 to 2013. These included controlled studies, systematic reviews and meta analyses. Additional inclusion criteria required comparison between interventions from multidisciplinary, multimodal medical rehabilitation. The studies looked at must have evaluated medical and/or economic target parameters.

Among the 21 studies evaluated, 18 are publications that address medical/socio-medical issues and nine deal with health economics (with some overlaps). Particularly in the case of the medical/socio-medical studies, it was apparent that research activity had lessened considerably over the past decade. Most of the medical/socio-medical papers involved prospective follow-up studies with a before-after comparison and a maximum follow-up period of twelve months. The health economics studies are largely cost comparison analyses.

Taken as a whole, the available studies do not support a conclusive assessment. Nonetheless, the findings of the (socio) medical papers show that there are no significant differences in efficacy between outpatient and inpatient rehabilitation. Health economics analyses indicate at least comparable if not lower costs.

Given the available evidence, there is still a need for further, methodologically higher-quality studies. In addition, an evaluation is needed as to the number of the rehab patients involved and the characteristics they demonstrate. Putting a number to the target group for potential outpatient rehab treatment is difficult at this time. It should, however, be higher than the currently observed market share for outpatient rehabilitation.

140. Further expansion of outpatient rehab services is needed. In particular, a combination of inpatient and outpatient measures could shorten treatment times and provide for patients' gradual reintegration into everyday life. This mix of inpatient treatment and follow-on treatment as an outpatient nearer to home is highly promising from both a medical and a financial standpoint. The potential harboured in these new interval models must be tried, tested and evaluated.

For patients who are unable to make use of traditional forms of rehab, mobile rehab could provide an alternative in which an interdisciplinary team supervised by a doctor visits the patient at home to provide outpatient treatment. Entitlement to mobile rehab should be defined in law and the establishment of such services promoted. However, these mobile approaches also need to be made more evidence-based.

4.5 Rehab centres run by rehab funders

141. In 2012, some 232/1,212 inpatient care or care/rehabilitation centres were operated by the state. These include rehabilitation institutions operated by statutory pension insurance funds. The legal framework allowing their operation is set out in Section 15 (2) SGB VI. In 2012, there were 78 such pension fund-owned centres and those numbers have remained relatively stable since then. With just over 200 beds each, these centres are fairly large. Their market share relative to bed number amounts to almost 10 percent of available rehab capacity. These centres turn over approximately €800 million annually.

As a rule, the funder decides the type, length and scope of treatment, and thus also dictates treatment approval and patient admissions. While this prevents uncontrolled increases in case numbers, it invites criticism regarding a lack of transparency in referral and admission practices.

For a long time, the waiving of procurement principles and publicly verifiable documentation regarding hospital selection attracted much criticism. Because the statutory pension insurance funds exposed themselves to such criticism regarding a lack of transparency, the process involved in entering into agreements with other institutions has changed in recent years. What still must be addressed, however, is the criticism regarding an unjustifiable preference for the funds' own centres, which leads to isolation from competitors in the field and less competition on quality and price.

Added to this is the criticism that some fund-owned centres operate at a loss. While there is no regularly collated, publicly accessible information, reference can be made to studies conducted by the Federal Audit Office (BRH), which takes up this issue at regular intervals.

From an operational perspective, bigger and better utilised hospitals should be in a position to offer more affordable services. If the statutory pension insurance funds are willing to operate their own rehab centres in the future, they must aim to make a profit to cover the associated business risk and use that additional profit in the treatment approval process. According to the BRH, scope for cost-efficiency improvements is highlighted most of all by the need for operating grants with which the pension insurance funds make good any losses. As supply of rehabilitation clinics and beds significantly exceeds current demand, there is no need to continue running unprofitable centres in order to secure the availability of rehab treatment.

142. The SHI also operates its own rehab centres. Under Section 140 SGB V, statutory health insurance funds may continue to operate hospitals which existed prior to 1989 and may open new hospitals as long as the care and rehabilitation services they are designed to provide cannot be secured in any another way.

Although competitive distortion effects cannot be ruled out, these hospitals are less harmful from a competition standpoint than those operated by the statutory pension insurance funds. The health insurance market is a highly competitive market. There is therefore less danger of an uneconomic situation across the market as a whole.

143. In sum, clear delineation between rehab funders and rehab providers is recommended, perhaps going so far as to privatise (or municipalise) existing fund-owned centres. In addition, selection of contract hospitals should occur by means of public calls for tender which could contain a component that provides for medium-term patient admissions guarantees on the part of the statutory pension insurance fund.

4.6 Recommendations

144. Harmonised statistics across all rehab funders are needed, with common definitions and standard groups for rehab cases, diagnosis groups and expenditure components. Also, data should also be collated on the socio-economic circumstances surrounding an application for rehabilitation.

145. To enhance the importance of the ‘rehabilitation before long-term care’ principle, responsibility for rehabilitation should be assigned to long-term care insurance. It would also make sense to include long-term care insurance in the group of rehab funders defined in SGB IX and to provide for financial compensation between long-term care and health insurance funds. Expenditure on rehabilitation measures that reduce the need for long-term care could be shared equally between long-term care insurance and health insurance. A more far-reaching solution would be to integrate long-term care insurance with health insurance.

146. As well as a demographic factor, the rehabilitation budget should also account for increases in pensionable age and length of working life – something which is technically easy to achieve. At the same time, use should be made of the available scope for efficiency improvements, for example in outpatient rehabilitation and the operation of fund-owned centres.

147. There is a need for a more finely divided patient and case classification system. Whether remuneration is based on a daily or per-case fixed fee is only of secondary importance, although classification-based daily rates are recommended. Centrally calculated relative weightings could serve as a basis for modification under individually negotiated agreements between rehab funders and rehab service providers that take in the per-case base rate and additional results-based, pay-for-performance incentives. With a view to opportunities for implementing the Council’s model for population-oriented, cross-sectoral, integrated health care system, mixed fixed-rate fees could be used for indications that lend themselves particularly well to this approach.

148. Promotion of research into rehabilitation should be stepped up to obtain methodologically higher-quality studies, and rehabilitation research should be organised so as not to focus only on one funding sector.

149. Innovative care models and structures are needed to meet the challenges posed by demographic change, an ever-changing treatment spectrum and altered patient needs. The rehabilitation process must thus be seen more as a health rehabilitation process, with preventive, work-related, social and/or psychological components. In particular, greater integration of rehabilitation into local networks and integrated care models would have promising results. Further expansion of outpatient services is also needed because patients tend to prefer them.

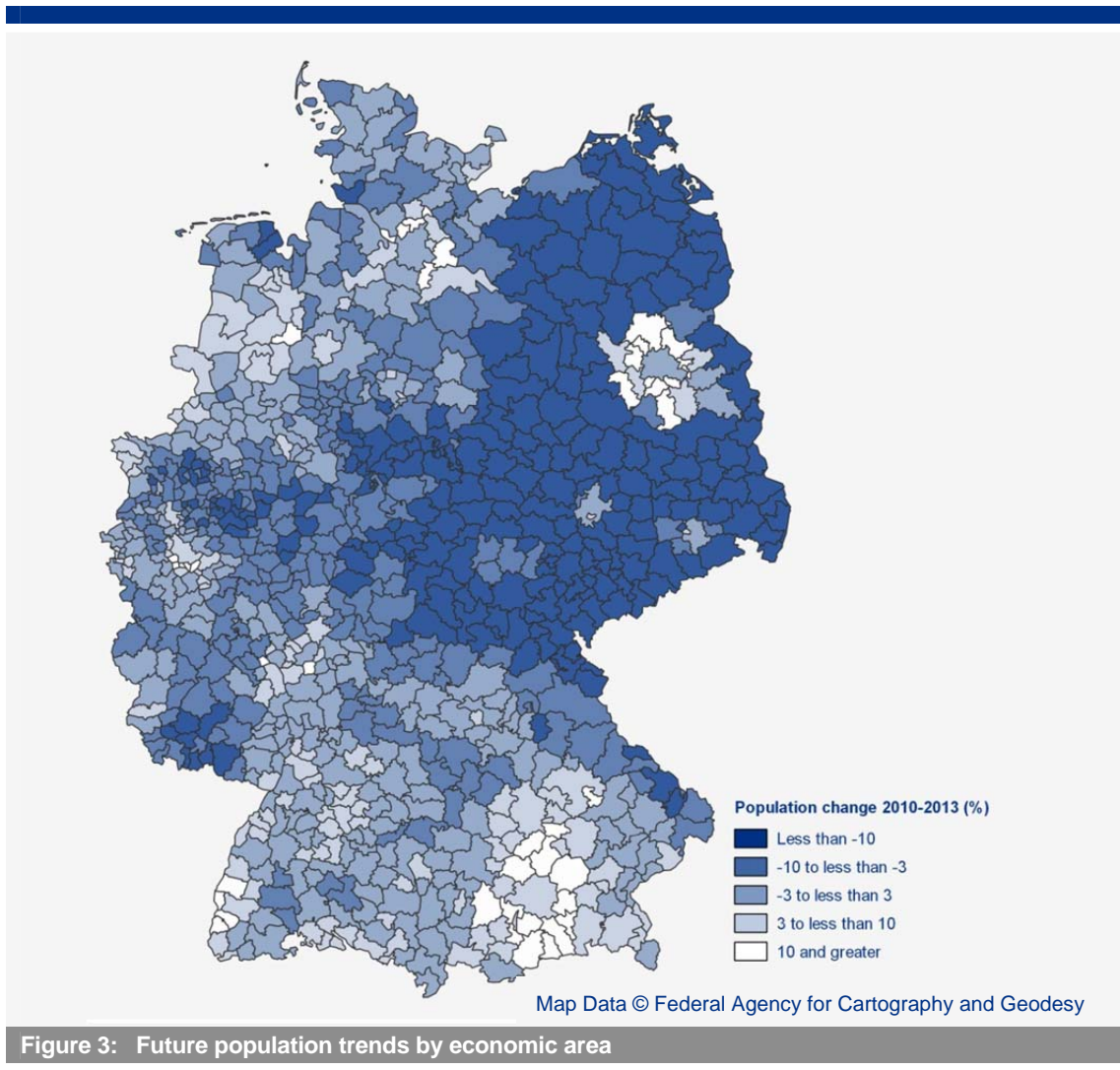
150. Clear delineation between funders and service providers is recommended, perhaps with privatisation (or municipalisation) of fund-owned centres.

Part II: Needs-based Health Care: A Rural Perspective

5 Introduction: Health Care in Rural Regions

151. In its reports, the Advisory Council has the task of setting priorities for the elimination of health care deficits and overprovision and of identifying paths for the onward development of health care in Germany. This present Report builds on the Report 2000/2001, 'Overuse, underuse and misuse', in which the analysis focused on potential underprovision for specific medical indications. In that report, regional-level underprovision appeared practically unthinkable or only as a result of extreme region-specific circumstances.

Since that report was published, the challenges involved in financing Germany's health care system in the face of demographic change, technological advancement and an expanded portfolio of services have attracted greater public awareness, as has the threat of provision deficits in some places, particularly in structurally weak rural areas. While health care capacity in Germany is at a very high level compared with other countries, there is a risk of an increasing imbalance between conurbations and rural regions. The Federal Government, the Länder governments, and self-governing bodies are all searching for ways to provide sustainable health care services in rural areas which are increasingly subject to rural exodus (see Fig. 3) and whose remaining populations are ageing faster than elsewhere.



Source: BBSR 2011; own compilation BBSR 2011; own compilation

The first changes to significantly affect health care provision in rural areas came with the Panel Doctors' Rights Amendment Act (VÄndG) in 2007 which, among other things, allowed branch practices and part-time work for SHI-accredited physicians, and allowed doctors in under-serviced areas to continue practising beyond the age limit of 68. Many measures aimed at remedying over and underprovision – including abolition of the residency obligation, came with the SHI Health Care Provision Act (GKV-VStg) of 22 December 2011. Based on a survey of all Panel Doctor's Associations conducted by the National Association of Statutory Health Insurance Physicians, the Council, in preparing this Report, looked at both the regional health care situation and use of the instruments provided for under the GKV-VStg. The findings are included in the sections on general medical and specialised care.

Apart from what has been the rather hesitant opening up of hospital resources in the provision of outpatient treatment, another important and expandable approach would be to establish joint bodies at Länder level to address cross-sectoral health care issues under Section 90a SGB V. All of the large Länder now have such bodies or similar entities. To identify additional efforts on the part of the Länder, districts and municipalities the Council looked at available literature, and also asked the Länder health ministries and district administrations for information regarding measures, projects and initiatives to secure health care services in rural areas. The findings are set out in Chapter 9 and are supplemented with illustrations of innovative models from Germany and also from Canada and Finland – two sparsely populated countries.

152. The measures taken so far have unfortunately not been enough to halt the ongoing trend, with underprovision already emerging in a small number of regions and impending in others. The Coalition Agreement provides for further measures that, although a step in the right direction, are similarly likely to be insufficient on their own to secure long-term, needs-based health care provision. Thus, further recommendations are made for the elimination of deficits and overprovision and with regard to promising, multi-professional models for more integrated health care services in rural regions.

6 Outpatient Care Provided by SHI-Accredited Physicians

153. Although Germany has a well-established system of outpatient health care provided by SHI-accredited physicians, and comparatively good coverage in terms of physician numbers and generally excellent patient access, it has significant problems when it comes to allocation: on the one hand, these involve marked differences in the spatial distribution of health care capacity, with disparities between rural and urban areas, and on the other, uneven distribution of general medical and specialised care. One key reason is the society-level process of (re-)urbanisation, which is also reflected in the recruitment of young doctors.

6.1 Securing nationwide, needs-based, localised provision

In response to the increasing regional disparities in outpatient provision, the SHI Health Care Provision Act (GKV-VStG) introduced in 2012 allowed for measures to secure conveniently located, nationwide provision of health care services. The revised Needs Planning Directive (Bedarfsplanungs-Richtlinie) issued by the Federal Joint Committee entered into force on 1 January 2013 and contains both new provisions on types of planning region and four care levels. It is to be welcomed that smaller geographical subdivisions are now applied for general medical care (886 versus the previous 398 planning regions), which far better matches actual health care needs. At 391, the number of planning regions for general specialised care has changed only marginally, while the number of planning regions for specialised care has dropped from 395 to 97. For highly specialised care, for which there has been no planning or restriction to date, the entire catchment area of a specific Panel Doctor's Association is selected as a region type, making for 17 planning regions. New figures for the targeted per capita physician and psychotherapist ratio were determined which can be adjusted to meet regional needs. Regional circumstances as regards demographics and morbidity are also taken into account to a certain extent. Many Panel Doctor's Associations and Länder committees make use of the newly created option to adapt needs planning to regional

conditions. Following a Council-conducted survey of all 17 Panel Doctor's Associations, the findings of which were collated by the National Association of Statutory Health Insurance Physicians, adjustments were made for eight Panel Doctor's Associations regions. These involved further subdivision or redrawing of, for example, planning regions for general medical care, alteration of region types and ratios, and region-specific planning of psychotherapists at the smaller-scale level of the general practitioner planning regions.

154. Contrary to the Federal Joint Committee's original expectations that the revised Directive would result in more practices nationwide and new accreditation opportunities for some 3,000 general practitioners, over 1,300 specialists at various care levels and more than 1,300 psychotherapists, the total number of practices decreased under the new Directive across all four care levels. This does not mean that new accreditation opportunities did not arise in individual cases as the planning regions were redrawn and new needs figures were introduced. The reduction in the planned number of practices affects all specialist groups included in planning so far, albeit to different degrees and with the exception of psychotherapists. As a result, according to the Council's survey of Panel Doctor's Associations, the target figure for general practices is reduced by almost 1,400 (2.8 percent) and that for practices in general specialised care by some 1,800 (5.2 percent); psychotherapists are not included in these figures due to incomplete data. In the case of specialised care (anaesthetists, specialised internists and radiologists combined; no comparative historical data was available for child and youth psychiatrists), there is a three percent reduction representing some 200 practices. As the new needs planning figures show, outpatient health care has to be provided in future with fewer doctors than has previously been the case.

6.2 Regional disparities in health care provided by SHI-accredited physicians

6.2.1 General medical care

155. Unless otherwise stated, the following figures are based on the Council's survey of all 17 Panel Doctor's Associations. The figures are as of 30 September 2013. The mean level of provision for general medical care in Germany is 108.6 percent, with a median of 109.3 percent. There are clear regional differences in provision within Panel Doctor's Association districts, and in almost one-third of planning regions the level of provision is less than 100 percent. There is one planning region nationwide for which a Länder committee identified underprovision by the criteria of the Needs Planning Directive (Hessen Panel Doctor's Association: 63.6 percent provision level). Some 52 planning regions served by eight Panel Doctor's Associations are at risk of underprovision, with

Panel Doctor's Associations in eastern Germany especially affected. The criteria used in calculating threatened underprovision differ significantly across the Panel Doctor's Associations, while several accreditation committees perform no such calculations at all.

6.2.2 Specialised care

General specialised care

156. The mean provision level for general specialised care is 145 percent (median 131.5 percent). There are differences according to specialist group and even more pronounced differences by region. Differences exist between the various Panel Doctor's Associations and more marked differences between planning districts within the region covered by each fund. The differences between the Panel Doctor's Associations are shown for the example of ophthalmologists as the group with the lowest mean provision level (123.6 percent) and surgeons as a specialist group with the highest mean provision level (170.0 percent) (Fig. 4). Despite considerable variation, none of the Panel Doctor's Associations surveyed provides health care below the 100 percent mark, let alone falling in the underprovision category (below 50 percent).

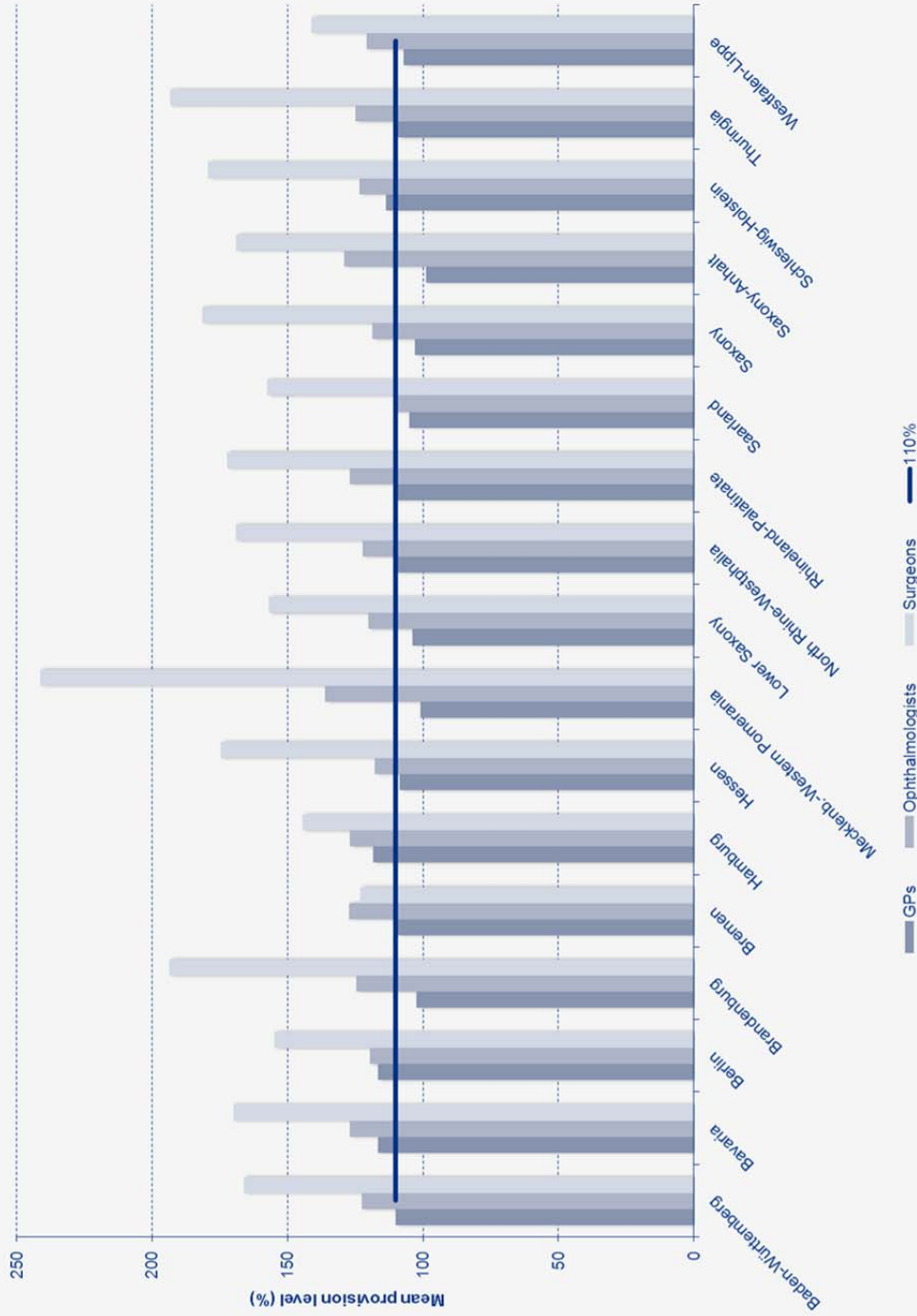


Figure 4: Average provision level (%) for GPs, ophthalmologists and surgeons, by SHI region

Source: Own survey/information request from SHI funds, as of 30 Sep. 2013

The regional differences, which more or less disappear when looking at the average degree of provision under one of the bigger Panel Doctor's Associations, stand out better looking at the number of planning districts with under and overprovision and the number of physicians above the 110 percent provision mark, because under the new needs planning system most specialist groups show a high provision level. According to the figures provided by the Panel Doctor's Associations, districts with underprovision in general medical and specialised care are found among the planning regions for ophthalmology (1 planning region nationwide), dermatology (3), ENT (1) and psychotherapy (1), and districts with a threat of underprovision in ophthalmology (3) and neurology (1). Also, more than three-quarters of all planning regions are above the 110 percent provision mark for general specialised care; this corresponds to 8,000 specialised practices in Germany as a whole. This compares with 43.9 percent above the same provision mark for general medicine, corresponding to about 2,200 practices.

Neurologists and psychiatrists are accounted for with a combined figure that given the differing intensity of psychotherapeutic care may conceal a shortage of psychiatrists. Statistics for the two professions need to be gathered separately in future. The same goes for orthopaedists and trauma surgeons. For psychotherapists, comparison between health fund regions was near-impossible due to the inclusion of different psychotherapist groups and in some cases a failure to include planning targets. Four health fund regions can be considered to have a shortage of psychotherapists as their average provision levels are below 100 percent. This is the only specialist group for which the inferred planning target relative to 100 percent provision has increased relative to the status before the new Needs Planning Directive.

A comparison of planning regions within specific health fund regions confirms a bias by specialism and region. With ENT specialists in Bavaria, for example, one district is under-served while more than two-thirds are over-served.

Specialised care

157. Specialised care is provided by anaesthetists, specialised internists, child and juvenile psychiatrists, and radiologists. The provision level among child and youth psychiatrists is below 50 percent in six Panel Doctor's Association districts. There are, however, districts with a provision level in excess of 250 percent (Hamburg, Bremen and Berlin). Among specialised internists, all planning regions have provision levels of above 110 percent, but the figures are not split down by specialism. This will become even more relevant in future as the number of internists in outpatient care who do not have a specialism within the meaning of the training regulations is set to decrease and the range of work common to all internists will continue to shrink. Excluding child and youth psychiatrists, very many planning districts have provision levels for specialised care in excess of 110 percent (more than 75 percent on average, or 90 percent of all planning

districts). Expressed in specialised practices, approximately 6,000 exceed the 110 percent provision mark.

Highly specialised care

158. This provision level includes laboratory physicians, human geneticists, neurosurgeons, nuclear medicine specialists, physicians for physical therapy and rehabilitation, radiation therapists and transfusion medicine physicians. According to needs planning, a majority of the 17 planning regions nationwide, which match the Panel Doctor's Association districts, exceed the 110 percent provision level (17 in human genetics, 15 in pathology, and 13 each in laboratory medicine, neurosurgery, radiotherapy and transfusion medicine, 11 in nuclear medicine, and six in physical therapy and rehabilitation). The number of practices above the 110 percent ceiling amounts to more than 1,200 nationwide.

6.3 Panel Doctor's Associations measures to combat under and overprovision

159. Where planning regions with under and overprovision are concerned, the Council's survey of Panel Doctor's Associations showed that funds responsible for securing outpatient services via SHI-accredited physicians have a range of options available for use in combating the situation. In 2013, a number of funds offered or paid service guarantee fees, investment grants and revenue guarantees to fend off (threatened) underprovision of general medical and specialised care. This plays only a marginal role in terms of actual figures, however. On the whole, and with the exception of Brandenburg and Saxony-Anhalt, fund-owned practices are rare, most of all in specialised care, and tend to be restricted to emergency practices (also known as on-call practices). Municipally owned practices and hospital care in the event of underprovision have not been reported to date. Branch practices run by SHI-accredited physicians exist in all Panel Doctor's Association regions, and branch practices run by medical service centres in 15. These appear to have gained in importance, possibly because they offer attractive working conditions for younger doctors.

When it comes to promoting general medical care, all SHIs have introduced measures such as the creation of a coordination office for further education and training, funding of further education and training institutes, and in some cases (five SHIs) funding of general medicine professorships or endowed professorships. Additional promotion involves student training, largely in the form of financial support for traineeships or practical terms. Two SHIs (Saxony and Saxony-Anhalt) offer stipends that obligate students to subsequent multi-year employment in an underprovided area of the SHI district once their studies are completed.

Systematic recruitment of foreign doctors for outpatient health care services plays virtually no role at all, according to the SHIs.

Measures to remedy overprovision play only a marginal role, as is shown, among other things, by the fact that in the whole of Germany, only one position has been bought up (in SHI district Nordrhein). The financial incentive for voluntary relinquishment has not resulted in a single practice being given up anywhere in the country. Solely in Bremen 11 psychological psychotherapy practices have been relinquished in this way, but no medical practices.

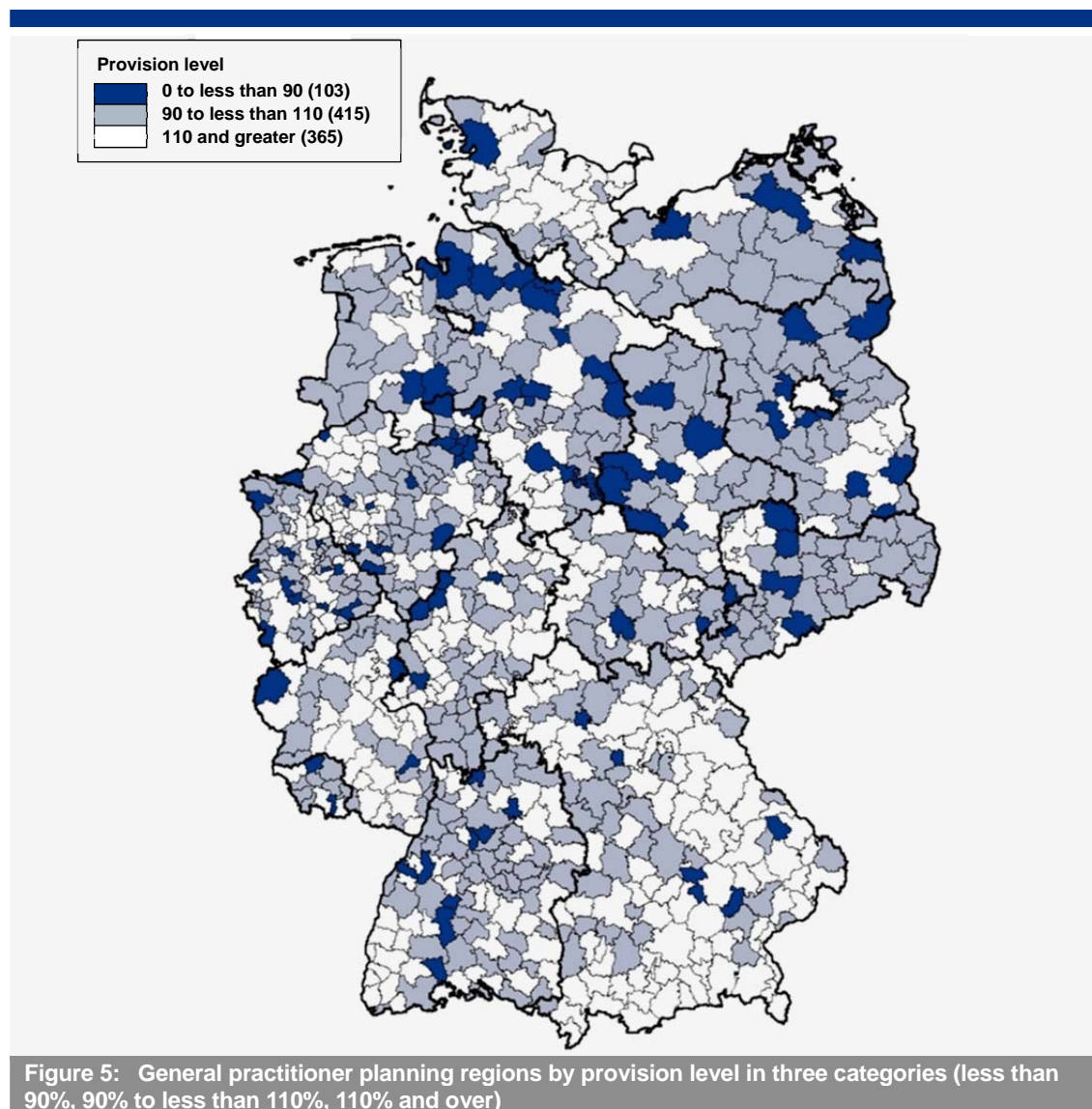
6.4 Recommendations to remedy under and overprovision

160. With a view to the uneven geographical distribution and securing nationwide health care provision, it is recommended that significantly greater incentives should be provided than has previously been the case to make medical occupations more attractive in regions merely at threat of underprovision. Specifically, a significant weighting allowance of 50 percent (country doctor allowance) is recommended for all Level I and II care (general medical and general specialised care) and for child and youth psychiatric care in underprovided regions. As an alternative to a blanket 50 percent allowance, an allowance on a sliding scale according to the level of care would also be conceivable, subject to a 50 percent ceiling. As it takes a long time to effect a shift from regions with overprovision to regions with (threatened) underprovision, the proposed provision level below which there is an entitlement to the country doctor allowance is deliberately set higher, at 90 percent for general medicine practitioners and 75 percent for general specialised care practitioners, than the Needs Planning Directive underprovision levels of 75 and 50 percent respectively (levels at which underprovision is already manifest). Figure 5 shows all general practitioner planning regions in which a country doctor allowance would have to be paid for general practitioners as of 30 June 2013. If a branch practice is involved, the allowance should be paid for the portion of care provided out of the branch practice. The recommendation provides for the allowance to be paid both to doctors who already work in an underprovided region and to those who decide to work in one for the first time. The allowances should be guaranteed for ten years and would thus provide planning security. The period should be extended if underprovision persists. If during this time a doctor opens a practice in such a region but the provision level there has since risen to 90 percent (or 75 percent, as appropriate) or more, they will not be entitled to the allowance. The recommendation also provides for the allowances to be paid at the expense of doctors in all specialist groups who do not work in underprovided planning regions, with the funds being taken, for example, from morbidity-related overall remuneration within the respective SHI. The mechanism

should kick in automatically so that the allowances constitute a legal entitlement and not an amount to be negotiated between SHI-accredited physicians and SHIs.

Similarly, the negotiating parties could agree, in selective agreements such as are defined in Sections 73b, 73c and 140a-d SGB V, an appropriate country doctor allowance (of 50 percent or on a sliding scale according to care level, see above). This would then also have to be taken into account in the adjustment of the overall remuneration amount.

For the event of specific SHIs becoming financially overburdened, a super-regional mechanism should be considered to lessen the impact on SHIs with disproportionately large numbers of underprovided planning regions or of doctors receiving allowances. The proposed model offers incentives to take up work in underprovided regions and can thus contribute to securing nationwide health care provision.



It was not possible to account for any boundary adjustments in the map. Planning regions for which a provision level was not available are assigned a level of 100%. The provision levels are calculated on the basis of regionally stipulated ratios for general practitioners.

Source: KBV compilation on basis of SHI needs planning as of 30 June 2013

Securing cross-sectoral health care provision

161. If a Panel Doctor's Association fails or is unable to meet its mandate to ensure outpatient care provision, the mandate is transferred (in whole or part – the transfer may be limited by region or specialism) to the SHIs, which then withhold the corresponding remuneration under the collective agreement. This transfer or partial transfer of the mandate to provide outpatient care occurs when the Panel Doctor's Association can provide no more than 50 percent of the required level of care in an SHI-accredited district or a planning region. Health insurance funds must provide the necessary

infrastructure themselves. Apart from the option of operating fund-owned practices, they may enter into agreements with service providers to secure health care services from SHI-accredited physicians. Remuneration of these service providers is not linked to the fee apportionment rules set out in Sections 85 (4) and 87b SGB V.

In the inpatient sector, by contrast, responsibility for securing health care provision lies with the Länder. The differing rules and regulations that apply in the two sectors make cross-sectoral regional planning difficult. In underprovided areas, it can be assumed that financial incentives will be needed to make these areas attractive for the outpatient sector. For regulatory reasons, these should, however, be funded via the taxation system. A cross-sectoral approach to resolving provision problems also speaks in favour of assigning joint responsibility for securing outpatient and inpatient provision to the Länder.

To cover demand in underprovided areas, public tenders should be used to allow flexibility as regards remuneration and investment grants. The public tender process could be managed by the joint Länder committees under Section 90a SGB V, with their powers of authority being extended accordingly.

To fund outpatient health care in areas where the mandate for provision has passed to the Health insurance funds (or to the Länder, as appropriate), funds from overall remuneration (after adjustment of the total budget), Länder-level tax revenue and funds from municipal budgets (especially for additional investment projects) could be used. To prevent ‘cream skimming’ on the part of the SHIs, meaning meeting the provision mandate in overprovided areas and strategic withdrawal from underprovided areas, the adjustment amount from the overall budget must be higher than the estimated share for the transferring areas. It is recommended that the amount be doubled and the threshold for potential transfer of the mandate be raised from the previous 50 percent to 75 percent. Additional Länder-managed funds would cover the remaining amount once the tender process is completed.

162. On experience to date, it is not enough to simply use instruments to incentivise doctors to work in planning regions threatened by underprovision. Instruments are also needed to counter existing overprovision. It must be noted that in overprovided areas especially, measures available so far have either been barely acknowledged or have failed where implemented. This is illustrated by the fact that, in the whole of Germany, the option to buy up vacant medical practice places in overprovided areas has only been exercised once.

Under the current Coalition Agreement, the government intends to modify the legal requirements to cut back overprovision through the purchase of practices, making the current optional arrangement mandatory subject to exceptions. It is recommended that where overprovision exists at a rate of 200 percent or more, the applicable stipulation

should be mandatory. Compensation is paid from the SHI revenue share in an amount matching the practice value. Table 4 provides an overview of the number of practices in excess of 200 percent that existed in Germany on 30 September 2013. One specialised group, psychotherapists, should be excepted from the mandatory rule because further research is needed here to complete the development of criteria for effective needs planning.

Planning group	Practices in excess of 200%	Practices in excess of 200% as percentage of all practices in specialist group
General practitioners	0	0%
Ophthalmologists	7	0.1%
Surgeons	171	4.4%
Gynaecologists	0	0%
Dermatologists	16	0.5%
ENT specialists	8	0.2%
Paediatricians	73	1.3%
Neurologists and psychiatrists	36	0.8%
Orthopaedists	14	0.3%
Urologists	9	0.3%
Anaesthetists	167	5.9%
Internal medicine specialists	994	12.4%
Child and youth psychiatrists	55	5.9%
Radiologists	80	3.1%
Human geneticists	13	n/a
Laboratory physicians	21	n/a
Neurosurgeons	2	n/a
Nuclear medicine specialists	4	n/a
Pathologists	13	n/a
Physical/rehab medicine specialists	25	n/a
Radiotherapists	15	n/a
Transfusion medicine specialists	16	n/a
Total	1 739	n/a

Table 4: For each planning region with over 200% provision, number of practices in excess of 200% and such practices as a percentage of all practices in each specialist group

Psychotherapists are not listed, requiring separate analysis; the computed figure is 1,144 practices (sum of psychological and medical psychotherapists)

Note: The number of practices in excess of 200% was not rounded at planning region level. The national total for each planning group is arithmetically rounded to the nearest integer.

* Where full figures available. Total numbers of practices as of 30.09.2013

Source: Panel Doctor's Association requirements planning, June 2013; KBV and own calculations

6.5 Disparities between general medical and specialised care

163. Apart from the key challenge relating to the uneven geographical distribution of health care provision, with numerous indications of overprovision in conurbations and underprovision in structurally weak regions, there are increasing deficits in the balance between medical care provided by general practitioners and that by specialist physicians. The distribution of SHI-accredited physicians across these two groups shows a strong and ongoing trend towards sub-specialisation. Relative to the base year 1993, the number of SHI-accredited specialist physicians had risen by 56.6 percent by 2012. In the same period, there was a 10 percent decline in the number of general practitioners. While the general practitioner-specialist ratio was about 60-40 in 1993, the unyielding trend will force a reverse of these figures in just a few years' time. Looking at trends in the number of doctors in German hospitals in the same period, there is clear evidence of a significant increase there, too. While the overall number of SHI-accredited physicians rose by 16.9 percent, the number of hospital doctors increased by 43.2 percent in the same period. An overview of accreditations of specialist physicians by discipline shows that in 2013, only 10 percent of all physicians who completed their training in 2013 did so in general medicine or in general medicine and internal medicine (general practice). This ongoing sub-specialisation is evident in that 90 percent (10,037) of all accreditations were in one of the other recognised (currently 82) disciplines or specialisms. As a result, only one in two general practitioners who closes their practice for age-related reasons finds a successor. According to estimates, and taking account of a range of influencing factors (such as demographically driven changes in morbidity and average weekly working hours), two 'traditional' general practitioners who close their practices must be replaced by approximately three younger counterparts. It must also be considered that given the number of internists who practice as general practitioners and employed doctors, and the (limited) potential for easing the burden placed on general practitioners through increased delegation and substitution using other health care professions, altered practice structures, telemedicine applications and reduced bureaucracy, at least twice as many general medicine specialists would have to be trained than is currently the case. If conditions remain unchanged, an estimated 20,000 general practitioners will have to be replaced by 2025.

6.6 Recommendations to improve general practitioner-provided health care

6.6.1 Greater focus on general practitioners

164. High-quality, localised medical care provided by general practitioners is indispensable in a functional health care system. General practitioner-based health care provision and coordination calls for increased use of general practitioners in the first instance rather than the uncoordinated use of doctors and institutions in the secondary and tertiary health care sectors. Given the internationally comparably high frequency in the use of specialist physicians who run their own practices and the comparatively very low co-payments paid by insured persons or patients in Germany, an assessment should be conducted into whether both management and improvement of general practitioner-centred health care via patient co-payment models makes sense and is practicable. One possibility would be a sliding-scale patient co-payment system, on the Scandinavian model, in the amount of the average additional costs (e.g. incremental charge of approximately 10 percent based on the EBM and ranging between €10 and €50; or alternatively a fixed amount) where direct use is made of the next highest care level, meaning treatment by a specialist physician or hospital outpatient department without the patient having been referred. The rules could be implemented to allow free access (without patient charges) to general practitioners, ophthalmologists and gynaecologists, and also in the case of emergencies and the treatment of minors. Instead of the effort-intensive and much criticised cash payments in practices (such as consultation fees), a cashless direct debit could be used via health insurance funds. An alternative might be a sliding-scale patient charge for pharmaceuticals (with the abolition of the currently very frequent exemptions) that would only be payable if the patient had not been referred by a coordinating general practitioner.

6.6.2 Improving general medical care

165. Causes for the fact that too few specialists are accredited in general medicine and for the associated underprovision with general practitioners can be identified in three main areas:

1. **Training:** A lack of presence, importance and attractiveness of general medicine in medical studies – especially in the practical year and during the subsequent state examinations.
2. **Further education and training:** The tedious and repeated switching of roles required by special further qualification requirements for doctors in further education and

training, in some regions together with highly unreliable financial support – especially concerning work in further training practices. A lack of specialist supervision and quality, and a lack of moral support or a ‘home’ for doctors in further education and training.

3. Working as a general practitioner: What are seen as the unattractive conditions that go with running or working in a medical practice in rural areas, especially for practitioners not working in a team, fear of becoming overburdened given the broad range of duties and the generally lower remuneration paid to general practitioners compared with specialist physicians.

166. With regard to training (medical studies), the following measures are recommended:

1. Greater focus on general medicine in medical studies, notably by introducing a mandatory three months in academic training practices for general medicine in the practical year (see Special Report 2009, at 718).
2. Funding of training in the mandatory phases concerning general medicine by assuming the remuneration provided for under medical licensing regulations for students in the practical year and compensation payments for academic training practices in which this training takes place.
3. A review of the acceptance criteria for applications to study medicine with the aim of recruiting more students who are willing, on completion of their studies, to enter into further training or work in the general practitioner field or in structurally weak rural areas. Because there are indications that students accepted purely on the basis of school leaving examination results are usually less willing to work as general practitioners than those accepted directly by universities (see Special Report 2009, at 686), a targeted selection process could be useful, as could recruitment of students who predominantly grew up in rural areas (see Special Report 2009, at 688f.). It would also be useful to assess the extent to which a work placement in health care institutions and practices to provide an insight into the profession prior to commencing medical studies would have the desired steering effect. The main aim would be to provide an opportunity for exposure to the practical side of working as a doctor before commencing medical studies. The current nursing placement could be reduced to six weeks and a further six weeks replaced by an optionally medical care-focused placement which must be arranged and secured before medical studies commence.
4. As in the past, it is recommended once again that independent professorships, institutes or departments for general medicine be introduced at all universities that offer medical studies.

5. The National Competence-based Learning Objectives for Undergraduate Medical Education should expressly include medical work in the general practitioner or primary medical care sector as a training objective.
6. To support the medical faculties which, in the course of medical training, are able to boost students' motivation to enter into further training in general medicine or to work as general practitioners at a later date, the existing criteria for allocation of Länder-managed funds for teaching should be revised. The existing practice of allocation to universities is largely based on the number of students who graduate after the standard period of study together with the results of state examinations. Because the best predictor of timely, successful completion of a course of academic study is the student's school leaving examination results, the faculties are also exposed to this strong financial incentive in the university entrance process. Funds used to finance universities could in future be linked to the extent to which the medical faculties visibly and sustainably promote the study of general medicine. They could, for example, use targeted recruitment strategies, enhanced status of general medicine in the curriculum, mentoring of students interested in the discipline, voluntary country doctor tracks, and so on. Independent of this process, long-term retention studies are needed which would supply valuable knowledge for future education and needs planning.

167. Further education and training of future specialists in general medicine should be promoted using the following measures:

1. Guaranteeing a seamless transition between study of and further training in general medicine by establishing and promoting university-linked centres of excellence for general medicine similar to those already operated in Baden-Württemberg and Hesse. These should also provide regional further education and training colleges with structured parallel seminars, individual or group mentoring programmes, train the trainer courses to provide qualified instructors, and ongoing evaluation and quality assurance processes.
2. Securing a reliable personal budget for each young doctor who enters further training to qualify as a specialist physician in general medicine for the entire 60 full-time months of the further training period and guaranteed and transferable if they move to another location.
3. Regional further training partnerships between hospitals and medical practices based on predetermined structural requirements to provide attractive, structured, seamless, ongoing and reliable rotation between the training phases involved in the study of general medicine.

4. An increase in funding (for practices) to match hospital collective agreement levels and thus secure similar rates of remuneration, including in outpatient care, to prevent the current frequently poorer conditions seen for doctors in the inpractice phase of post-graduate medical training.
5. An increase in the practice budget when recruiting a doctor into further training in an amount relative to the share of effort and expense incurred in their supervision and support.

To promote and improve both the quality and attractiveness of initial and further education and training, concerted and targeted use of funding is needed. Given the deficits already outlined, the establishment of a strictly purpose-focused foundation for initial and further medical education and training is recommended. The foundation should provide targeted support in the outlined activities and coordinate these in a national or cross-Länder approach. Its mandate could also include promotion of model projects to secure the availability of qualified doctors, particularly in structurally weak regions and in rural areas, along with specialist exchange between regional coordination offices and centres of excellence. For regulatory policy reasons, the foundation should be funded from tax revenue. However, funding could also be secured in a sustainable way by amending the rules on promotion of further education and training in general medicine (Article 8 of the SHI Solidarity Enhancement Act/GKV-SolG) to include a system surcharge (similar to the rules on funding the Federal Joint Committee or the Evaluation Committee).

168. With a view to the practical side of working as a general practitioner and securing high-quality, nationwide basic medical care, the Council recommends providing greater incentives by means of the ‘country doctor allowance’ model and the obligatory purchase of practices in substantially overprovided planning regions in order to promote working as a general practitioner in areas at risk of underprovision. This can be supported by further activities, some of which are described in detail in the Special Reports 2009 and 2012, and are only briefly outlined here. These include: 1) Measures enabling doctors to focus on their core competencies; 2) measures to counter the declining numbers of active doctors or to reduce their workload, 3) improved remuneration for general practitioners, and 4) reduction of overprovision and misprovision.

With regard to 1) above, this includes the delegation of services currently performed by doctors or a re-division of responsibilities within a team. One problem, however, is the lack of qualified individuals – both here and in other health care professions. Lessening of the workload regarding documentation and administrative duties by transferring these to administrative personnel and utilising online information systems are also part of this approach.

In terms of 2), the most important factor is the improvement of work-life balance to aid retention or re-entry of doctors in the medical profession. Also, given the increasing number of women doctors and prevailing gender-specific roles and responsibilities, measures are needed to provide flexible childcare services close to the workplace, back-to-work programmes following a period of childrearing or caring for a dependant, and most importantly, new models allowing flexible working hours and the opportunity to perform administrative work from home. More part-time jobs, less burdensome organisation of emergency and stand-in duties, and dual career models which allow work opportunities for the physician's partner are also an option. The aim of all these measures is to increase the working life of available physicians.

As regards 3), improved remuneration for general practitioners and other advice-intensive, patient-focused services is needed (see Special Report 2009, at 728) as called for by the Health Ministers Conference (GMK). Given that general practitioners currently earn a third less than the average income of several other specialist physician groups despite a longer working week, incentives are needed in the form of significantly better remuneration to compensate for these disadvantages, especially for doctors working in structurally weak regions.

On 4), the changes to health care structures involve better integrating inpatient and outpatient treatment, eliminating duplicate structures, reducing hospital beds in over-provided areas and most of all reducing regional imbalances and the uneven distribution of specialists. One of the most urgent problems here is the lack of general practitioners in rural and structurally weak areas. In recent years, measures and programmes have been developed, and changes enacted in the SHI Health Care Provision Act to combat this trend (exemption of services from the volume limit in structurally weak areas, allowances for services, establishment of structural funds by the SHIs, abolition of the residency obligation, support for mobile provision, etc.). In particular, cross-sectoral, population-related, multi-professional organisation and cooperation models are needed. Using selected examples and providing appropriate recommendations, Chapters 9 and 10 look at the related national and international approaches for regionally integrated health care in rural areas as well as the concept of local health centres (LHCs) for primary and long-term care.

7 Acute Inpatient Care

7.1 Regional disparities in acute inpatient care

169. On an international comparison, Germany is very well provided with inpatient care. This remains the case despite a substantial, nearly 25 percent decrease in the number of beds since 1991. Hospital staff numbers went down by some four percent between 1991 and 2012, although within this figure the numbers of physicians increased by just over 50 percent and the numbers of non-physicians (notably nursing staff) decreased by just under 11 percent.

170. While there is a relatively high level of provision across the country in Germany, there is also some regional variation. The number of beds per 100,000 population varied among the German Länder from 538 to 788 in 2012. The key factor in ensuring nationwide provision for the population, however, is not the number of beds available but most of all the accessibility of general hospitals. Specifically, hospital density (in terms of average size of catchment area per hospital) is relatively low and thus may present challenges as regards ubiquitous coverage in Mecklenburg-Western Pomerania, Brandenburg, Saxony-Anhalt and Thuringia; hospital density is above-average in North Rhine-Westphalia, Hesse, Saarland and, as would be expected, in the city states (Berlin, Bremen and Hamburg).

171. Hospital densities (in this instance in terms of the size of population served by each general hospital) are plotted against population densities in Figure 6. Three large states – Brandenburg, Lower Saxony and Schleswig-Holstein – benefit from shared provision with the three city states and are therefore each shown additionally in the chart in combination with the respective city state. Such shared provision is non-negligible in volume, but at the same time not all inhabitants of the peripheral regions in the larger states are able to make use of it, hence the true situation with regard to health care provision in these three states will most likely be somewhere along the connecting line between the separate and the combined data points.

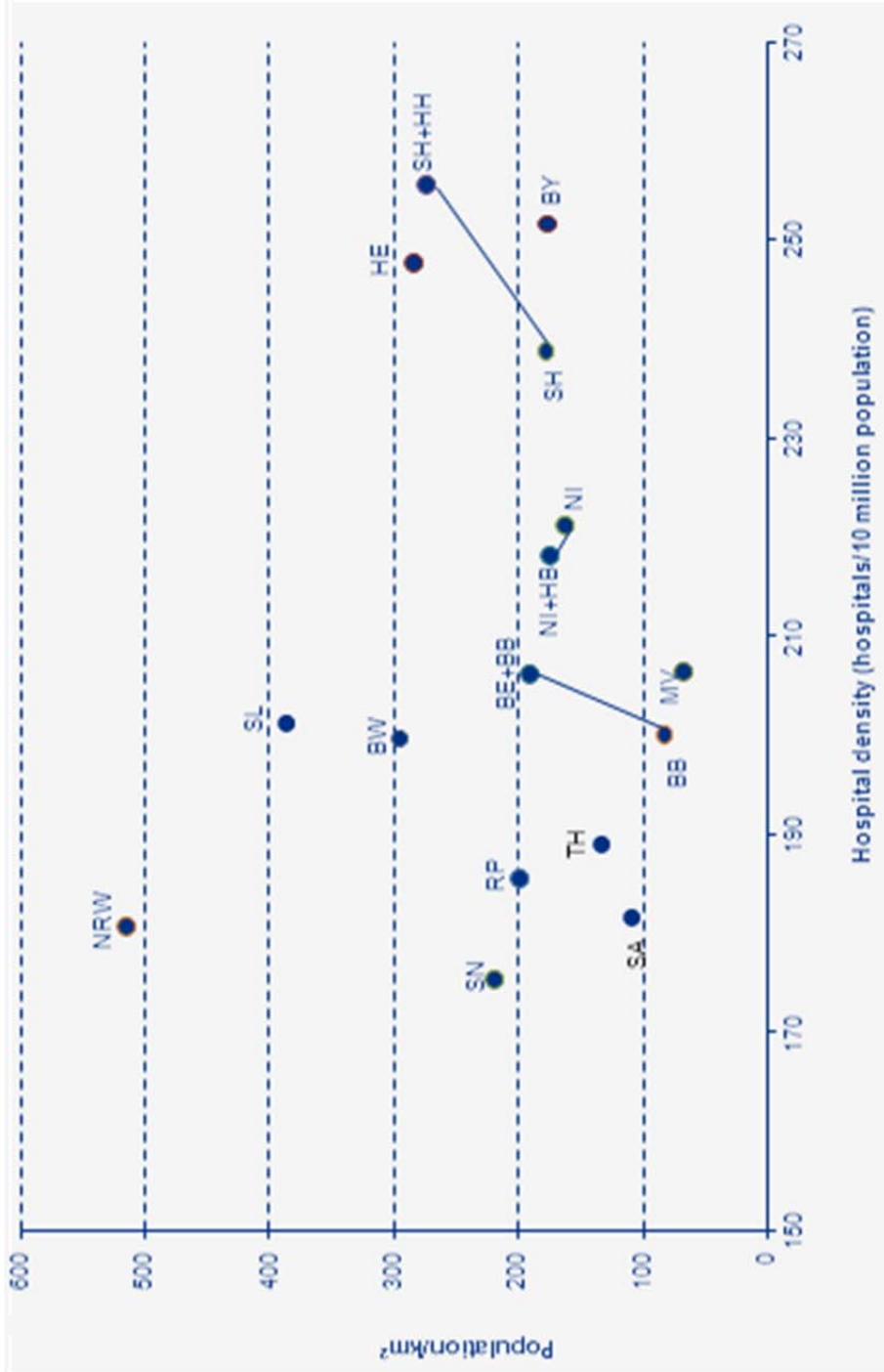


Figure 6: Hospital density and population density 2012

Note: General hospitals only, including university hospitals. Key: BB Brandenburg; BE Berlin; BW Baden-Württemberg; BY Bavaria; HB Bremen; HE Hesse; HH Hamburg; MV Mecklenburg-Western Pomerania; NI Lower Saxony; NRW North Rhine-Westphalia; RP Rhineland-Palatinate; SA Saxony-Anhalt; SH Schleswig-Holstein; SL Saarland; SN Saxony; TH Thuringia.

Source: Own compilation after Augurzky et al. 2013a; Federal Statistical Office

172. An assessment of the local provision situation calls for smaller-scale and ultimately also cross-sectoral analysis, because capacity availability can be subject to variation within individual Länder and notably between rural and urban areas. The data nonetheless gives an initial impression of the hospital landscape in each of the sixteen Länder. To an extent, cutting capacity in overprovided urban areas could free up resources for less well-provided regions – including within individual Länder – and thus promote needs-based hospital care provision.

173. Germany is also among the frontrunners internationally with regard to the use of hospital services, as OECD statistics regularly show. While the number of hospitals and the number of beds have fallen in recent years, the number of inpatient cases has increased significantly nationwide. But because there has been a similarly sharp decrease in the length of stay, the number of days' care has fallen so steeply that average capacity utilisation has gone down.

174. As with inpatient hospital provision, the use of hospital care is likewise subject to regional variation. Figure 7 shows the number of cases per 100 inhabitants at administrative district level.

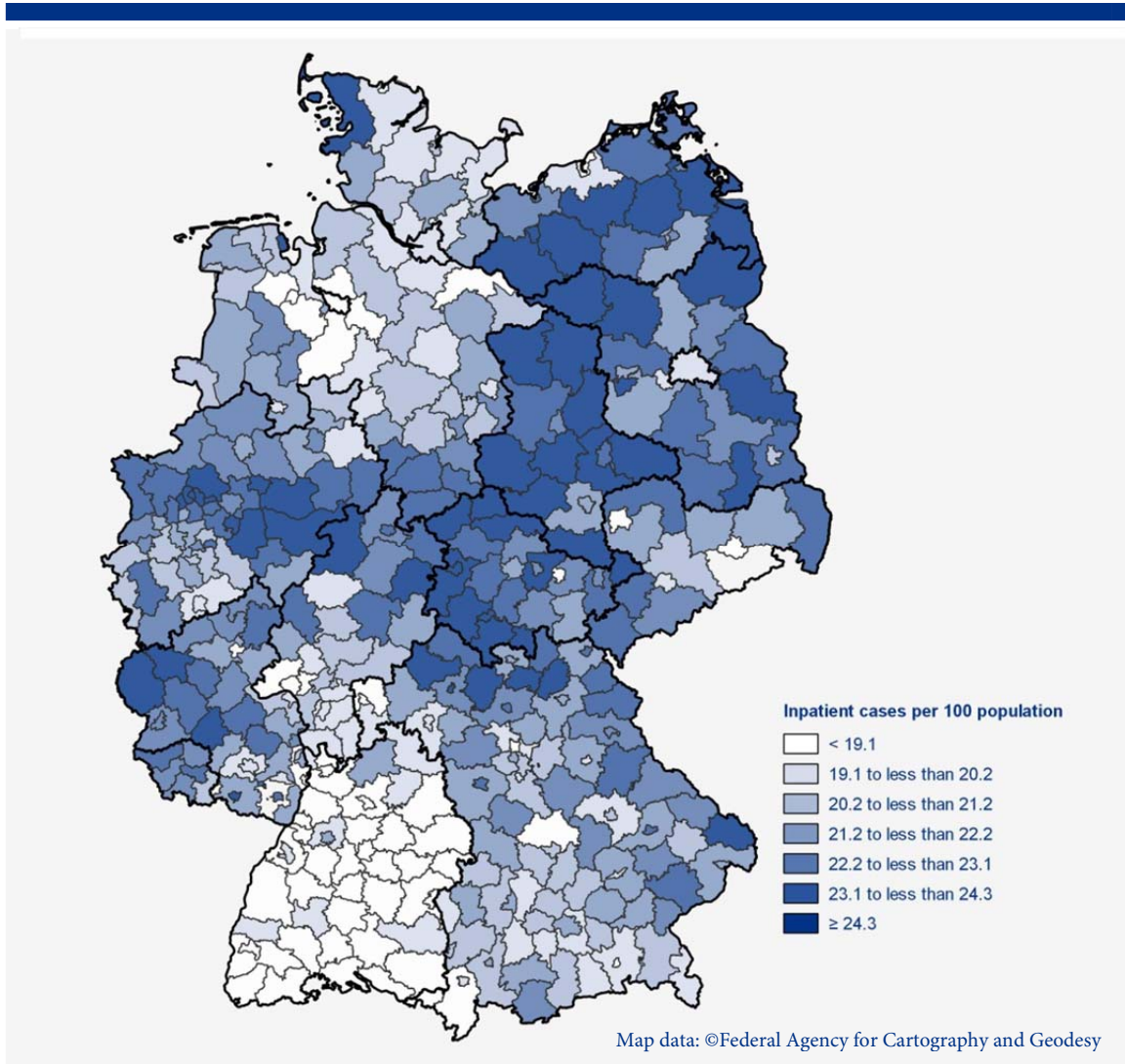


Figure 7: Age and gender-adjusted number of inpatient cases per 100 population, 2010

Adjusted for patient age and gender; cases by place of domicile

Source: Augurzky et al. 2013a

The fact that this is age and gender-adjusted data obstructs the task of explaining the regional variation. This may involve demand-side factors such as further – not entirely age and gender-driven – variations in morbidity and supply-side factors possibly related to incentive structure or differing structure of provision. A number of relevant studies are referred to in the unabridged version of this Report.

175. With regard to any shakeout of the kind often described as desirable in the hospital sector, it is necessary to consider not just current demand and utilisation, but most of all future needs. As population age and gender structure is a major determinant of variation in the numbers of inpatient cases, population forecasts can be combined with current age and gender-specific diagnosis rates to predict the trend in this regard.

Table 5 shows the expected numbers of hospital cases in each of the Länder in total and for two major diagnosis groups.

Länder	Total			Cardiovascular disease			Neoplasms		
	2008	2030	Change 2030 vs. 2008	2008	2030	Change 2030 vs. 2008	2008	2030	Change 2030 vs. 2008
	1 000	1 000	%	1 000	1 000	%	1 000	1 000	%
Baden-Württemberg	1 985	2 251	13.4	285	381	33.9	204	251	23.2
Bavaria	2 693	3 070	14.0	381	505	32.8	267	330	23.5
Berlin	666	761	14.1	103	142	37.9	73	88	20.6
Brandenburg	613	672	9.7	99	133	34.1	70	87	23.4
Bremen	138	143	3.7	18	21	16.1	15	16	8.9
Hamburg	337	382	13.5	45	57	28.4	34	43	26.3
Hessen	1 286	1 410	9.7	188	241	28.3	133	157	18.3
Mecklenburg-Western Pomerania	401	410	2.3	63	82	29.6	44	49	10.3
Lower Saxony	1 684	1 794	6.6	249	307	23.3	161	184	14.5
North Rhine-Westphalia	4 159	4 408	6.0	633	771	21.8	427	486	13.9
Rhineland-Palatinate	935	1 005	7.5	142	175	23.8	96	111	16.1
Saarland	252	253	0.3	42	48	15.0	27	29	8.5
Saxony	951	938	- 1.3	143	168	18.0	113	118	4.8
Saxony-Anhalt	608	564	- 7.3	98	109	11.4	67	68	1.1
Schleswig-Holstein	599	648	8.3	88	112	27.4	60	69	15.5
Thuringia	564	549	- 2.6	93	110	18.8	63	67	6.6
Germany	17 869	19 291	8.0	2 667	3 368	26.2	1 853	2 160	16.6

Table 5: Hospital cases 2008 and 2030, by Länder and in two diagnosis groups (status quo scenario)

Source: Federal Statistical Office, Länder statistical offices, Demographic Change in Germany 2010

Despite a fall in population, the number of hospital cases will go on rising in most of the Länder, with disproportionately large increases in relation to specific indications. In rural areas especially, demographic change and the rising morbidity burden evident from the table pose major challenges for hospital planning and financing. These challenges must partly be addressed by means of action within the hospitals sector, in the long-term however cross-sectoral measures will be needed.

7.2 Hospital planning and investment financing

7.2.1 Planning inpatient care capacity

176. Responsibility for ensuring ubiquitous hospital coverage lies with the Länder under Section 6(1) and (4) read in conjunction with Section 1(1) of the Hospitals Financing Act (KHG). The Länder meet this responsibility primarily by drawing up hospital plans. Alongside this (superordinate) responsibility on the part of the Länder, the Länder themselves each have hospitals legislation under which ensuring universal hospital coverage is a municipal responsibility. In other words, municipalities must run municipal hospitals where sufficient provision with hospitals is not ensured by other providers.

The introduction of DRGs and the abandonment of the cost coverage principle from 2003 pitted state capacity planning into conflict with the more competition-based financing system. In parallel, the Länder delivered less and less on their responsibility to match their hospital planning with investment funding, as a result of which not merely the effectiveness, but also the legitimacy of hospital planning has been repeatedly questioned in recent years. For political and also legal reasons, the Länder had little real scope in the past to intervene, at least with a view to scaling back surplus capacity. While the number of beds has been significantly reduced in recent years and in some cases hospital departments have been closed or transferred by merger or cooperation with other hospitals, there have been far fewer actual location closures than the hospitals statistics would suggest.

177. As other health care sectors such as outpatient medical care show signs of impending coverage shortfalls in some regions (though massive surplus capacity persists elsewhere), concerns regarding ubiquitous coverage are increasingly entering the public mind. This also explains the governing coalition's plans to evolve hospital planning from location-based to accessibility-based health care provision planning. As the very word 'provision planning' here implies, the aim is to ensure sufficient provision not so much in terms of traditional hospitals as in terms of needs-based basic and emergency inpatient care. Currently, however, hospital accessibility can still be considered good or in international terms even very good. Accessibility criteria can nonetheless be useful in judging whether a regional coverage crisis could occur. It would also be desirable for such criteria to be applied not merely as denoting a minimum level of accessibility, but as indicators of excessively high hospital density and hence of a need to eliminate surplus capacity. It remains to be noted that the dominant problem in the hospitals sector to date is regional overcapacity rather than any impending undercoverage. In Germany's rural regions, on the other hand, which already tend to be less well provided

with inpatient capacity, the challenge is to keep the existing, sufficient capacity economically viable.

178. While real location closures would be desirable, especially in regions with excess provision, the importance of combined structures emerging as a result of mergers should not be underrated. When hospitals are amalgamated into a single economic unit, it is usually possible to tap into efficiency reserves, and the funding provider has a strong incentive to shed uneconomic capacity within the combined entity over the medium term. Mergers and amalgamations face opposition from various quarters, however, arguing that they lead to excessive concentration and hence to hospital providers gaining too much market power. Merger regulation lies with the Bundeskartellamt, which has blocked numerous mergers in the past. For the rural regions under consideration here, however, with their sparse populations and hence low demand for inpatient care, a high level of market concentration is the natural state of affairs, possibly even with a single hospital holding a market monopoly. A regional situation of this kind is not something that can be altered. Abuse of dominant market power in terms of price is prevented by the DRG system (which still gives strong price guidance even if partially modified in rural regions for the purposes of ensuring provision). Abuse in the form of poor quality is countered by (notably structural) requirements, although these require further development. State mergers regulation should give greater account to this aspect with a view to ensuring provision in rural regions.

7.2.2 Investment financing

179. Inclusion in a hospitals plan as drawn up by each of the Länder entitles a hospital to remuneration of its health care services on the basis of performance-based rates (under its mandate to provide care) and to public investment funding. For this purpose, the Länder allocate grant funding on a lump-sum basis and in some cases for individual investment projects. The investment appraisal ratios computed by InEK now provide the Länder with a tool with which they can calculate investment grants on a performance-driven lump-sum basis by applying an investment price. It is to be expected that more and more of the Länder will allocate investment funding on a lump-sum basis by this or by other means.

180. Changing the way in which funding is allocated does nothing, however, to alter the insufficient level of funding provided by the Länder in recent years. Statutory limits on new borrowing are likely to further compound this situation in future. The same applies, albeit with a time lag, for the structural condition of hospitals in eastern Germany, which for the time being is relatively favourable as a result of the hospitals investment programme for the region under the 1992 Health Care Structure Act (GSG).

181. Investment funding can in principle be allocated not only for adding to and maintaining acute inpatient capacity but also, on application, for facilitating the closure of hospitals or for conversion (including of individual departments) to other uses (Section 9 (2) 5 and 6 KHG). A fund of the kind initially considered in coalition negotiations would have provided one way of promoting the necessary market shakeout, although the aim of turning surplus capacity into nursing care facilities can likewise result in misallocation. Preference should be given to transitional payments so that hospital operators can withdraw from areas of activity in which they do not expect for the foreseeable future to attain the required contribution margins or quality levels. This could prevent the medically unjustified quantitative expansion that would otherwise take place to make up for narrow contribution margins.

182. Given the Länder withdrawal from investment financing, it is more urgent than ever to go over to a unitary funding basis where investment, too, is refinanced out of the fee system. The Council – like the German Council of Economic Experts – has recommended unitary funding across the board on several occasions in the past.

7.3 Financing of hospital care in rural regions

7.3.1 Financing arrangements

183. Under the Hospitals Financing Act (KHG) and Hospitals Remuneration Act (KHEntgG), hospital operating costs are mostly funded through fees per case. These are uniform within any one of the Länder but can vary between Länder because of differing Länder-specific per-case base rates (Landesbasisfallwerte/LBFW). The aim in a first convergence phase (2005 to 2009) was for hospital-specific per-case base rates to be brought into line with Länder rates. In the current, second convergence phase (beginning 2010), the Länder base rates are gradually converging within a set corridor around a dynamic national per-case base rate (Bundesbasisfallert/BBFW). The Länder base rates are negotiated with self-governing bodies for inpatient care at Länder level subject to a maximum percentage change agreed at national level.

Commencing in 2010, any Länder base rates thus negotiated that are not already within the corridor are gradually being brought closer to the corridor boundaries. The Länder base rates may no longer be lower than the bottom limit of the corridor for the first time in 2014. Accordingly, the Länder-specific per-case base rates of nine Länder are equal to the corridor floor of €3,117.36 in 2014. In some cases this marks a sharp rise on the rates a year earlier. Six Länder have base rates within the corridor, while that of Rhineland-Palatinate is 105.3 percent of the federal per-case base rate and hence above the maximum of €3,235.74 (102.5 percent). In 2014, any higher Länder-specific base rate

is in principle capped at the maximum, although the cap cannot exceed 0.3% of the Länder rate concerned. The convergence phase is thus prolonged accordingly. After that, any further convergence of the Länder-specific base rates as agreed in the government coalition agreement, and for which the Federal-Länder working group on hospitals reform is to consult on implementation, would require a new statutory basis.

184. A 2013 report commissioned by the Federal Ministry of Health went into the reasons for the gradually narrowing but still large spread between Länder-specific per-case base rates. It emerged that while about one-third of the discrepancy was explained by cost differences and variation in investment funding by the Länder, the roughly two-thirds remaining could only be accounted for by other determinants relating to the 'historical' progression from hospital budgets on a cost basis to Länder-specific per-case base rates under the DRG system. The influence of variation in Länder investment funding may be taken as an indication that the dual financing system has effectively already been replaced by unitary financing by the back door, with health payers making up for the missing Länder funding with higher Länder-specific per-case base rates without any basis in law.

7.3.2 Service guarantee fees

185. Service guarantee fees are a feature of the hospital financing system provided to make allowance for the special circumstances of rural hospitals. They are agreed between health insurance funds and hospitals. The precondition for their use is that a hospital or hospital department must be unable to cover its costs due to low demand, but the service in question is necessary to public health provision and no other suitable hospital that already offers the same type of service is able to deliver that service without an additional monetary incentive. If the health insurance funds and hospitals fail to reach agreement, the Länder-level authority responsible for hospital planning decides.

186. Service guarantee fees were first agreed for hospitals on Baltic Sea and North Sea islands in Schleswig-Holstein in view of their specific problems in terms of structure and health care provision. Applications from further hospitals – including some on the mainland – were ruled on in some cases by the courts, which in decisions handed down so far have interpreted the relevant statutory provisions as relating to the financial situation not of the hospital as a whole, but of the specific departments that deliver the service whose costs are not covered by the DRG revenues. The case law so far also suggests that inclusion in a Länder-level hospitals plan is not in itself proof of essential service on the part of the hospital concerned such that a service guarantee incentive is justified. Instead, applications for service guarantee fees are subject to the (stricter) criterion that no other suitable hospital be able to provide the service unsubsidised.

187. In principle, service guarantee fees are a suitable means of furnishing rural hospitals identified as providing an essential service with financial support so that they can deliver that service without incurring deficits. The course of negotiations on service guarantee incentive applications to date and the need for resolution through the courts nonetheless show that the current legal situation leaves too much interpretive leeway. To better align the system around its objectives, the Coalition Agreement of 27 November 2013 sets forth that the scope for agreeing service guarantee fees is to be clarified in law with criteria to be laid down by the Federal Joint Committee.

Besides laying down the specialisms essential to nationwide basic provision, it is also necessary to stipulate minimum accessibility criteria, preferentially based more on travel times than distances. These criteria would then be applied to limit the numbers of hospitals and specialist departments that may qualify for service guarantee fees. Once a specialist department has been identified as providing an essential service according to the criteria, it is then necessary to determine whether the department is entitled to a service guarantee incentive based on a disparity between costs (including contingency costs) and revenue (because of operating below capacity). This requires a standard for department-level contribution costing based on the DRG calculation system and to be drawn up by InEK. Higher budgeted amounts for staff costs may also have to be included to account for the increased difficulty of recruiting.

As to whether the funding for service guarantee fees should come at the expense of Länder-specific per-case base rates or from additional resources, a solution using tax revenue outside of the base rates is recommended.

7.3.3 State aid

188. European competition law and its rules on state aid (Article 106 ff. TFEU) can pose problems when public providers absorb the losses of their hospitals, or provide them with additional capital, grants or other economic benefits. Unless a private-sector operator would have done the same acting on a commercial basis, this may constitute illegal state aid.

While the problem is not fundamentally new, implementation of the exemption for 'services of general economic interest' (SGEI) – which is of central importance for the hospitals sector – has so far proved difficult in practice (see, for example, the action brought against the public funds provided by the district of Calw to its municipal hospitals enterprise, Kreiskliniken Calw GmbH).

189. The survival of small rural hospitals is under threat if service guarantee fees are not enough to make up for the funding problems caused by operating below capacity. Consideration must also be given to the fact that municipalities must meet a subsidiary

service guarantee and are not allowed simply to give up on a hospital if an alternative funding provider cannot be found. Care must therefore be taken to avoid subsidising areas that run a deficit due to mismanagement and distorting local competition with hospitals not under public management. Municipalities must nonetheless be enabled to meet the service guarantee with reasonable effort and expense. This is also important in connection with the proposal to develop hospitals into local health centres (see below, section 7.7), which could need public funding especially in the development phase.

190. There would be no need even for legal state aid if service guarantee fees worked perfectly, although deficits not related to the provision of essential services would justify neither state aid nor service guarantee fees. Because service guarantee fees and public grants are financed through different sources, however, very different incentive mechanisms result. It also needs to be considered that only municipalities with relatively strong financial resources can afford to grant aid to their hospitals, hence state aid cannot serve as a universal way for municipalities to take a financial share in providing a regionally differentiated range of (inpatient) treatment capacity. Service guarantee fees are likely to be or become the primary instrument, and sufficient investment funding would also help remove the need for municipalities to absorb deficits.

7.4 Quality aspects in hospital planning and financing

191. A major weakness of hospital planning today and also a reason why there has not yet been a shakeout is the lack of consideration given to quality issues. With a view to rural provision, quality has to be looked at from the perspective of securing high-quality basic provision while channelling highly specialised services (spinal fusion, elective endoprosthetic implants, atrial ablation, transcatheter aortic valve replacement, etc.) to institutions better suited to them and with corresponding infrastructure. In parallel, on the basis of regional or even trans-regional coordination, it would be both thinkable and desirable for a basic or standard provision hospital, too, to feature more specialised care in specific disciplines, although only to the extent that sufficient volume can be reached by means of patient pooling to ensure the medical expertise, routine and necessary backup care needed to guarantee high-quality treatment.

A twin-track approach appears promising here. First, basic provision must be adequately funded. Service guarantee fees – implemented in binding form – present themselves for this purpose. In parallel, structural quality requirements need to be specified if more specialised care is to be provided.

The aim is to achieve this using minimum quantities; introduced primarily out of quality considerations, and subsequently a subject of heated controversy and judicial challenge, according to the coalition agreement these are now to be established securely

under the law. This appears unlikely to be attainable in the short term, however. Ensuring quality focus in further provision planning in both inpatient and outpatient care calls for a research programme. In particular, specific requirements in terms of structural quality would be useful.

192. In the medium term, the new Institute for Quality Assurance and Transparency in the Healthcare System soon to be established under Section 137a of Book V of the Social Code could contribute to resolving these issues. It is not possible to derive valid quality data from routine data for all health care services, however. For very small service provision areas catering to only a few patients a year, comparative quality measurement is impossible in any case for statistical reasons. This further limits the relevance of outcome quality measurement for rural hospitals. Structural quality will therefore continue to play an important part.

193. Another fundamentally promising idea is the scope provided in the coalition agreement for entering into model quality contracts with specific hospitals on a trial basis. Agreeing not just incentives (bonuses) for target attainment but also disincentives (penalties) for below-average performance would make economic sense but would be statistically, ethically and possibly also legally questionable, because service of less than a certain minimum quality should not be provided in the first place.

7.5 Securing professional staff in rural hospitals

194. Good health care personnel are essential to needs-based patient care. However, a skills shortage involving both physicians and non-physicians makes it difficult to fill vacancies in inpatient care. In 2013, this affected 58 percent of German hospitals and an average of three percent of physicians' appointments. An increase in the proportion of part-time physicians means there is no inherent contradiction in the number of hospital-employed physicians going up despite a shortage of physicians. Comparing different types of regions, that shortage is less pronounced in conurbations.

In 2013, two-thirds of hospitals used fee-based physicians, with an average of 2.4 full-time positions (2.2% of positions) occupied in this way. 28 percent of hospitals made use of the possibility of employing practice-based SHI-accredited physicians on a limited-term basis. The use of fee-based and SHI-accredited physicians enabled hospitals to reduce the shortfall in the number of physicians from a notional 4,500 to approximately 2,000. Appointing practice-based SHI-accredited physicians can be one means of linking together the outpatient and inpatient sector (as can the external hospital physicians system, though this has been in decline for many years due to unfavourable remuneration incentives). The fee-based physicians system can be useful for covering

demand peaks but is not suitable for use as a fundamental, designed-in component of inpatient care provision.

195. The hospitals sector in particular benefits significantly from the influx of foreign physicians. The verification of medical qualifications was made subject to uniform national criteria in 2014. Language proficiency is also important to the quality of patient care. Assessing this is the responsibility of Länder authorities, although no proof of language proficiency is required for EU countries of origin. A process is currently underway towards more uniform framework. In the interests of patient welfare and interdisciplinary cooperation, demonstration of adequate knowledge of everyday and medical German should be required.

196. Problems in filling vacancies for non-physicians have also been widespread in recent years; in regular nursing, this affected 34 percent of hospitals and on average three percent of positions in 2013. The difficulties in recruiting qualified nursing staff reflect a general skills shortage in nursing. Ideas to resolve this include making the profession more attractive by improving qualification levels. A recent proposal to improve the attractiveness of nursing training aimed at abolishing course fees nationwide.

197. Immigrant labour also plays a part in meeting demand for nursing staff in German hospitals, though national data is not yet available as it is for foreign doctors. The number of applications for acceptance of foreign professional qualifications in the various Länder, which can serve as a proxy, has increased significantly in recent years. Recognition of professional qualifications is the responsibility of the Länder. In many cases there is a skills gap: The hospitals sector in particular tends to recruit foreign nurses with degree qualifications (in their countries of origin), as the academisation of nursing education is at a substantially more advanced stage in some other health care systems. However, such qualifications are not generally recognised in Germany. Language proficiency requirements vary across the Länder. As with physicians, occupation-specific requirements as to language proficiency are to be recommended here.

7.6 Emergency care in rural regions

198. Emergency care is divided into three sectors in Germany: on-call service by practice-based SHI-accredited physicians, rescue services, which come under Länder law, and hospital accident and emergency units. The aim of the on-call service organised by the regional associations of SHI-accredited physicians is to guarantee provision by SHI-accredited physicians outside of regular surgery hours. The focus of the rescue services, including the ambulance service, is on life-saving first aid, action to prevent severe harm to health, and ambulance transportation to hospitals. Accident and emergency units take in and provide care both for ambulance patients and for patients

arriving by their own means. On-call work outside regular service hours is an increasing, if not perceived as the leading, source of occupational stress for hospital and practice physicians.

199. Large regional variation in the availability of SHI-accredited physicians, and most of all general practitioners, creates a problem in terms of uneven distribution of on-call service by SHI-accredited physicians. The burden of frequent on-call service is a major obstacle to setting up practice in rural areas, creating a vicious circle that compounds the shortage of provision in such areas. Almost all Panel Doctor's Associations have now carried out geographical restructuring, among other things to reduce the number of times a year each physician has to provide on-call service. Some Panel Doctor's Associations have developed models to improve remuneration, for example with higher fees for emergency cases or revenue guarantees for emergency practices. To reduce the burden on on-call physicians, several Panel Doctor's Associations have set up external transportation services, in some cases qualified to provide rescue service. A majority (nine) of Panel Doctor's Associations have set up or plan to set up centralised emergency/on-call practices or are expanding provision of this kind. Calling on practitioners from other, non-primary care disciplines such as pathologists, laboratory physicians, radiologists, and medically qualified psychotherapists to take part in on-call service does not appear an option for guaranteeing provision of the required quality outside of regular surgery hours.

200. According to the National Association of SHI-accredited Physicians, 3.9 million patients a year are treated by SHI-accredited physicians providing on-call service, while according to a survey by the German Hospital Institute (DKI) some 10.7 million patients received outpatient emergency care in hospitals in 2009. At the same time, hospital accident and emergency units are confronted with growing numbers of patients, many of whom could be treated on an outpatient basis by SHI-accredited physicians and, moreover, for whom the remuneration paid to hospitals fails to cover the cost if they go away again still as outpatients. The result is a false incentive to admit people as inpatients; the remuneration arrangements for emergency services operate in the same way. A number of hospitals have now brought specialists in general medicine into their accident and emergency units as a relatively low-cost means of providing primary care for a substantial share of patients and referring them back to SHI-accredited physicians.

201. To improve emergency care, a reorganisation would be desirable, ideally by bringing together all three areas: physician on-call service, rescue services and hospital accident and emergency units. In rural regions especially, in view of the contingency costs and the strain on scarce human resources, this is needed not only for qualitative but also for economic reasons. A further idea to be considered is that of giving general practitioners limited drug dispensing authority in order to improve the availability of medicinal products during on-call service times. Effort should be directed towards

avoiding widespread overprovision – most of all unnecessarily frequent utilisation and use of overly specialist care. Where possible, a central clearing point with a standard telephone number should be established for patients in each region to direct people to the right kind of care. In hospitals, an interdisciplinary accident and emergency unit integrating broadly qualified general medicine specialists is to be recommended; ideally, emergency practices should be integrated or at least associated with such units. A linked emergency and short-stay ward can be a useful addition, and not only in rural regions. For multimorbid patients needing only short-run intervention but frequent readmission, the focus at such wards could be placed on care planning by a multiprofessional team.

7.7 Role of hospitals in cross-sectoral care in rural regions

202. Pooling resources in rural regions not only calls for greater cooperation and coordination within the hospitals sector, but also cross-sectoral planning of care structures across all levels. While capacity for general practitioner primary care and emergency care will have to be kept as local as possible, outpatient or inpatient specialist care can be made more centralised. This means patients must travel further, but they would be able to obtain better-coordinated and possibly even higher-quality care in regional centres than is the case in regions with quantitatively ‘normal’ provision or even overprovision under sectorally separate care regimes. Hospitals in some regions have the potential here to serve as regional care hubs.

203. In the process, hospitals can come together with other care providers in a region to establish local health centres (LHCs). The LHC of the future will provide outpatient and inpatient care under a single roof or on a campus. It will be specially geared to providing care for the ageing rural population including, as integrated or associated units, institutional and outpatient-based short-term and long-term nursing care, a geriatric clinic and other health facilities.

204. Outpatient physician care will primarily be provided by practice-based general practitioners and specialists and by medical service centres (MSCs) located directly in or close by the hospital. Coordinating transport infrastructure with health care is an important facet here. Centralising medical care and thus channelling passengers towards a single destination aids transport planning. In parallel, LHCs will also offer regular surgeries with practitioners and medical professionals in the region’s communities, most of all to guarantee ongoing primary care without patients having to travel further for it. Physician on-call service and emergency care will be organised jointly from the LHC by hospitals, SHI-accredited physicians/MSCs and rescue services. Telemedicine applications will aid cooperation within the LHC and with other health care providers in the region. Where outpatient care cannot be provided by practice-based physicians, such

care will be provided by hospitals, as is already possible via the use of various instruments today. The further opening of hospitals for outpatient treatment as planned by the governing coalition, notably by making mandatory the option under Section 116a SGB V, may be of further help in this regard.

205. Inpatient care provided by LHCs primarily consists of the disciplines typical of basic provision and geriatric care. On the other side of the coin, instruments need to be found that prevent hospitals from providing more specialised care on account of economic incentives and constraints when in quality terms they would be better leaving such care to a higher provision level or specialised clinics.

206. The LHC model makes rural employment more attractive for physicians, nursing staff and other medical personnel because it provides a team context and the burden of on-call service and emergency care can be shared more broadly. It may be possible to offer physicians and nursing staff significantly better pay by providing additional funds for a 'country doctor' allowance along with service guarantee fees for rural hospitals that are needed to ensure provision. Higher remuneration would also make it attractive especially for young doctors who wish to or have to remain living in urban locations to go on limited-term secondments at LHCs. The possibility already provided for in the SHI Health Care Provision Act (GKV-VStG) for physicians to work both as SHI-accredited physicians and in inpatient care provides a way for the responsibility for health care provision shared by all parties to an LHC to be reflected in staffing, with a better allocation of resources. Cooperation between a range of disciplines and professions and between outpatient and inpatient care under one roof enables patients to be directed more quickly to the form of care matching their needs. Consideration must be given to the fact that the advocated restructuring here would need initial funding (both for investment and operating costs) and that the ongoing coordination effort and expense will be greater, although the need for initial funding is unavoidable and the coordination effort and expense can be offset by savings elsewhere.

8 Long-Term Nursing Care

8.1 Long-term nursing care needs and provision in Germany: Regional issues

207. In the face of demographic and epidemiological change, long-term nursing care² will play an increasingly important role, not just in Germany but worldwide. However, in most countries, long-term care has yet to reach a qualitatively satisfactory level across the board. Germany still faces a number of challenges when it comes to securing needs-based, long-term care that provides for autonomy and participation, with both qualitatively and quantitatively adequate residential, semi-residential and non-residential care. The long-term care sector faces urgent problems and there remains much to be done. The situation is further exacerbated by regional differences: Both demographic change and the trend towards more people needing long-term care are developing at different rates across the country, creating a need for different health care and long-term nursing care models.

Trends in the need for long-term nursing care

208. Since the introduction of long-term care statistics in Germany, there has been a steady increase in the number of people requiring long-term nursing care. In the period 1999 to 2011, there was a 24 percent rise, to 2.5 million, with very different rates of change from region to region. In some Länder (Bavaria, Hamburg and Schleswig-Holstein), the increase was exceptionally small, amounting to about only half that of the national average. Large increases were, however, seen in states in eastern Germany: Berlin, Brandenburg, Mecklenburg-Western Pomerania, Saxony-Anhalt and Thuringia all saw increases of over 30 percent. But there were also Länder in other parts of the country, such as Baden-Württemberg and Hesse, that experienced increases of similar magnitude. Differences in regional population age structure had a significant influence on the regional figures. The greater the size of higher age-groups, the greater the number

² Long-term nursing care targets people with permanent health impairments and loss of physical or mental ability, and takes in both inpatient and outpatient forms of medical care.

of people in need of long-term care (see Table 6). The Länder in eastern Germany differ from the rest of the country in one particular respect: among people aged 90 or older, an exceptionally large number are in long-term care. The trend towards the need for long-term nursing care in this part of the country exhibits a special dynamic in two ways: not only are there a higher number of older people among the population, but the elderly population is more frequently affected by the need for long-term care than comparable groups in western German states.

Länder	Total number requiring long-term care			75+ age group as percentage of total population		
	1999	2011	Increase (%)	1999	2011	Change
Baden-Württemberg	210 837	278 295	32.0	6.8	9.2	2.4
Bavaria	294 294	329 341	11.9	7.1	9.1	2.0
Berlin	80 871	107 917	33.4	6.5	8.0	1.5
Brandenburg	64 340	95 970	49.2	5.7	9.9	4.2
Bremen	17 143	22 178	29.4	8.5	10.0	1.5
Hamburg	42 001	47 207	12.4	8.0	8.6	0.6
Hesse	145 445	199 655	37.3	7.2	9.4	2.2
Mecklenburg-W. Pomerania	45 531	67 559	48.4	5.3	10.0	4.7
Lower Saxony	209 257	270 399	29.2	7.4	9.7	2.3
North Rhine-Westphalia	465 850	547 833	17.6	7.0	9.6	2.6
Rhineland-Palatinate	92 340	112 743	22.1	7.4	10.0	2.6
Saarland	27 194	32 793	20.6	7.5	10.7	3.2
Saxony	118 124	138 987	17.7	7.7	11.5	3.8
Saxony-Anhalt	66 616	88 021	32.1	6.8	11.0	4.2
Schleswig-Holstein	75 991	80 221	5.6	7.5	9.6	2.1
Thuringia	60 257	82 322	36.6	6.6	10.4	3.8
Germany	2 016 091	2 501 441	24.1	7.0	9.6	2.6

Table 6: Growth in numbers requiring long-term care and old-age population, by Länder

Source: Federal Statistical Office 2001 and 2013; own calculations

At municipal and district level, too, there are in some cases significant differences in the number of people in need of long-term care. These differences cannot, however, be explained by age structure. While there is a large number of elderly people and a comparatively large number of people receiving long-term care, there is no linear correlation between them. The municipalities and districts with the highest average age do not necessarily show the highest rate of people in long-term care. It would thus appear that other factors play a role, such as differences in people's general state of health, regional deviations in application patterns, various types of informal assistance

networks and regional inequalities in the availability of care services. There are, however, no reliable research results that would allow conclusions to be drawn regarding the impact of these factors or their importance.

209. These regional differences in the need for long-term care are expected to broaden in future. This will in turn cause disproportionate increases (compared with the national trend) in the challenges arising from demographic change, both in specific Länder and also in some regions. These disparities highlight the need for regional assessment of the requirements to be met in securing needs-based, long-term care.

Trends in and utilisation of long-term nursing care

210. Apart from the increase in the number of people requiring long-term care, there was an increase in the extent to which long-term care insurance services were used. That increase was not, however, balanced across the different types of services. There was a disproportionately large (30.5 percent) increase in full residential long-term care. By way of comparison, the number of people receiving nursing care at home increased only moderately, by around 22 percent, although a trend is evident in this group towards greater use of professional long-term care services – and with a very large number being cared for by family members.

211. Long-term care statistics for 2011 indicate that 12,300 non-residential services were available, representing an increase of 14.1 percent since 1999 (see Table 7). In contrast, the number of people in need of long-term care and who received it via non-residential services grew by 38.8 percent, to a total of 576,264 – a bigger rise than can be expected solely on the basis of the change in the number of institutions offering such services. Available capacity has also grown: while in 1999, an average 38.4 people receiving long-term care were cared for by one service, that figure had grown to 46.7 in 2011. Looking at the situation from a regional perspective, there were huge differences in the trends in availability of long-term care services during the period 1999 to 2011. Growth in the number of non-residential care services fluctuated across the regions, ranging between -24 percent (Saarland) and +69 percent (Berlin), although there were no visible trends as regards eastern versus western Germany or between rural and urban Länder.

Länder	Number of home care providers			Number requiring long-term care (non-cash and combined cash/non-cash)		
	1999	2011	Change (%)	1999	2011	Change (%)
Baden-Württemberg	845	1 110	31.4	42 408	57 617	35.9
Bavaria	1 591	1 829	15.0	56 658	73 459	29.7
Berlin	310	524	69.0	18 437	26 398	43.2
Brandenburg	516	598	15.9	15 443	27 892	80.6
Bremen	126	109	-13.5	4 545	6 222	36.9
Hamburg	343	343	0.0	11 480	13 513	17.7
Hesse	860	1 002	16.5	29 506	41 466	40.5
Mecklenburg-W. Pomerania	398	438	10.1	8 965	17 186	91.7
Lower Saxony	926	1 189	28.4	40 421	63 525	57.2
North Rhine-Westphalia	2 205	2 309	4.7	93 916	122 249	30.2
Rhineland-Palatinate	411	446	8.5	17 578	23 284	32.5
Saarland	153	116	-24.2	5 249	6 883	31.1
Saxony	845	1005	18.9	29 971	38 085	27.1
Saxony-Anhalt	481	521	8.3	14 198	22 525	58.6
Schleswig-Holstein	439	399	-9.1	14 329	15 964	11.4
Thuringia	371	411	10.8	12 185	19 996	64.1
Germany	10 820	12 349	14.1	415 289	576 264	38.8

Table 7: Regional growth in home nursing care over time

Source: Federal Statistical Office nursing care statistics (various years); own calculations

Use of non-residential care services also changed from region to region (see Table 8). In 2011, the most frequent use of non-residential long-term care services was seen in Brandenburg (11.3 persons per 100 aged 75 and over) and Mecklenburg-Western Pomerania (10.5 per 100 aged 75 and over). Non-residential long-term care was used comparatively rarely in Baden-Württemberg (5.8), Rhineland-Palatinate (also 5.8) and Schleswig-Holstein (5.9). The highest growth since 1999 was recorded in Mecklenburg-Western Pomerania (a 91.7 percent increase in patient numbers) and Brandenburg (up 80.6). With the exception of Saxony, all Länder in eastern Germany showed exceptionally high growth rates.

In eastern Germany in particular (except Saxony), provision of long-term care is secured through relatively few institutions, each of which cover large catchment areas. More detailed analysis is needed to clarify how the services are distributed geographically over smaller-scale areas and how this affects both reachability and accessibility.

Looking at the number of patients receiving non-residential long-term care relative to the elderly population in the respective Länder, it is evident that adjusting the figures for age produces no significant change regarding use of non-residential long-term care.

Thus, for every 100 inhabitants aged 75 and over in Baden-Württemberg in 1999, 6.0 of those in need of long-term care used non-residential services. This figure had hardly changed by 2011 and had, in fact, dropped slightly to 5.8 (see Table 8).

Länder	1999	2011	Change
Baden-Württemberg	6.0	5.8	-0.1
Bavaria	6.6	6.4	-0.1
Berlin	8.4	9.4	1.0
Brandenburg	10.5	11.3	0.9
Bremen	8.0	9.4	1.3
Hamburg	8.4	8.7	0.4
Hesse	6.8	7.2	0.5
Mecklenburg-W. Pomerania	9.4	10.5	1.0
Lower Saxony	6.9	8.3	1.4
North Rhine-Westphalia	7.5	7.1	-0.3
Rhineland-Palatinate	5.9	5.8	-0.1
Saarland	6.5	6.3	-0.2
Saxony	8.7	8.0	-0.8
Saxony-Anhalt	7.8	8.9	0.9
Schleswig-Holstein	6.9	5.9	-1.0
Thuringia	7.5	8.7	1.1
Germany	7.2	7.3	0.1

Table 8: Numbers requiring long-term care served by home care providers per 100 persons aged 75+

Source: Federal Statistical Office nursing care statistics (various years); own calculations

Similarly marginal changes can be observed in Bavaria, Hamburg, North Rhine-Westphalia, Rhineland-Palatinate and Saarland. Comparatively large increases ranging between 11.9 percent and 20.3 percent were seen in Berlin, Bremen, Mecklenburg-Western Pomerania, Lower Saxony and Thuringia. Given that the observation period covers some twelve years, it is evident that no far-reaching changes occurred in these areas.

212. Short-term and daily nursing care constitute key complementary services for people in need of long-term care in the home. They are designed to supplement home-based care arrangements and to ease the carer's burden. The growth seen in these services in recent years underlines their importance. The number of dedicated short-term care places rose by 9.3 percent between 1999 and 2011, to some 10,800. This appears low when compared with the trend in non-residential and full residential care, but it does not include short-term care provided using temporarily unoccupied long-term care places. The overall situation can only be explained by looking at the number

receiving short-term care in 1999 and in 2011. This figure rose from 8,500 in 1999 to almost 20,000 in 2011, representing a 130 percent increase. Comparing 1999 with 2011, the number of day-care places rose by 150 percent. Actual use of day-care centres exceeded this significantly. At the end of 2011, the number of people being cared for in day-care centres was 43,800 – four times as many as in 1999. The increased use of such services is, among other things, the result of improved services introduced with the Long-term Care Further Development Act (PfWG) in 2008.

213. There has been a steady increase in the number of people in residential long-term care in recent years. In 2011, there were some 723,000 patients in full residential long-term care. Compared with 1999, this represents a rise of 169,000 or 30.5 percent. These figures understate the increased importance of residential long-term care, however, because they do not include a growing number of patients who moved into residential care but died between one survey and the next. According to estimates, the actual number of people in need of long-term nursing care and who will use residential care in the course of a given year is significantly more than 800,000 and could be even closer to 900,000.

A similar trend is evident in the use of care capacity in full residential long-term nursing care. The number of care facilities grew from 8,100 in 1999 to 10,700 in 2011. In the same period, the number of places rose by 33.7 percent, to 830,800. Since about 2003, capacity expansion has exceeded the increase in the number of residents. It must, however, be remembered that the increasing fluctuation in resident numbers is not captured in the statistics. Looking at the figures, it would thus be wrong to assume that there is overcapacity.

214. There are also regional differences with regard to full residential long-term care. Compared with the national average, there has been a marked increase in the number of full residential long-term care facilities – most notably in Baden-Württemberg, Saxony, Saxony-Anhalt and Thuringia. This amounted to more than 50 percent in the period 1999 to 2011, and to as much as 84.4 percent in Saxony-Anhalt. With the exception of Baden-Württemberg, the number of residential care homes in these particular Länder remains low. When analysing the capacity growth, it must be remembered that the number of people needing long-term care who were in full residential care was below-average in most eastern German Länder in 1999. The above-average growth in full-residential care in the large eastern German Länder between 1999 and 2011 (with increases ranging from 41.3 to 60.5 percent) thus reflected a mix of demographics and ‘catch-up’ demand for care capacity. A change has evidently taken place here to reduce the capacity shortfall relative to demand. Despite the apparently large expansion in capacity, however, provision is still relatively sparse in these large and predominantly rural Länder.

215. An insight into use of residential long-term care can be obtained from the number of people in residential care relative to the elderly population. In 1999, for every 100 inhabitants aged 75 and over, an average of 9.7 were in residential long-term care. During the period 1999 to 2011, the national average dropped slightly, to 9.2. Contrary to the opinion sometimes expressed that there is a problem trend towards overuse of full residential care, looking at the figures on an 'age-adjusted' basis actually shows a slight downward trend – an unexpected situation in the light of demographic change. The trend varies among the Länder, however. For example, in Bremen the number of people in residential care per 100 elderly inhabitants rose from 7.8 to 9.0, while in Rhineland-Palatinate there was a slight drop, from 8.3 to 7.8. There are no clear trends evident in the predominantly rural or predominantly urban Länder. Trends in both directions can be seen in conurbations like Berlin, Bremen and Hamburg, and also for the more rural Länder. On the whole, a trend towards the national average can be seen in most Länder.

216. The analysis of the trend in residential care shows that the arguments often put forward in the socio-political debate regarding uncontrolled capacity expansion or overcapacity in residential long-term nursing care must be viewed with caution because, when looked at relative to demographic change, and given the lacking or inadequate capacity in rural areas recorded for the 1990s, those arguments are only possibly fitting in isolated instances or for some regions. Based on the national average and taking account of regional demographics, no patterns are evident that the arguments mentioned might explain.

In general, additional data is needed on regional trends, the geographic distribution of long-term care needs, the social circumstances of people in need of long-term care and those who support them, and the extent to which long-term care services meet prevailing needs.

8.2 Availability of qualified long-term care personnel

217. The growing shortage of qualified personnel in the long-term care sector was addressed in detail in the Special Report 2012. In that report, special focus was placed on regional differences and the challenges they bring because they are key in developing and improving long-term care provision.

218. According to data on health care personnel costs in 2011 (the most recent data available), there are currently some 1,545 million people employed in long-term care in the various types of health care institutions. Of these, 826,000 are qualified nurses, 275,000 are nursing assistants and 444,000 are geriatric nurses and geriatric nursing assistants. All care professions, especially in geriatrics, have seen significant rises in workforce numbers in recent years. This is primarily due to the rise in long-term care

employment, meaning in both non-residential and residential care. The considerable increase in the workforce does not, however, involve full-time positions – the rise has largely been seen in part-time work and low-paid positions. Also, the number of care employees with university-level qualifications remains extremely low and is significantly below the required quota of 10 to 20 percent called for by the German Science Council in 2012.

219. The overall growth in the workforce is not sufficient to cover current staffing needs. An analysis conducted by the Federal Employment Agency shows persistent shortages and a lack of qualified personnel since 2011, most notably with regard to geriatric care staff with a three-year apprenticeship. This lack is seen across all Länder and has worsened since 2013. In general health care, it is largely vacancies for qualified nurses and specialist nurses that take time to fill or stay unfilled. As in the past, this situation is mostly seen in western Germany and in Berlin. There is consensus in the literature that this lack of qualified staff will increase in severity in the years ahead unless measures are taken to ensure the availability of quantitatively and qualitatively adequate long-term nursing care.

220. Given the regional differences in the number of people in need of long-term care and in workforce potential, forecasts concerning the availability of qualified personnel will differ from region to region. The situation will continue to worsen in parts of Saxony in particular. But major cities like Berlin and Hamburg will also be affected, as will various areas of North Rhine-Westphalia. There are, however, no typical processes or patterns evident in rural or urban regions. Regional analysis could provide a better insight into what factors are relevant.

221. To counter the lack of qualified personnel, the states of Hesse, Rhineland-Palatinate and North Rhine-Westphalia have introduced regular monitoring to keep abreast of the current and future situations. The results highlight that there are already disparities between the Länder. In future, regional differences should be monitored more closely and greater attention be paid to securing qualified personnel in both suburban and rural areas.

222. There are already signs of an impending supply-demand mismatch in long-term care personnel, especially in rural areas. Structurally weak rural regions subject to demographic ageing are assumed to be caught in a downward spiral in which sections of the employed population move away to urban areas, thus exacerbating the situation and causing an even greater dearth of qualified staff than forecasts have indicated to date. This results in a dual loss in the provision of long-term nursing care: as the region loses qualified people and thus professional care resources, the potential for informal nursing care goes down and with it the opportunity for care to be provided by family members.

223. When looked at as a whole, the availability of long-term nursing care is threatened by the ongoing state of emergency in care provision and the lack of qualified staff. Only few regions remain unaffected by the lack of personnel, so that the problem can be seen as a nationwide one which can be expected to worsen in structurally weak rural regions. This situation can only be remedied in the shorter term by investing significant amounts in the expansion of initial vocational education and training capacity, and additional further education and training in the long-term care sector. Other measures are also needed to secure the availability of qualified personnel. These include efforts to make the profession more attractive and to enhance the status of people working in long-term care. There is currently a risk that working in this sector will become even less attractive due to the all-encompassing lack of personnel. To counter this, a push is needed in the reform of vocational education and training in long-term nursing care (by integrating initial vocational training across geriatric, general and paediatric nursing). In addition, efforts must be promoted to professionalise nursing care and make it more academic, as should the establishment of fundamental, primary qualification bachelor degree courses with integrated vocational education and training, and subsequent master degree opportunities. Also, measures must be stepped up to secure upcoming scientists and researchers because they will be needed to ensure sufficient tertiary capacities. Appropriate career opportunities are also needed, not least to boost the attractiveness of working in structurally weak rural regions. General improvements in working conditions and pay for long-term care workers are needed across the board. And finally, broad-based, regional monitoring of the situation regarding qualified staff is needed, as are studies on regional trends in availability to aid assessment of care provision in specific regions. Only by means of such a package of measures can needs-based long-term care be secured with an adequately qualified workforce.

8.3 Recommendations for regionally adapted approaches to long-term care provision

224. Given the expected increase in the numbers of people needing long-term care and the parallel worsening in the availability of qualified care personnel, regional provision approaches and models are needed to prevent the risk of underprovision in rural communities and regions especially, and to secure the provision of needs-based long-term care. Consensus has largely been reached regarding how this can be achieved and the requirements that must be met in doing so. In future, greater focus should be placed on securing autonomy and applying preventive approaches, the provision of information and advice, and the use of non-residential care, which includes informal helpers. Care provision should also meet regional needs with integrated, coordinated

services established in close cooperation with the respective health care professions to provide community-type care in line with regional or municipal structures. This naturally gives rise to a range of different requirements.

Improving health promotion in old age and preventing the need for long-term care

225. In recent years, numerous studies have shown that prevention and health promotion, including in old age and despite health impairments, can lead to improved health and quality of life. Promotion of exercise and mobility, nutrition campaigns and fostering skills to cope with everyday life and maintain personal health are increasingly important. Awareness of these factors is growing apace, but there are many challenges involved. Many activities primarily target young people, with the elderly population largely excluded from activities and studies. The same applies when it comes to prevention of the need for and prevention during long-term care – a topic which is only gradually gaining in acceptance because prevention research had not placed sufficient focus on the need for long-term care and the long-term nursing care sector. There is thus a lack of empirical knowledge and of suitable models for health promotion that target people with health impairments and elderly people at risk of needing or who need long-term nursing care, and for prevention of the need for and prevention during long-term care. Apart from the predominantly behaviour-oriented approaches currently in use, more relationship-focused approaches are needed which are suited to people who are not in the best of health, suffer cognitive restrictions and have few social resources available to them. Great importance is also placed on the development of health-promoting settings, with greater focus on municipalities and local communities. This applies in particular to rural regions, which have received little attention in the prevention debate so far. Efforts must also be stepped up to develop target-group specific models which focus on personal environments and in which elderly rural populations receive particular attention.

Improving long-term care advice and information services

226. To secure preventive health care and long-term care based on autonomy and participation, sustainable structures are needed in the provision of care advice and information, as these afford support for people who are either at risk of or are in the early stages of needing long-term care and can make a significant contribution to allowing patients to remain in their homes, thus preventing or postponing the need for residential care. Such services are especially important in rural regions, but they are not universally available. The organisation of and models for long-term care advice and support centres must also be improved to provide for better accessibility, especially in rural areas and particularly for difficult-to-reach user groups. Improvements are also needed in the type of advice provided. Where rural regions are concerned, it is recommended that outreach-based, mobile advisory structures be established and that

telephone advice services and the provision of information be expanded to take in new communications media. It is also necessary to change user-unfriendly fragmentation of the advisory landscape and the sectoral division of advice for patients and users (including people in need of care) under SGB V, IX and XI (Special Report 2012). Measures to promote integration along with new, cross-sectoral advice models are needed.

Improving informal networks and supporting family carers

227. More than two-thirds of people receiving long-term nursing care as defined under SGB IX are cared for at home. Of these, two-thirds are cared for by family members and with no professional care support as defined under SGB XI. Primary carers are usually women: daughters, spouses, partners and daughters-in-law. In many cases, men (spouses and sons) are now assuming the role of primary carer. Also worthy of note is the increase in the number of older and elderly couples who care for each other, and also the growing importance of children and teenagers who provide care in the home. So far too little national data is available on the extent and type of long-term care provided by family members in the different population groups, whether and to what extent there are regional differences in this regard, and how the situation looks in rural areas. The role played by informal partnerships and their potential for solidarity and assistance has received little research attention to date. But what goes uncontested is that family members harbour key potential in securing needs-based health care and long-term care provision. Forecasts have long pointed to the fact that the care potential of families will be reduced over time on account of age structures, altered family constellations and the increasing numbers of people living alone. Hence, greater attention must be paid to promoting the willingness and potential of families, companions, friends, social networks and informal assistance networks – a challenge faced everywhere, but which is especially difficult in rural areas where the middle generation is moving away to live in cities. There are some trends which must not be overlooked in this connection, including the increasingly important new forms of long-term care (elderly couples, patchwork families, informal partnerships, etc.), the increasing age of family carers and groups which have to date received little attention, such as children and teenagers and people with differing migration backgrounds. Here, too, new forms of support and promotion of the necessary resources and skills are needed, with target-group specific models that focus on personal environments. Family carers and informal helpers should be involved in the development of these models and measures must be taken to ensure they are needs-based and meet personal expectations. To prevent health risks and avoid over-burdening, it is also necessary to improve health promotion for family carers. Apart from behaviour-oriented approaches, educational and relationship-focused approaches must be given greater priority here than has been the case so far. This also applies to the establishment of monitoring structures to offer support and reassurance. Given the

reservations held so far with regard to existing services, new models for health promotion are needed, with special focus on conditions in rural regions. Efforts must also be made to ensure equal recognition of home-based childcare and care of dependent relatives across all areas of society and in (social) policymaking.

Expansion and differentiation of non-residential long-term nursing care

228. Apart from expanding and differentiating non-residential long-term care, home care must also be boosted to maintain people's autonomy and quality of life despite health impairments and long-term care needs. From a user standpoint, non-residential or home care is the preferred option, as many studies show. It has also assumed an increasingly important role with the trend towards outpatient health care services in general, be it to compensate for shorter hospital stays and to allow follow-on treatment of chronic health impairments and illnesses, or to allow patients to remain in familiar surroundings despite being seriously ill, fragile or in need of long-term care. The approach offers the greatest possible quality of life and opportunities for social participation. It is thus important to further expand long-term care services in such a way that they take account of the patients' home environment. What also speaks in favour of this approach is that the scope for providing home care has grown significantly thanks to medical-pharmacological advancements allowing non-residential care to be used even for difficult, complex cases.

229. The range of patient needs in outpatient care has changed in that it has become broader and more diverse, and non-residential long-term nursing care is no exception. Thus, despite the growth seen in recent years, further expansion in capacity is needed simply to meet the increasing demand. But non-residential long-term care must also be improved in terms of quality. Incentives must be provided to ensure greater population focus and differentiation so that non-residential care can meet the full range of highly diverse needs. Attention should be given to the growing number of people with complex needs, as they require equally complex solutions ranging from assistance in coping with everyday life to sophisticated forms of clinical care. Also, the increasing number of single people in need of long-term care poses a particular challenge in providing non-residential care, because they also need different types of help and network structures are necessary to make it possible for such patients to be cared for at home.

230. Alongside placing non-residential long-term care on a needs-based footing, incentives are needed to allow for new forms of organisation in non-residential care – whether at the level of work organisation and management (introducing case management/primary nursing to improve individual continuity and quality of care) or in terms of organisational structure and size. To improve flexibility in regions with poor availability of care services, it would make sense to increase the size of the organisational units – either by forming partnerships or networks, or by creating local health centres

for primary and long-term care in which a full range of medical and long-term care services and support can be provided under one roof and ideally from a single source. Models showing how such local health and long-term care centres might be organised can be seen in other countries. What they all have in common is that they provide multi-professional, integrated health care across all phases of life, including in old age and during chronic illness and periods of long-term care, when the need for support becomes increasingly more complex. Such centres are a highly promising approach and should be systematically tried and tested, particularly with a view to preventing underprovision in ageing rural regions. It must be stressed that, given the increasingly complex needs of the ageing population and the growing complexities in providing long-term care, such centres must be based around greater flexibility with regard to the rules on care provision and a broad interpretation of the nursing care concept.

Redefinition of the need for long-term care in SGB XI

231. Needs-based further development of (non-residential) long-term nursing care calls for a redefinition of the need for long-term care under SGB XI. Up to now, this sets out a narrow interpretation of the need for long-term care in which such care is reduced to support in coping with everyday situations and leaves little scope for the communicative, educational and care management activities involved in the provision of professional long-term care. Various bodies under the Federal Ministry of Health have put forward proposals for the redefinition of the need for long-term care, both in the last and in this current legislative period. These should be taken up without delay as they are both the basis and a precondition for overcoming many of the challenges faced in providing long-term care, not least in improving non-residential care in this sector.

New forms of cooperation and reassignment of responsibilities

232. Needs-based health care is reliant on new forms of cooperation and an altered mix of professions (see also Report 2007 and Special Report 2009) to meet changing responsibilities and requirements. This is a huge challenge given the lack of qualified personnel in rural regions. To secure provision of services in rural areas that are at risk of underprovision, multi-professional models are needed which are based on team work and a task-focused assignment of responsibilities are key, as experience gained in other countries shows. Introducing such models in Germany and replacing rigid hierarchies with horizontal cooperation approaches has long been proposed (Report 2007). Legislative measures have been taken (Section 63 (3) SGB V) to achieve a new structure, a redistribution of responsibilities and a different professional mix, and also the gradual transfer to other health professions of specific responsibilities so far assigned to physicians. Implementation has, however, been halting and is made difficult by complicated implementation requirements. The arrangements made thus far should therefore be reassessed. In addition, incentives are needed to accelerate implementation and allow

innovative solutions to specific health care service problems to be trialled in rural regions. Also, centres should be created for inter-professional learning and practice. These, too, are important in achieving and maintaining new forms of cooperation between the various health care professions.

Further development of residential long-term care

233. It is increasingly the case that the transition into a residential care home occurs in a late phase of long-term care. This results in the need to focus care on people who are exceptionally vulnerable, have serious health problems, considerable cognitive difficulties and very limited life expectancy. Given the growing number of people in this situation, steady and increasing demand for care can be expected of the kind that involves the typical characteristics of residential long-term care. Alongside a broad range of care, this includes constant presence of qualified personnel, integration and coordination services performed by different disciplines, and networking with other health care services. In addition, residential long-term care must be adjusted as part of an ongoing process to allow needs-based service provision.

234. Also, the staff shortages which exist in many residential care homes must be remedied and staffing overall must be improved in both quantitative and qualitative terms, with attention being paid to providing an appropriate mix of qualifications and skills. This means not only maintaining adequate staff numbers, but raising the requirements regarding the educational level of qualified personnel. Meeting the changing needs of care home residents also calls for targeted integration of specialised (clinical) skills and expertise, partly with university-level qualifications (such as in palliative care and gerontopsychiatry).

235. What is also needed is the introduction of new forms of work organisation that allow the assignment of case management and coordination responsibilities to specially qualified personnel. This optimised approach should be supplemented by rigorous use of benchmarks for in-house quality assurance to reveal weaknesses, identify areas for improvement and assess progress made in quality enhancement. External audit systems should be aligned to promote ongoing improvement rather than exerting pressure on homes to apply bureaucratic, inefficient quality assurance processes. It is necessary to arrive at a methodologically appropriate approach in quality assessment for reliable quality assurance reporting. Optimised structures are also called for, as they are a prerequisite for improved integration of informal helper potential in everyday care activities and for improved integration of residential long-term care facilities into neighbourhood and/or regional provision. They also form the basis for the long-called-for qualitative further development of residential long-term care – something that must be pursued with more determination. This includes boosting resource-enhancing care, better integration of medical and care support, and a professional approach to behav-

itorial difficulties. A further need is for a new form of inpatient, post-acute transitional care which is similar to the care provided in dedicated short-term care facilities but better equipped.

Needs-based enhancement of regional structures

236. Additional challenges arise in the many regional disparities and the need to find appropriate solutions for needs-based adaptation of regional structures. Depending on regional conditions, for example, residential long-term care facilities can take on extensive responsibilities consolidating and integrating regional health care services and can evolve into local health and long-term care centres. Consolidating services for different target groups, better integrating non-residential, residential and semi-residential care offerings, integrating of low-threshold support services and household helpers, support for self-help groups and, not least, the integration of physician-provided care and the securing of structural conditions for mobile outpatient rehabilitation measures can all contribute significantly to reducing structure-related problems that hinder access to needs-based health care in rural regions. There remains, however, a lack of models for such cross-sectoral, integrated long-term care centres. Developing, testing and evaluating such models is key in this regard.

Municipal-level challenges

237. Securing health care and long-term nursing care provision poses particular challenges for municipalities in structurally weak rural regions. In many of these regions, the group of older and elderly people is growing, while younger people and employed members of the population (and with them children and teenagers) are migrating to more attractive urban, economically more stable regions. Outward migration and demographic change have diverse impacts on rural communities, however: They lessen the need for public transport, generate vacancies in housing and business premises, lead to closures of schools and throw into question the existence of institutions (for example with regard to social participation) that are usually taken for granted. At the same time, the willingness of health care professions, including long-term care professions, to work in these regions is on the decline.

To avoid underprovision, shortfalls in care provision and quality deficits, and to enable their timely identification, ongoing monitoring of health care needs and provision is needed (see Special Report 2009). Also, systematic health care provision planning is needed (based on the morbidity structure of the regional population), on the basis of municipal health assessments for which mature, evidence-based instruments remain lacking in Germany. Such instruments should therefore be developed, tested and evaluated without delay. It is also necessary to enhance municipal planning and implementing powers, as recommended in the Special Report 2009. Creating the

necessary conditions in the municipalities remains of key importance. The legislative conditions in the various Länder must thus be assessed and improved as appropriate. Also, there is a need to create the necessary specialist expertise in the municipalities and communities to enable a pro-active approach in developing needs-based long-term care infrastructure. At the same time, a different model and understanding of planning must be found in which planning does not constitute top-down management. In a plural stakeholder and management system, such as in long-term care provision and its associated care sectors, regional, democratically legitimised planning can only develop if it is done via dialogue and participation. Such cooperative, participative regional planning calls for a new culture and competencies with which to initiate participative planning and implement suitable participation processes. It is thus recommended that experience gathered to date be collated and evaluated with the aim of identifying well-founded information on which the municipalities can base their actions.

238. In addition, development of new, customised, social-space-oriented long-term care provision models is needed for rural regions. These must build on existing structures and be adjusted to prevailing conditions with the aim of enabling high-quality, local, comprehensive (basic) health care, while highly specialised care measures are provided in appropriate centres located in towns and cities. The Council sees multi-professional local health centres for primary and long-term care provision as a promising approach because, by consolidating all necessary services, they offer integrated, comprehensive provision, allow the greatest possible flexibility and can compensate for staffing shortfalls through the use of teamwork. At the same time, they make it easier to test and adopt new forms of cooperation and work distribution. Especially in rural areas at risk of underprovision, they make for an interesting model with which to provide needs-based health care and long-term care services.

Further expansion of nursing science and research

239. The further expansion of nursing science and research is essential in meeting the enhanced needs in long-term care and growing demands in terms of cooperation and coordination (see Special Report 2012). The empirical knowledge and research needed to address many issues is lacking (including for the development of models for structurally weak rural regions), thus hindering both qualitative improvements in long-term care and the provision of evidence-based health care services. This has structural reasons and is, among other things, due to the inadequate expansion of nursing science (especially at tertiary level) and the lack of ongoing funding for research in this sector. It is thus necessary to promote tertiary-level nursing science and to make funding available for research on an ongoing basis. In addition, the financial resources available to the long-term care funds under Section 8 (3) SGB XI should be allocated in the amount of 30 percent to the further development of long-term care research. It is recommended

that these resources flow into BMBF funds for health care research and be awarded in accordance with the prevailing criteria for nursing research. As part of the planned expansion of health care research, care provision research must be promoted in a targeted way – not least in order to obtain substantiated knowledge and models for health care and long-term care – especially in structurally weak regions.

240. In sum, it must be remembered that in the provision of long-term care, many reforms have been introduced in recent years to meet the growing needs of this health care sector. Numerous improvements have been made, but these met only some of the challenges faced. Many of the changes introduced and the reforms in long-term care provision have involved piecemeal service improvements which left the health care landscape largely intact. But because of the diverse challenges driven by demographic change and the rapid shift towards non-residential long-term care, the piecemeal improvements have not necessarily resulted in an overall improvement or to needs-based health care provision. Given the rise in the number of people in need of long-term care, the increasing lack of qualified long-term care personnel and what are in many cases difficult working conditions and poor pay, many of the reform approaches currently under debate do not go far enough. What are needed are structural reforms that go beyond the changes currently planned and focus on the architecture of both health care and long-term care provision, are based on a vision of a needs-based, integrated, professional and high-quality long-term care service, and aim to improve participation and community focus. This is all the more important in that in the future, long-term care provision will play an ever-increasing role both nationally and internationally. Investment in a sustainable long-term care provision landscape, in the quality and expertise required to support that provision, and also in sectoral research and professionalisation, is needed more urgently than ever in order to keep pace with demographic change and achieve needs-based health care and long-term care.

9 National and International Approaches

241. Regional analysis shows health care provision to be increasingly unevenly distributed across Germany. Rural regions with usually sparse infrastructure face special challenges. Such regions tend to be hit particularly hard by a combination of adverse sociodemographic and infrastructure trends. Various factors typically come together, including an ageing population with increased medical and care needs, a parallel rise in the average age of medical professionals, and poor accessibility.

9.1 Examples of approaches to rural health care provision

242. Lacking an overview of initiatives to safeguard health care provision in structurally weak regions, the Council asked health ministries and county associations in the larger German states to provide information on such initiatives between October 2013 to February 2014. 14 out of 14 ministries and nine out of 13 county associations responded (two ministries responded from Brandenburg). The answers spanned a wide range, from brief email responses to detailed paper replies, in some cases with detailed supplementary information. More than 380 existing or planned initiatives were named, with most replies relating to medical provision. The responses to this information request are summarised in the following. Responses focused on several thematic areas: Retaining rural doctors and practices/new forms of cooperation (n = 90), networking and coordination (n = 113), overcoming distance (n = 83), community provision approaches (n = 43), establishment of local health centres (n = 3), and policy bodies, analysis and strategies (n = 52). A full presentation of the results and (non-exhaustive) examples of projects from Germany, Canada and Finland are to be found in the unabridged version of this Report. The inclusion or non-inclusion of specific projects as examples does not represent a recommendation or otherwise. An overview of projects described in-depth in the unabridged Report is provided in the table below (see Table 9).

Retention of rural doctors and practices/new forms of cooperation
Saxony-Anhalt SHI fund branch practices* Facilities operated by SHI funds themselves under Section 105 SGB V, with salaried physicians
Networking and coordination
South Brandenburg Practitioners Network* Network of general and specialist practitioners, with multiprofessional cooperation
Landshut Oncological and Palliative Network* Treatment network (clinic and practice) with mobile services and hospice
Local Health Hubs* Cross-sectoral community provision networks in Canada
Huron-Perth Healthcare Alliance** Network of small and medium-sized hospitals and clinics in Canada
Home First** Discharge/transition management programme for patients with chronic illnesses and seniors in Canada
Overcoming distance
Rolling Practice: Wolfenbüttel Health Region Providing five communities with general practitioner service using a van converted into a practice
“Mallu” Mobile Practice** Mobile practice in South Karelia (Finland) run by nursing staff
Community provision approaches
Arnsberg Dementia Learning Workshop* Community project for the inclusion of dementia patients, with advice and coordination through a project office
Muschenheim Community Nurses Project* Community health care provision through specially trained nursing staff and medical assistants in close consultation with general practitioners
Establishment of local health centres
Gelstertal Health Centre* Rural health centre with branch practices in surrounding places
Community Health Centres in Finland** Population-oriented health centres providing medical treatment, prevention, health advice, outpatient care, physiotherapy, occupational health, and emergency care
Community Health Centres in Ontario** Local multiprofessional primary care health centres with health and social services in Canada
Policy bodies, analysis and strategies
Landkreis Reutlingen Municipal Health Conference* Steering group and communication platform for health care professionals
“Zukunftsregionen Gesundheit”: Community Health Landscapes in Lower Saxony Mobility, prevention and health promotion projects coordinated across Lower Saxony
Table 9: German, Canadian and Finnish projects on regional rural health provision

* InGe project; ** DIVER project

The examples of projects included are from research projects at the University of Frankfurt am Main (Institute of General Practice: Innovative Health Care Models/InGe) and at the University of Bielefeld (Faculty of Health Sciences: Regional Differentiated Provision – comparative international analysis of rural provision models/DIVER)

Source: Own compilation

243. The examples of projects included are from research projects at the University of Frankfurt am Main (Institute of General Practice: Innovative Health Care Models/InGe) and at the University of Bielefeld (Faculty of Health Sciences: Regional Differentiated Provision – comparative international analysis of rural provision models/DIVER).

Retention of rural doctors and practices/new forms of cooperation

244. In many rural regions, population ageing is compounded by cities once again becoming increasingly attractive, most of all for young people of working age. This renewed trend towards urbanisation causes a corresponding population drain in rural regions. This makes it hard to attract or keep qualified professionals in rural areas. According to responses to the information request, efforts to attract young people into rural medicine focus on the general practice sector. This includes grants for medical students to do internships, traineeships or part of their practical year at rural general practices. Practitioners are supported in further training by coordinating centres for further training in general practice (at SHI funds or Länder medical associations), by regional further training alliances between clinics and practices, and by university-linked centres of expertise on further training in general practice (so far in Hesse and Baden-Württemberg). The SHI funds also carry out regional campaigns, offer advice and have programmes to promote rural practices. An indirect form of promoting rural practices consists of SHI funds setting up and running facilities of their own. A further incentive is provided by opportunities for ancillary staff to train to carry out tasks reducing the workload on practitioners, as with the VERAH scheme enabling medical assistants to train as care assistants in general practice. The use of such approaches is obstructed, however, by the fact that services outside of SHI contracts for general practitioner-centred care can still only be billed in a limited number of exceptions. It must also be emphasised that a sole focus on reducing practitioner workloads is not enough. More far-reaching reforms are needed to establish new ways of cooperating and sharing responsibilities. A smaller number responses to the information request reported initiatives to promote nursing care provision. Express mention was made of campaigns to recruit skilled geriatric and nursing care personnel in Germany and abroad.

Networking and coordination

245. A growing number of alliances pursue the goal of coordinated health care at local and regional level. These include practice or practitioner networks, and alliances between general and specialist practitioners – including psychotherapists – taking part in the system of health care provision by SHI-accredited physicians. The Agentur deutscher Arztnetze, which is the umbrella organisation for practitioner networks, estimates that there are currently about 400 such networks in Germany. Since the SHI

Health Care Provision Act (GKV-VStG) came into force in 2012, practitioner networks have been able to receive grants in their own right (Section 87b of Book V of the Social Code (SGB V)). The National Association of SHI-accredited Physicians published guidance on the recognition of practice networks in 2013, reflecting the diversity of potential areas for cooperation and care objectives such as patient-centeredness, cooperation in practice and enhanced efficiency. To date, however, no significant grant funding has been awarded. A broader organisational form consists of regionally oriented, cross-sectoral alliances between networked practices and acute-care inpatient facilities. The boundaries between these and networks solely consisting of SHI-accredited physicians are often blurred.

An additional cooperation vehicle consists of alliances for the care of specific patient groups or conditions. The initiatives mentioned in responses to the information request suggest a broad range of action areas and players. One focus area is care of vulnerable groups such as nursing home residents, geriatric and palliative care patients and people with mental illnesses.

New forms of cooperation are also being adopted in emergency care. The regional associations of SHI physicians, for example, have revised their regulations on on-call service to introduce emergency practices and on-call practices as a new form of service. In Baden-Württemberg there are plans to trial an emergency centre jointly supported by outpatient and inpatient practitioners, while in Brandenburg trials are underway involving cooperation between on-call services, rescue services and the rescue departments of municipal hospitals.

Shared patient data management systems are an important aid with regard to information exchange. The Council has examined the importance of such systems together with introduction and implementation problems in an earlier report (Special Report 2012). The responses to the information request indicate that additional effort is still needed to implement systems that are suitable for everyday use.

Overcoming distance

246. In sparsely populated regions, democratic change goes hand in hand with increasingly poor accessibility to health services. The consequences tend to be worst for older people, who often have both limited mobility and increased health care needs. Various initiatives targeting these problems place the focus on making transportation and mobile services available on a regional basis for patients or practitioners or for a range of health care professionals, and also on telemedicine.

Patients' buses and mobile practices are two complementary ways of improving accessibility to health services in low population density regions. Patients' buses can take the form of dial-a-bus services and volunteer escorted services. Only very few mobile

practices are in operation, on a trial basis. Examples include a travelling general practice in Lower Saxony and a mobile dental surgery in Brandenburg. A pilot project in Mecklenburg-Western Pomerania provides mobile advice and care for dementia patients and their relatives. There are numerous current projects trialling telemedicine applications.

Spotlight: Telemedicine/telenursing

247. Telemedicine covers a wide range of ways of providing or delivering health care services making use of information and communication technology to span geographical distances between patients and health care professionals, or between teams of professionals. This includes smartphone apps, sending physiological data from patient to health care service provider (telemonitoring), and sending diagnostic images to remote experts for assessment (teleconsultation).

Widespread use is made of teleneurology in the treatment of acute stroke with experts linked-in by video, notably for rapid diagnosis for thrombolysis (dissolving blood clots on the brain by pharmacological means). Timely diagnosis and immediate therapy significantly reduces mortality and aids regeneration, and now features in national and international guidelines.

Older people are among those who benefit most from house calls. Telemedicine applications may further enhance the usefulness and efficiency of such personal visits, for example as a means of transferring physiological data. National and international studies indicate that telemedicine applications can have positive effects. However, different forms of intervention have not been shown to have different outcomes. Thus for a number of conditions, sophisticated telemonitoring is no better than structured, regular contact by telephone. Specifically in relation to heart failure – a frequent choice of subject for studies – telemonitoring has been shown to have an overall positive effect in terms of mortality, quality of life, hospitalisation frequency and cost. Meta-analyses suggest that there may be publication bias, i.e. that preferences tends to be given to publishing studies with positive outcomes. The majority of studies exhibit methodological weaknesses and small case numbers, and the interventions featured are hard to compare. Overall, there is not yet sufficient evidence as to what forms of telemedicine have the greatest effect for chronic illnesses or are particularly cost-effective.

Telemedicine in the broadest sense offers many options for improving health care provision. It can help compensate for regional underprovision and most of all it can enable older people to stay in their home surroundings while maintaining good quality of life. Teleconsultation likewise comes into its own in regions where there are few practitioners (general or specialist) and hospitals, and for putting patients

suffering from rare conditions into contact with specialist centres. Other facets to consider include data protection and providing quality assured medical services in telemedicine, as established for example in teleradiology.

There is a visible trend, however, towards supply-driven implementation, in many cases with little or no proof of the benefits. It is not enough merely to roll out the technology: Telemedicine applications should be regarded and trialled as part of an integrated approach that takes both patient preferences and the needs of health care professionals into account. Applications must also stand up to cost-benefit analysis. It is recommended that technical applications should be tested with a range of health care services as a form of complex intervention in cluster-randomised controlled trials.

The inclusion of telemedicine services as part of outpatient provision is to be appraised under the framework agreement between the National Association of Statutory Health Insurance Funds and the National Association of SHI-accredited Physicians (in accordance with Section 87 (2a) SGB V). The key points listed in the framework agreement, including benefits in relation to patient-relevant endpoints and/or improved cost-effectiveness criteria, should also apply to inpatient provision. The appraisal should be carried out by the Federal Joint Committee.

Community provision approaches

248. Efforts to strengthen local communities are aimed at maintaining a functioning infrastructure and hence at securing local health care provision. This is reflected in the responses to the request for information from Länder ministries and county associations, which refer to a range of initiatives to reinforce the social fabric of specific municipalities and neighbourhoods.

An aim of inclusive neighbourhood management is to ensure that provision remains available at local level in order to reach people in their individual living environment. According to the responses to the information request, a focus of activities to date has been on provision for elderly, infirm and dementia patients. Rural neighbourhood alliances have emerged in which villages pool health care provision.

Counselling and service centres provide patients and their relatives with health and nursing care-related advice and services. The examples referred to in responses to the request for information show a clear focus on the areas of nursing and geriatric care. Aside from nursing care support centres, there are services relating to patient and user counselling (Section 65b SGB V), on living arrangements for seniors and on rehabilitation (joint service centres).

Promotion of volunteering is a supporting measure to reinforce the social function of family ties and neighbourhood groups. The projects mentioned in the responses to the request for information aim to provide training and support for relatives providing care and to establish low-threshold support services and support groups.

Establishment of local health centres

249. Securing nationwide health care provision is generally equated with the availability of local basic health services. In regional planning terms this follows from central place theory, which posits a tiered concentration at lower, middle and higher-order places. Maintaining such structures in some rural regions poses a growing problem, and a trend towards centralisation can be observed as a result. The responses to the Council's request for information show that the shift from local structures to regionally oriented shared provision centres proceeds in phases and is currently at an early stage. Health centres were explicitly mentioned only three times in the answers to the information request.

Policy bodies, strategies and analysis

250. Coordinated responses to the impacts of demographic change and unequal regional living conditions require consensus on the problems and the measures needed to address them. Various activities at Länder, county and local government level aim to ensure ubiquitous health care provision by cross-cutting action.

The responses to the Council's information request show that a range of bodies and professional, health and care conferences are involved in policy advice on the design of regional provision structures. All of the large German states have moved to establish joint bodies to consult on cross-sectoral provision strategies, in accordance with Section 90a SGB V. Consultation at local and county level generally takes place in health and care conferences, in some regions (e.g. North Rhine-Westphalia) on a combined basis. In response to the information request, the states of Baden-Württemberg, Bavaria, Hesse and North Rhine-Westphalia explicitly stated that measures to improve health care provision are inferred from empirical analysis of the current situation with regard to such provision.

In response to the information request, several Länder health ministries named master plans and funding programmes developed at Länder level to ensure ubiquitous health care provision: a programme on ageing in Mecklenburg-Western Pomerania, a master plan on enhancing outpatient medical care in Rhineland-Palatinate, a strategy on securing health care provision in Brandenburg, a pact on securing health care provision in Hesse, and a nursing care pact in Thuringia.

9.2 Conclusions

251. As early as in its Special Report 2009, in which it set out a future concept for cross-sectoral, coordinated, community-based care with a regional dimension, the Council called for targeted further development of the German health care system, notably by means of improved coordination generally, improved regional coordination, and generation-based care (Special Report 2009). The projects mentioned now display very promising approaches in this regard. To facilitate the necessary reorganisation of health care provision, most of all in rural areas, it would seem advisable to establish ongoing provision monitoring and, if this identifies a state of underprovision or a risk of underprovision, specifically to commission a body – to be appointed for the purpose – with planning and implementing a data-based, cross-sectoral, comprehensive, multi-professional provision planning system tailored to the region in question. Such a body could be a joint state-level body under Section 90a SGB V equipped with additional powers; regional or municipal health and care conferences are also a possibility.

Regardless how such a body is constituted in detail, provision strategies should be developed in such a way that they unite a well-coordinated combination of provision and support services geared to regional needs.

Institutionalised cooperation between local players is especially important in this regard. In practical implementation, it is advisable to conduct a thorough analysis and balancing of interests and involvement for all groups. With regard to health care provision, an example could be aiding the recruitment of a successor for a rural practitioner with grant funding from the SHI, provision of a suitable building by the community, or local government-organised transportation services. Professional management structures are also needed in order to provide all health care professions with targeted support in establishing coordinated and interconnected provision. The idea of local health centres is proposed for primary and long-term care, especially in rural regions. Figure 8 (see Chapter 10) highlights the importance of primary and long-term care as the centrepiece of regionally interconnected care in rural regions.

10 Recommendations

252. The main aim in a patient/user-focused health care system must be to create and secure needs-based provision that is both freely accessible and reachable. The present Report looks at the various health care sectors and highlights the regional differences found. Health care in Germany takes a very sectoral approach, and in its previous reports the Council has called for the sectoral boundaries between inpatient and outpatient health care to be softened by means of integrated health care (see, for example, Special Report 2009, at 1138ff) and solutions to remedy interface problems (see Special Report 2012). While serious allocation problems exist within individual sectors, Germany's health care service is largely well-developed and enjoys above-average physician coverage compared with other countries. Cause for concern, however, is seen in the increasing misallocation of capacity: between rural and urban regions on the one hand, and between general practitioner-provided and specialist physician-provided care in the outpatient sector on the other. In the inpatient sector, there is an overall overprovision of health care capacity. But there are also marked numbers of loss-making clinics and hospitals – including in structurally weak rural regions – that must fight for economic survival. In long-term nursing care, which is severely affected by a lack of qualified personnel, the current capacity levels and forms of care are not sufficient to meet the demographics-driven rise in the number of people needing long-term care and the associated changes in morbidity.

253. Strategies to optimise health care services are thus aimed at reducing both regional and discipline-specific over and underprovision, at targeted improvements in specific sectors and the establishment of future-focused models for integrated, better-coordinated health care. This Report thus looks at various approaches and sets out a range of recommendations to support them.

To boost structurally weak regions with provision deficits, the existing regulatory instruments, such as the SHI Health Care Provision Act (GKV-VStG), must be used effectively, and new, more effective incentive systems and more far-reaching health care provision models must be developed. The improvements needed within the various sectors involve balancing regional capacity distribution (both outpatient and inpatient)

and sustainable enhancement of general practitioner-provided primary health care and long-term nursing care. When developing regional health care models, particular attention must be paid to the older population.

Outpatient general medical and specialised care

254. For outpatient medical care provided by SHI-accredited physicians, it is evident that the measures introduced so far have not been sufficient to remedy the increasing capacity misallocation leading to concentration in urban areas and poorer availability in rural regions. Greater incentives are thus needed to attract doctors to work in areas at risk of underprovision.

Two complementary legislative measures are thus recommended: Firstly, a ‘country doctor allowance’ to attract doctors to open their own practices in a planning region with health care provision levels of below 90 percent for general practitioners and less than 75 percent for specialist physicians. This involves a ten-year guaranteed bonus of 50 percent on all basic medical care provided at health care levels I and II (general medical and general specialised care) and also for child and youth psychiatry. As an alternative to the standard 50 percent bonus, a sliding-scale allowance relative to the level of care provided up to a maximum of 50 percent is also possible. The allowances should be automatic following determination of the level of care involved and are thus not to be interpreted as an amount to be agreed between the SHI-accredited physician and the Panel Doctor’s Association or the health care payers. Because the allowances are to be funded at the expense of physicians in all specialist groups who do not practice in planning areas at risk of underprovision (and thus by transferring remuneration funds within the various groups), patients incur no costs under this model. Similarly, the negotiating parties could agree, in selective agreements such as are defined in Sections 73b, 73c and 140a-d SGB V, an appropriate country doctor allowance (of 50 percent or on a sliding scale according care level, as outlined). This would then also have to be taken into account in the adjustment of the overall remuneration amount.

255. Secondly, supplementary measures are needed to enforce the reduction of overprovision on which scarcely any progress has been made so far. The mandatory rule subject to exemptions set out in the Coalition Agreement between the CDU/CSU and SPD regarding the purchase of vacant physician places in the event of overprovision is to be welcomed. In addition, it is also recommended that for planning areas with provision levels of 200 percent and over, purchase of vacant physician places in all planned groups by the Panel Doctor’s Associations should be made mandatory by law to prevent ongoing overprovision of outpatient services. Psychotherapists should be regarded as a separate case and be excluded from this rule until suitable needs planning criteria can be developed and a better insight has been gained into the current situation regarding provision of psychotherapy services.

256. One fundamental problem is that there is no data on the demand for doctors with an adequate empirical basis. In particular, there is no data available to show the number of SHI-accredited physician hours that are needed to provide an appropriate level of care for a specific population group. Scientifically founded information must be obtained to enable the development of targeted, population-oriented needs planning. The wide variety of criteria used in different health care regions to determine the risk of underprovision should be standardised as part of the same process.

257. Where a planning district falls short of the 75 percent threshold for both general medical and general specialised care, the mandate to secure outpatient health care provision should no longer be assigned to the Panel Doctor's Associations (or the health insurance) and thus separately to the inpatient sector, but also concurrently to the Länder. The Länder should be responsible for cross-sectoral, regional health care provision in accordance with supra-regional needs planning. In ensuring provision, it is recommended that public tenders be used to allow flexibility in remuneration and investment grants. This should be implemented by the joint Länder committees under Section 90a SGB V, whose mandates should be extended accordingly. Outpatient care in areas where the Panel Doctor's Associations have surrendered their mandate to secure provision should be funded out of a suitably (up to 100 percent) increased share of overall remuneration, Länder-level tax revenue and investment aid from municipalities.

258. Working conditions must be improved to make practising as a doctor more attractive, especially when it comes to basic medical care. New types of working arrangements, such as employment in a medical service centre and family-friendly working hours play an important role. Also, delegation and substitution arrangements can help to establish new forms of multi-professional and interdisciplinary teams (e.g. in local health centres) which could also improve allocation of scarce specialist resources.

259. As well as geographical disparities in health care services, there is also an increasing imbalance between general and specialised medical care. There is also a significant imbalance between supply and demand in general medicine. Given the increasing difficulties involved in recruiting replacements for general practitioners who go into retirement, and not least given the threat of provision deficits in rural areas, targeted promotion of general medicine is needed at various levels.

The status of general medicine in the medical faculties must be improved. This could be aided by changes in the curriculum, such as a mandatory three months in academic training practices for all students during their practical year, with guaranteed cost reimbursement both for students (at the level applied during hospital placements) and for the participating training practices. One important issue here is the establishment of general medicine professorships at all medical faculties (see Special Report 2012, at 107). Possible changes in the selection process and funding of tertiary education, both of

which need to be assessed with regard to the desired impact, should aim both to increase the number of students accepted and promote students who show an interest in working either in a rural area or an area at risk of underprovision once their studies are completed. A six-week advance placement, which must be completed prior to commencing medical studies, would give students an earlier insight into working life as a doctor. It should be introduced as a mandatory requirement, with the option to take it in a doctor's practice, and should replace half of the current three-month nursing placement.

260. Improving further education and training structures in general medicine calls for a range of targeted and so far largely neglected measures: University-linked centres of excellence for general medicine should secure seamless transitions between university studies and subsequent further training, while regional further education and training colleges with structured parallel seminars, individual mentoring programmes, train the trainer courses, and ongoing evaluation and quality assurance monitoring should secure high degrees of specialist knowledge and boost attractiveness. Regional further education and training alliances should provide for uncomplicated rotation between the various further training phases in hospitals and medical practices. Increased funding for participating training practices to match the levels for hospitals should prevent doctors in further training being disadvantaged during the medical practice phase. When accepting a doctor into further training, the practice budget could be increased in the amount incurred in providing specialist training and support. A personal guarantee for every doctor in further training of a transferable further training budget would give the additional security young doctors repeatedly call for. A new foundation for initial and further medical education and training could assume coordinating responsibility for funding for doctors' training institutes and centres of excellence, cost reimbursements for students and training practices in the practical year, and provide funding for model projects to secure the availability of qualified personnel.

261. With regard to patient-focused, coordinated medical care, the Council sees potential in promoting general practitioner-centred primary health care provision. To promote a medically appropriate stratification of health care provision, the establishment of targeted incentive systems is recommended, along the lines of a co-payment for direct use of high-level health care (treatment by practice-based specialists or hospital outpatient care) without a referral from a general practitioner. The rules could be implemented to allow free access (without patient charges) to general practitioners, ophthalmologists and gynaecologists, and also in the case of emergencies and the treatment of minors. Another possibility would be a sliding-scale patient co-payment, on the Scandinavian model, in the amount of the average additional costs, payable by direct debit via health insurance funds (e.g. approximately 10 percent based on the EBM and ranging between €10 and €50; or alternatively a fixed amount). An alternative might

be a sliding-scale patient charge for pharmaceuticals (with the abolition of the currently very frequent exemptions) that would only be payable if the patient had not been referred by a coordinating general practitioner.

Inpatient care

262. Levelling out the in some cases significant specialist and regional overprovision and underprovision is also an aim in the inpatient sector. One general problem is the long-observed underfunding of hospitals by the Länder, which calls for a fundamental reform of investment finance. The Council reiterates its repeated proposal (most recently in Special Report 2012, at 341) to provide for unitary financing for hospitals. Low and in many Länder further declining rates of investment have effectively introduced unitary financing by the back door. Looking at individual underprovided hospitals, there is a lack of qualified personnel that must be compensated for. Also, targeted development of models is needed to assess and compare the quality of inpatient care, and then apply the findings to improve the situation for patients and for hospital planning purposes, for example by means of structural quality requirements.

When it comes to the financial situation of hospitals in rural regions, there is little explicit data available. Studies indicate, however, that these hospitals are not fundamentally at any greater financial risk than those in urban areas, but that small and less-specialised hospitals tend to be financially worse off than bigger, more specialised ones. Also, in regions affected by dwindling population figures, a problem arises in that there comes a point when the population is no longer big enough to warrant running a hospital via the usual financing instruments.

263. To secure funding of easy-to-reach inpatient capacity for people in rural areas and to take account of the conditions affecting hospitals in such areas, the Council believes that the existing and in regulatory policy terms appropriate instrument of service guarantee fees should be strengthened and further developed as called for in the Coalition Agreement. As well as stipulating the specialist disciplines necessary for ubiquitous health care provision, appropriate minimum access or reachability criteria must also be specified – preferably based on journey times rather than distance. Application of these criteria would in turn define the group of hospitals and specialist departments deemed vital in providing health care services for the local population and to be considered for service guarantee fees. The calculation of service guarantee fees requires a standard for department-level contribution costing to be drawn up by InEK. Higher budgeted amounts for staff costs may also have to be included to account for the increased difficulty of attracting qualified personnel. Meeting the criteria for service guarantee fees should create a legal entitlement for the hospital concerned.

Service guarantee fees, including the staff cost surcharges contained in them, should be funded out of tax revenue outside of the Länder-specific per case base rates system. As a secondary measure, municipal subsidies could also be useful where they do not distort local competition. They are not, however, suited to securing broad-based health care provision in rural areas, not least because they depend on municipal spending power.

264. At the same time, a planned reduction of overcapacity is also necessary. This could also help in overcoming the increasing lack of qualified personnel in many hospitals. Defined reachability criteria should be used to obtain an insight into threatened regional shortfalls and hospital overprovision. Consideration should once again be given to creating a fund to promote the reduction and conversion of no longer needed hospital capacity by providing the Länder with the resources to eliminate such overcapacity and thus leading to the necessary market shakeout. Care should be taken in the process to avoid misallocation in favour of unneeded long-term care capacity, with preference given to transition payments.

265. In the interests of more integrated, multi-professional provision, further opening of hospitals to provide outpatient treatment makes sense and will be necessary over time. As a result, a mandatory provision should be added to Section 116a SGB V, requiring licensing committees to authorise suitable hospitals to provide outpatient health care to combat underprovision or meet additional local needs.

Greater use of the external hospital physicians system would also be useful because in some cases it can help in linking the outpatient and inpatient sectors. It is recommended that negative pay incentives be eliminated for this purpose. Recruitment of qualified doctors from other countries can help to fill the capacity gap, but it is highly recommended that they be required to prove proficiency in German – both in everyday situations and in medicine.

266. One weakness in current hospital planning is the lack of attention paid so far to quality issues. In respect of the controversial debate on minimum quantities, and with a view to establishing these under the law, a targeted research programme should be launched to assess quantity and structure-independent scope for quality improvement. Looking at rural regions, it is not necessary for all hospitals to provide the full range of services in the disciplines set out in their health care provision agreements. Instead, focus should be placed on high-quality basic care, with highly specialised care being transferred to better-equipped hospitals with the necessary infrastructure. Better coordination of highly specialised care between hospitals should be promoted, including in rural areas, in instances where providing specific forms of more specialised care in conjunction with the necessary infrastructure and expertise can make hospitals more economically viable.

Emergency care

267. Improving the cross-cutting emergency care sector makes it desirable to integrate, both in terms of location and disciplines, the three areas involved: physician on-call service, rescue services and hospital accident and emergency units. Even without this degree of integration, however, better coordination is still both useful and possible. The important role played by hospitals today is likely to increase even further in the future. A central clearing point with uniform emergency service numbers for all patient requirements can decide on the type of care needed in a given case, thus easing the burden and preventing unnecessary use of overly specialised services (such as the emergency ambulance service). The establishment of interdisciplinary emergency units in hospitals should also be pursued, integrating broadly qualified general medicine specialists (for example on an employed basis or as external hospital physicians) to take over caring for patients who would otherwise be treated by SHI-accredited doctors on standby duty. This can also help counter the false financial incentives in favour of unnecessary admission into inpatient care. An emergency or short-stay ward, case managers and contact to SHI-accredited doctors and nursing care services could assist further needs planning.

In addition, there is an ongoing need to extend opening times at SHI-accredited medical practices. On-call service districts have already been redrawn in some regions and can help share the workload more evenly among SHI-accredited physicians. Blanket geographical enlargement of on-call service districts, with a significant increase in journey times for doctors and patients, appears less useful for quality reasons.

Long-term nursing care

268. The importance of long-term nursing care will grow in future as a result of demographic change and the shifting morbidity spectrum. Like many countries, Germany's long-term care sector has yet to reach a satisfactory level of quality and robustness. There is also a marked lack of qualified personnel in some regions. This calls for the promotion and further development of the long-term care profession along with expanded and more clearly defined care provision to prepare in both qualitative and quantitative terms for the mostly complex needs of people who require long-term care.

269. Diverse measures are needed to counter the lack of qualified staff, among them greater training capacity and a reform of vocational education and training in nursing care which includes the integration of basic training. It is also necessary to increase the attractiveness of the nursing care sector and to provide new career options. This includes continued pro-active professionalisation of long-term care work, the provision of fundamental, primary qualification bachelor degree courses with integrated vocational education and training, subsequent master degree opportunities and intensified efforts

to secure upcoming scientists and researchers. Tertiary capacity in nursing science must also be increased, and improvements in working conditions and pay for long-term care workers are needed in order to secure a qualified workforce.

270. Because empirical knowledge is lacking in many aspects of long-term nursing care, improved data and more extensive research are needed. This is necessary because long-term care research in Germany has yet to match that performed at international level and has also come up against structural and, most importantly, financial barriers to date. To change this situation and provide for improved research promotion, the long-term care funds should allocate 30 percent of the resources available to them for long-term care improvement to long-term care research. It is recommended that these funds flow into the BMBF long-term care research budget and then be allocated in accordance with the prevailing criteria for such research.

271. With regard to the many challenges faced in the provision of long-term care, the new definition of the need for long-term care must be introduced without delay. Various bodies under the Federal Ministry of Health have put forward proposals for the redefinition of the need for long-term care, both in the previous and in this current legislative period. These should be taken up as quickly as possible as they provide the basis for overcoming the challenges involved in remedying the misprovision and underprovision that exists in many places.

272. Prevention of the need for and prevention during long-term care must be intensified, as must measures to promote health in old age. Alongside behaviour-oriented models, relationship-focused approaches are needed here, because these are especially well suited to vulnerable patients and those in fragile health, including people in need of long-term care. Great importance should be placed on the development of health-promoting environments, especially at municipal level. This also applies when developing models to prevent the need for long-term care and to avoid a worsening of a patient's condition during the provision of such care, and also for rehabilitation provided during long-term care.

273. Long-term care aimed at retaining patients' autonomy calls for adequate provision of information and advice services. Despite the incentives put in place, these are not widely available and are not always organised satisfactorily. Thus the structure, management and models used in long-term care advice and also in care support centres must be reassessed and revised as appropriate. Given the fragmentation of Germany's advisory landscape, new forms of integrated advice services must be developed that cut across sectoral boundaries (separation under SGV V, IX and XI). Outreach-based, mobile advice services must be expanded in rural areas and more intensive use of online communications media is also recommended.

274. Particularly in rural regions where the middle generation is gravitating to cities, intensified promotion of solidarity and assistance potential in families, companions, friends, social networks and informal help groups is needed. As part of this process, attention should be given to emerging forms of care (such as elderly couples, patchwork families and informal partnerships), the increasing age of family members providing care, and also groups not necessarily seen as care-relevant to date. New forms of support and new ways to boost resources and skills are also needed, with target-group specific models that focus on people's immediate environments and have been co-developed by family members who provide home-based care.

To prevent health risks and stress-related ailments, health promotion for family carers must also be improved. Educational and behavioural approaches are needed, as is the establishment of monitoring structures. Efforts must also be made to ensure equal recognition of home-based childcare and home-based care of dependent relatives across all areas of society and in (social) policymaking.

275. Non-residential care must be given priority in the future as patients tend to prefer home-based care. The quantitative and qualitative growth of non-residential care is also necessary given the expected increase in the number of people needing long-term care. Incentives must also be provided to foster population-oriented, differentiated non-residential care so that this can meet the entire breadth and diversity of regional needs. Special attention must be paid to the growing number of people with complex needs as well as those in need of long-term care who live alone. Added to this is the need for incentives to spark new forms of work organisation for improved staffing continuity and better-quality care. Bigger organisational units are of particular importance to provide greater flexibility in regions with poor service coverage. Local health centres for primary medical care and long-term nursing care which provide comprehensive general health care and long-term care services under one roof seem a highly promising option.

276. New forms of cooperation and a reassignment of responsibilities are also vital, especially in rural regions. A reform towards this should be pushed for under Section 63 (3c) SGB V. This has been made difficult so far by complex implementation requirements and the process must be simplified. To support the process, inter-disciplinary forms of learning must also be promoted.

277. Residential long-term care in homes will remain important for some people, although the needs of those involved have changed in response to the growing availability of non-residential care services. This development demands a response. The residential care sector needs the right personnel and the models to create needs-based care services for residents of long-term care homes. This primarily involves improved staffing, targeted integration of specialised (clinical) expertise and training (such as palliative and gerontopsychiatric care), transfer of management and coordination

responsibilities to appropriately qualified personnel and rigorous use of benchmarks to assess internal quality assurance processes.

What is also necessary is the establishment of new inpatient transition care similar to the current services provided for in dedicated short-term care, but equipped to cope with acute care and rehabilitation needs following early hospital discharge.

278. Many of the reform approaches currently under discussion have only a limited effect. Far-reaching structural reform is necessary, built on the notion of needs-based, integrated, professional and high-quality long-term care provision and aiming to boost both participation and community/neighbourhood focus. As part of this process, the municipalities must be better integrated into and play a responsible role in the structuring and planning of long-term care provision. Evidence-based municipal needs and provision planning is required based on the morbidity structure of the population. Appropriate assessment instruments are needed for this purpose. In the interests of participative planning, mandatory institution of long-term care consultation meetings at municipal level is recommended.

Solutions for integrated, multi-professional health care provision in rural regions

279. Given the complex challenges in Germany's health care system, with its cross-sectoral issues and regional inequities, one especially promising solution for rural regions would be to consolidate resources in an integrated, multi-professional form. Thus, apart from the outlined intrasectoral improvements, there is also a need for cross-cutting, population-oriented health care models, the piloting and implementation of which have been too halting to date. Also, successful implementation of integrated health care models in rural areas provides an opportunity to demonstrate their qualitative and economic potential in regions that currently have normal provision or are overprovided.

It can be assumed that the trends outlined in this Report will gain momentum in the future. Building on the future-focused model of coordinated health care with regional focus, which the Council presented in its Special Report 2009 (see Special Report 2009, at 1138ff), there is thus an urgent need to establish graded primary and secondary health care provision structures in rural regions which meet the criteria for a regionally-integrated health care service and are tailored to the needs of older people. Because this kind of process can only be maintained if it is part of a long-term, sustainable strategy, then in addition to isolated projects, institutionalised cooperation structures are needed as are targeted planning, implementation and evaluation. Promotion of innovative integrated health care models should also be taken into account when allocating resources under the planned innovation fund. Allocation criteria could include the degree of integration, meaning the diversity and number of participating institutions

and service providers in the various sectors, and suitability in securing health care provision in rural regions.

280. When it comes to planning, the recommendation is for cross-sectoral, Länder-level health care planning that goes beyond individual health professions. The establishment of joint Länder committees under Section 90a SGB V should be made a mandatory provision. Where a region is at risk of underprovision (for which more standardised criteria need to be developed), the mandate to secure health care provision would fall to these committees. Regional and municipal-level health care and long-term care conferences would subsequently be assigned ongoing responsibility for health care planning and monitoring in order to ensure structured cooperation between the stakeholders. These responsibilities would include the monitoring of long-term care services, which would in turn require improved availability of data on regional distribution of long-term care needs, the social circumstances and personal environment of long-term care patients, and the respective long-term care services involved.

Local health centres for primary medical and long-term care in rural regions

281. With regard to innovative health care models, the more or less centralised medical services that have been tried and tested at both national and international level appear to offer a fitting solution, with the aim of creating more efficient and effective structures that afford far better quality of service and care. These should involve greater mobility for patients and employees (doctors and the various health care professions), which can be achieved via a range of mobile (collect and return) services or the provision of 'mobile surgeries'.

With regard to rural regions in particular, the model of local health centres for primary medical and long-term care is recommended (see Fig. 8).

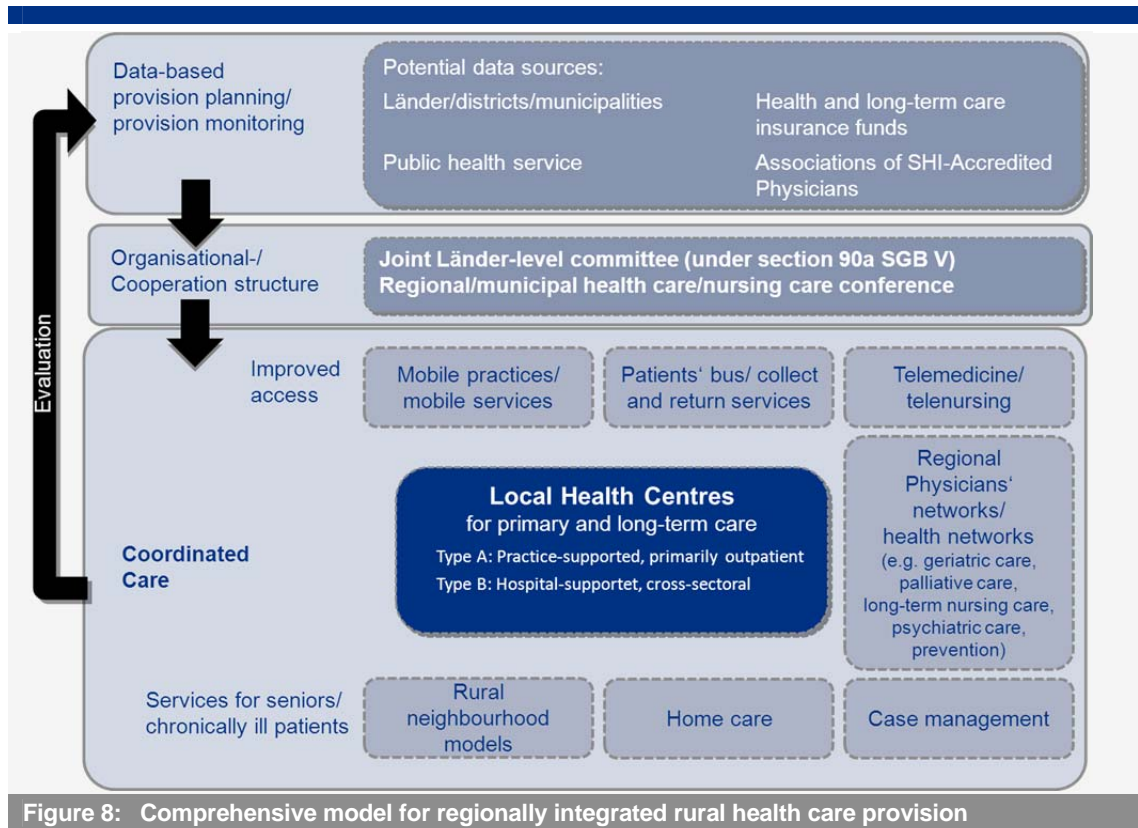


Figure 8: Comprehensive model for regionally integrated rural health care provision

Source: Own compilation

Depending on the range of health care services available in a given area, such centres can differ in composition and the provision offered. A practice-supported centre (Type A), with outpatient medical and long-term care services is one option. Further development of professional communities (formerly known as joint practices), practice partnerships/practice clusters and medical centres and practice clinics could all serve as a basis in this regard. A similar strategy could be applied for long-term care provision.

Hospitals, by way of contrast, could enter into partnership with other health care providers in the region to form a hospital-supported service (Type B) which would be adapted to local conditions and needs. The same would apply to residential care facilities or geriatric rehabilitation centres. In both cases, the health centre model would provide a range of outpatient/non-residential and, where appropriate, inpatient/residential services at a central location, either in a single building or on a campus.

The permutations outlined here should ideally take in (by integration or association) all of the medical, long-term care and social services, and other health care institutions needed to provide comprehensive health care, in particular for the elderly and chronically ill population. Inpatient care offered by health centres primarily involves geriatrics-related care. With responsibilities assigned on a regional or even transregional basis, it is possible and in some areas desirable for centres to provide highly specialised

services where, by 'pooling' the patients involved, a big enough patient group can be achieved to secure routine and specialist medical expertise along with appropriate back-up services to guarantee high-quality treatment. Also, a strong inter-disciplinary mix of health centre personnel can foster effective and efficient team work.

Outpatient medical care is primarily provided by SHI-accredited general practitioners and general specialist physicians with practices in the vicinity of a hospital and who are associated with that hospital. A local health centre can assume a coordinating role and also offer regular branch surgeries with doctors and medical staff in local communities. In this way, primary medical care provided via outpatient services can be further guaranteed without the need for patients to travel long distances.

Case managers can support patient-focused, cross-sectoral health care provision, coordinate appointments, make the necessary arrangements for treatment phases and, as part of a well-organised team with clearly divided responsibilities, ease the administrative burden on doctors when treating patients. Particular importance is placed on securing low-threshold access, via public transport connections and targeted mobile services – perhaps with local health centres providing their own patient transport services or some special form of public passenger transport (such as on-call taxi services). Regional accident and emergency services (SHI-accredited on-call physicians, rescue services, and accident and emergency units) could be integrated into and coordinated by hospital-supported local health centres.

282. Telemedicine applications could also be integrated into a local health centre, say in the form of teleconsultations and teleradiological services or telemonitoring. However, there is currently a tendency towards supply-driven use of telemedicine applications whose costs are significant and whose uses have in many cases not been adequately proven. It is thus recommended that these technological applications be tested as part of a package of health care services using complex interventions in (cluster) randomised, controlled studies. Telemedicine applications should always be seen as components of an overall model whose main focus lies in the benefits to patients.

283. To gain an insight into trends in the further development of new health care models for rural regions, a scientifically-founded model must be developed, tested and evaluated – something which has only occurred in part to date. Both the promotion of innovative health care models as set out in the Coalition Agreement and the planned promotion of health care research are an excellent foundation on which to develop, systematically implement and evaluate the proposed targeted, evidence-based health care models in rural regions. In the interests of scientific autonomy, the evaluative health care research should be conducted by methodologically experienced, producer and supplier-independent research institutes and a sustainable budget allocated to secure that research over time.

Appendix

Legal basis for the activity of the Advisory Council on the Assessment of Developments in the Healthcare System (from 1 January 2004)

Social Code, Book Five

Chapter Five

Advisory Council on the Assessment of Developments
in the Healthcare System

Section 142

(1) The Federal Ministry of Health and Social Security shall appoint an Advisory Council on the Assessment of Developments in the Healthcare System. The Federal Ministry of Health and Social Security shall establish an office to support the work of the Advisory Council.

(2) The Advisory Council shall have the task of preparing expert reports on the development of healthcare services, including the medical and economic effects. In the framework of the expert reports, the Advisory Council shall, giving consideration to the financial framework conditions and existing efficiency reserves, develop priorities for the reduction of medical services deficits and existing overuse, and indicate ways and means of further developing the healthcare system; it may include developments in other branches of social security in its reports. The Federal Ministry of Health and Social Security may define the subject of the reports in detail and also commission the Advisory Council with the preparation of special reports.

(3) The Advisory Council shall prepare the report at intervals of two years and submit it to the Federal Ministry of Health and Social Security, generally on 15 April and starting in 2005. The Federal Ministry of Health and Social Security shall present the report to the legislative bodies of the Federal Government without delay.

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Gutachten des Sachverständigenrates

Annual Report 1987

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(*Challenges and Prospects of Healthcare Provision*)
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Gesundheitsversorgung und Krankenversicherung 2000 – Eigenverantwortung, Subsidiarität und Solidarität bei sich ändernden Rahmenbedingungen
(Healthcare Provision and Health Insurance 2000: Self-Responsibility, Subsidiarity and Solidarity under Changing Framework Conditions)
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Appropriateness and Efficiency

Vol. I: The Formulation of Aims, Prevention, User Orientation and Participation

Vol. II: Improving Quality in Medicine and Nursing

Vol. III: Overuse, Underuse and Misuse

Addendum: Zur Steigerung von Effizienz und Effektivität der Arzneimittelversorgung in der gesetzlichen Krankenversicherung
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Vol. II: Quality and the Healthcare Infrastructure

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Vol. I: Cooperative Coordination and Competition, Socio-Economic Status and Health, Strategies of Primary Prevention

Vol. II: Interfaces Between Health Insurance and Long-Term Care Insurance, Therapeutic Appliances and Remedies in SHI, Factors Influencing the Prescription of Drugs

Stuttgart 2006

Report 2007

Cooperation and Responsibility – Prerequisites for Target-Oriented Healthcare

Baden-Baden 2008

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Coordination and Integration – Healthcare in an Ageing Society

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Competition at the Interfaces between inpatient and outpatient Healthcare

Bern 2012