A precise fit

Digitalisation in the healthcare system

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The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) is the central association of the health insurance funds at federal level in accordance with section 217a of Book V of the German Social Code (SGB V). It also acts as the national association of long-term care insurance funds in accordance with section 53 of Book XI of the German Social Code (SGB XI). The National Association of Statutory Health Insurance Funds is a public-law corporation with self-government. In accordance with section 217b subsection (1) of Book V of the Social Code, an Administrative Council is to be formed as a self-government body which is elected by the Members’ Assembly. With this Annual Report, the Administrative Council of the National Association of Statutory Health Insurance Funds is complying with its mandate in accordance with the Statutes to submit to the members, through its Chairperson and in agreement with the alternating Chairperson, an Annual Report regarding the activities of the Association (section 31 subsection (1) No. 9 of the Statutes). The Report covers the business year 2019.

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Dear Readers,

The fast pace of our time is clearly demonstrated by the corona pandemic. This issue is omnipresent; it changes priorities, and poses immense challenges particularly for stakeholders in statutory health and long-term care insurance, including social and joint self-government. These challenges must be overcome.

With all due respect for the seriousness of the current situation, we take a look back on the legislative activity of 2019, which has been pushed into the background, but is nevertheless significant. The reforms that have been adopted constitute an attack on social and joint self-government in several respects. There were even plans at times to completely abolish social self-government at federal level.

It is thanks to the great commitment on the part of many of those involved that this did not come to pass. In the discussion with Federal Health Minister Jens Spahn during the first extraordinary Members’ Assembly of the National Association of Statutory Health Insurance Funds, held on 26 September 2019, the delegates made it clear that the future of social co-determination in German healthcare must not be put at risk.

The alternative proposal put forward by the Federal Minister of Health with regard to the cabinet decision was no less problematic, however. In its form as initially planned, the Steering and Coordination Committee would have had the effect of reducing the decision-making rights of the Administrative Council in the National Association of Statutory Health Insurance Funds, and limiting the Board’s operational capacity to act. The regulation was rightly substantially relaxed before the decision was taken: The Steering and Coordination Committee now only makes recommendations. The competence of the Administrative Council remains intact. In retrospect, it took a lot of persuasion from self-government to prevent the massive restrictions that were planned. This is a fatal signal to those engaging voluntarily in self-government.

Despite numerous successful interventions, the Medical Service Reform Act (MDK-Reformgesetz) imposes several major restrictions on social self-government. The regulations on the limitation of terms of office and of functions in the Medical Services are completely new and alien to the system. It is no longer to be possible in future to elect anyone who already holds more than one honorary position in a self-government body of an insurer, an association of insurers, or another Medical Service. The incompatibility rule has nevertheless been deleted, so that the connection to the administrative councils of the member funds will be maintained at least in the Medical Services. This has unfortunately not been done for the Medical Service of the Federation.

The reforms furthermore also present statutory health insurance with enormous financial challenges. Together, the Appointment Service Act (Terminservicegesetz), the Act to Promote Nursing Staff (Pflegepersonal-Stärkungsgesetz), and the Medical Service Reform Act, are costing contributors several billion Euro. As far as these are necessary investments in better care, this is not objectionable. Especially in long-term care, improving the personnel situation is an important concern for those in need of long-term care and their relatives. What is however unacceptable is that the community of insured persons will have to accept incorrect invoices from hospitals in future, without any verification.

It is also inevitable that the predictable economic slowdown and the resulting developments on the labour market will have an impact on the currently still stable financing basis of statutory health insurance. Policy-makers would be well advised to prepare for the anticipated economic development in such times, and to preserve the financial reserves of statutory health insurance. Instead,
the Federal Ministry of Health has reacted to its own legislative proposals by raising the average additional contribution.

From the point of view of insured persons and of employers, it is important that the financial basis for statutory health insurance should be sustainably secured. This is the only way to maintain the balance between high-quality care and its affordability. We – that is the legislature and self-government - should work constructively on this.

Yours faithfully,

Dr. Volker Hansen
Uwe Klemens
Dear Readers,

If you take up this report and read it, many topics will seem familiar to you, but they will seem somewhat far removed in view of the current situation. Even though the year 2019, as depicted in this Annual Report, with its fast-moving health and long-term care policy, is in the not-so-distant past, and has occupied the stakeholders in many different ways, we are now confronted with a reality in the face of the corona pandemic that has placed many of the issues presented in the Report onto the backburner, shifted the emphasis within care, and made forecasts obsolete.

Despite all the scepticism, which should be taken seriously, we can say with cautious optimism that our healthcare system has proven to be highly flexible and very robust in the face of the immense challenge posed by the pandemic. The comparison of severe symptoms of the disease between different countries can be taken as an indication of this. Despite all the room for improvement that exists in the details, the structures of our healthcare system have nonetheless proven to be viable when it came to cushioning the corona-related peaks in strains. A prerequisite for this was rapid, joint action on the part of policy-makers and self-government.

The corona pandemic once again forcefully highlights the enormous value attaching to well-functioning self-government with sufficient room for manoeuvre. In preparation for and in support of the quickly-adopted legislation, self-government started by quickly and decisively stabilising the healthcare system by making it easier to take up benefits and facilitating billing procedures, initiating protective measures, and later implementing statutory stipulations on its own responsibility. In order to ensure a nationwide medical infrastructure for the general public as well as for particularly vulnerable groups in view of the changed priorities, self-government provided the necessary...
planning security with the rapid implementation of the protective shield for physicians, hospitals and remedy suppliers as well as long-term care and rehabilitation facilities.

The example of digitalisation has furthermore shown that some developments have been further accelerated by the pandemic. For example, the telemedical procedures were further reinforced in order to minimise the risk of infection for physicians and patients alike, against the background of the contact restrictions that were ordered. At the same time, it will be necessary to look back and reflect critically on where further-reaching basic principles are needed in order to accelerate the digitalisation of medical care even more with the current horizon of experience.

The sound financial situation of statutory health insurance, as well as the financial viability of the statutory health insurance funds, have proven to be an important stabilising factor in combating the pandemic and managing its side effects. The truth is, however, that the previously good financial situation of statutory health insurance has turned into the opposite within a short period of time, and the statutory health insurance funds now have a heavy financial burden to bear. The existing expenditure dynamic of the previous legislation is drastically intensified by the corona-related additional expenditure, whilst on the revenue side considerable losses are being recorded due to the foreseeable economic slump. Attention must therefore be urgently focused on the financial stability of the statutory health insurance funds, so that they do not get into trouble through no fault of their own.

Even if the current pandemic and its management largely determine day-to-day business in all areas, health and long-term care policy will have to face changed conditions and questions regarding the future orientation of medical and long-term care after the pandemic has been overcome. We will actively engage in this debate, and will work to ensure that self-government, as a mainstay of statutory health insurance, is once more accorded the status that it has again impressively demonstrated in overcoming the crisis.

It is not yet possible to predict at present in what state our healthcare system will emerge from this stress test, but we see good reasons for an optimistic outlook. Together with the Administrative Council, with the newly-established Steering and Coordination Committee, and with our partners in joint self-government, we will continue to do everything in our power to contribute to successful pandemic control, and also to ensure high-quality medical care for insured persons over and above this.

We wish you a stimulating read.
Yours faithfully,

Dr. Doris Pfeiffer
Chairwoman of the Board

Gernot Kiefer
Deputy Chairman of the Board

Stefanie Stoff-Ahnis
Member of the Board
The health policy scene was kept on tenterhooks in 2019 by Federal Health Minister Jens Spahn. This will also be the case in the first year of the new decade. More than 20 legislative projects have been initiated or already implemented. The political management of the Federal Minister of Health was characterised in 2019 by consistently working through the Coalition Agreement and a flair for topics that triggered a public response.

Important topics from the Coalition Agreement are in particular:
- more nursing care staff in hospitals and in geriatric care
- faster doctors’ appointments
- digitalisation of the healthcare system
- financial reform in statutory health insurance
- greater medicinal product safety

Topics such as the willingness to donate organs or undergo vaccinations against measles were necessary in content terms, and took on a high profile.

Sustainability of new statutes questionable
It remains to be seen how sustainable the effect of the legislation for the improvement of healthcare and long-term care will be. The planned coercive mechanism for reducing reserves in the health insurance funds makes little sense, as it is clear at the same time that the legislative machinery will lead to considerable additional expenditure. Moreover, the reduction in additional contributions may be popular, but it is not far-sighted in view of the expenditure dynamic that has already set in. The increase in expenditure is again more than 5%, whereas revenue is set to increase by only about 3%. It must be feared that there will be a tendency for the structural gap between revenue and expenditure to increasingly widen. This will trigger a yo-yo effect in contributions in the short term, thus leading to a significantly higher contribution rate requirement in the medium term.

Statutory misincentives
The Digital Care Act (Digitale-Versorgung-Gesetz) facilitates market access for digital health applications. The aim is to make greater use of the opportunities and potentials of digitalisation in order to benefit insured persons’ healthcare. The implementation of this goal is urgently needed, and is an overdue step. However, light and shadow are close together in this reform because the speed with which digital health applications are to be pushed into the reimbursement obligation of the health insurance funds is not everything. Rapid approval must not be allowed to contradict the basic principles of patient protection and economic efficiency. There is a risk of misincentives coupled with high costs, especially in the first year of a planned trial phase, since neither proof of benefit, nor proof of positive effects of care, is required. It is clearly predictable that the financial burden on the contributors ensuing from digital health applications will be offset by uncertain benefits.

Strengthening, not weakening, self-government
A characteristic feature of the political style of the Federal Minister of Health is also the desire for a constructive dialogue in public which not only does not shy away from conflicts, but which actually provokes them. This is particularly pronounced in the relationship with social self-government. The elimination of the self-governing bodies with the health insurance funds in the Administrative Councils of the Medical Services, as envisaged in the first draft, was prevented in the context of the reform of the Health Insurance Medical Service. The limitation of terms of office and of functions in the Administrative Councils of the Medical Services, which is alien to the system, is an onerous burden. Since the Medical Service of the Federation will in future be financed by the Medical Services, and no longer by the National Association of Statutory Health Insurance Funds, the members of the Administrative Council of the National Association of Statutory Health Insurance Funds are no longer represented on the Admin-

The sprint towards reforms in the healthcare system
Another draft departmental bill also planned to appoint full-time board members of health insurance funds to the Administrative Council of the National Association of Statutory Health Insurance Funds. This would be a breach of the system, and also an outright breach of promise in terms of the Coalition Agreement. The CDU/CSU and SPD explicitly and unambiguously stipulated in the Agreement that self-government should be strengthened.

This attack on self-government, which at the same time was intended to end the active social partnership in the National Association of Statutory Health Insurance Funds, was only just prevented in time. This has however not yet averted the danger. For example, the draft Fair Fund Competition Act (Fairer-Kassenwettbewerbs-Gesetz) that was passed as a substitute by the Federal Cabinet provided for a steering and coordination committee with extensive powers that was to be set up within the National Association of Statutory Health Insurance Funds. The Federal Minister of Health intended that the full-time Board members of the health insurance funds appointed to this new body would be entitled to veto decisions of the Administrative Council. It was possible to avert this unacceptable restriction of the Administrative Council’s ability to act by means of final amendments shortly before the adoption of the draft Bill.

The outlook for 2020
Further reforms are expected in 2020: The procedure is already underway for the draft Bill on Protection against Conversion Treatments, as are provisions for health insurance funds for electronic data transmission and online social elections. A fundamentally-revised draft for an Intensive Care and Rehabilitation Strengthening Act (Intensivpflege- und Rehabilitationsstärkungsgesetz) is about to be debated in Parliament. A Bill to promote local pharmacies is on the waiting list. A Digital Care Act II and the Reform of Emergency Care have already been announced. In addition, an overall concept for “cross-sector care” and a continuation of the hospital reform are expected, as the structural challenges here are still considerable.

There is an urgent need to reinstate the principle for 2020, not least in view of the financial development in statutory health insurance: Diligence before speed. Policy-makers will also have to face up to a further long-term care reform, which will focus in particular on relieving those in need of long-term care of the increasing co-payments for long-term care. One thing must be clear here: Long-term care is a task for society as a whole, and the State must step in with tax subsidies in future.

There is an urgent need to apply the principle of diligence before speed once more for 2020, not least in view of the financial development in statutory health insurance.
Federal Health Minister Jens Spahn attended the extraordinary Members’ Assembly of the National Association of Statutory Health Insurance Funds, held in September 2019, where he answered questions on his reform plans from representatives of social self-government and full-time board members of health insurance funds. The background for convening the Special Members’ Assembly was the present draft Bills on the Fair Fund Selection Act (Faire-Kassenwahl-Gesetz – GKV-FKG) and the Reform Act of the Health Insurance Medical Service (Medical Service Reform Act). Both legislative projects contained provisions aimed at abolishing social self-government in key institutions of statutory health insurance. For instance, the Statutory Health Insurance Fair Fund Selection Act provided that the Administrative Council of the National Association of Statutory Health Insurance Funds was no longer to consist of honorary administrative council members of the member funds, but of 40 full-time board members from the funds. According to the provisions contained in the draft Medical Service Reform Act, administrative council members of a health insurance fund were expressly no longer to be allowed to belong to these bodies. What is more, in addition to representatives of the health insurance funds, the Medical Service Administrative Boards are also to include representatives of patient organisations and care-providers among their members in future.

Statements against disempowerment
Roswitha Weinschenk, Chairwoman of the Members’ Assembly, already made it clear in the welcoming address: “In order to meet the challenges of the complex healthcare system, we need more social self-government and co-determination - not less.” Dr. Doris Pfeiffer, Chairwoman of the Board of the National Association of Statutory Health Insurance Funds, added in her keynote address: “Co-determination based on social partnership is part of the fundamental social consensus. The Ministry’s plan must therefore be removed from the Bill without replacement!” Prof. Peter Axer from the University of Heidelberg examined the draft Bills from a legal point of view. His conclusion: “The Medical Service Reform Act makes the Medical Service an expert organisation - but without the expertise of the health insurance funds.” In a subsequent chaired discussion with the two Administrative Council Chairmen of the National Association of Statutory Health Insurance Funds, Dr. Volker Hansen and Uwe Klemens highlighted the successful, fast, effective work of self-government. At the same time, they called on policy-makers to make a clear, unambiguous commitment to self-government and social partnership.

The position of the Federal Health Minister
The Federal Health Minister then explained to the approximately 260 attendees that he intended to stick to his fundamental reform plans, but was also prepared to compromise. For example, he could envisage retaining a smaller version of the honorary Administrative Council of the National Association of Statutory Health Insurance Funds, which was to continue to consist of representatives of employers and insured persons. In addition, he wished to uphold the greater equality of women and men in the Administrative Council. A new supplementary body, consisting of full-time board members of health insurance funds with decision-making powers, would enhance the voting culture of the National Association of Statutory Health Insurance Funds. Spahn considered that the exchange with the self-governing bodies would be promoted by including the board members of health insurance funds in what he referred to as “feedback loops”. This would help the Association as a whole to gain a more practical understanding. Spahn also defended the reform of the Medical Service. This would lead to greater acceptance of decisions among persons with statutory insurance, since the Medical Services would be completely free from the influence of the health insurance funds in future.
The position of the delegates present

The delegates of the member funds present, and the Administrative Council members, vehemently rejected Spahn’s statements. The planned legislative initiatives were said to be no more and no less than a direct attack on one of the fundamental principles of the German social system. Social self-government was said to be an expression of living democracy and to have proven its effectiveness in practice. Furthermore, the reform proposals were said to be factually unfounded, as the members of the Administrative Council were said to experience at firsthand the most diverse needs in healthcare and long-term care, given their close proximity to the insured persons, patients and contributors. So-called professionalisation, as mentioned in the explanatory memorandum to the Statutory Health Insurance Fair Fund Selection Act, was therefore said to be superfluous. With an Administrative Council consisting of full-time board members of health insurance funds, the social partners at federal level would furthermore be deprived of the opportunity to assert the interests of insured persons, patients and contributors vis-à-vis policy-makers. The Medical Service Reform Act was also said not to be necessary, since the health insurance funds and their administrative councils already had no influence on the evaluation practice in the Medical Service today.

Weakening key points of the legislative plans

The Federal Cabinet adopted the new version of the Statutory Health Insurance Fair Fund Selection Act in October 2019 under the new name of Fair Health Insurance Competition Act. The Federal Government reacted to the criticism voiced by the social partners, by the administrative councils of the health insurance funds and their associations, as well as by the National Association of Statutory Health Insurance Funds, and dropped the plan to provide for an Administrative Council made up of full-time board members. The planned legislative initiatives are no more and no less than a direct attack on one of the fundamental principles of the German social system.

Self-government presents a united front

The extraordinary Members’ Assembly showed that social self-government at the National Association of Statutory Health Insurance Funds stands together in difficult times. There were lively discussions on an equal footing, and a willingness to confront the Minister of Health with conclusive arguments. Social self-government is firmly opposed to any aspirations that jeopardise the independence of its tasks and its actions vis-à-vis state authorities.
The encroachments that have been carried out in recent years on the rights of social self-government culminated in the year under report in the plans to do away with self-government in the National Association of Statutory Health Insurance Funds and in the Medical Services. On the occasion of the visit by Federal Health Minister Jens Spahn, the Administrative Council sharply criticised the increasing restriction of the rights of action of joint and social self-government in the past and current legislative periods at its meeting held on 19 March 2019. The Federal Health Minister was asked for a statement with regard to topical examples - the change in the shareholder structure of gematik, the intervention in the financial autonomy of self-government through statutory stipulations for the reduction of financial reserves in the health insurance funds, or the intervention in the method evaluation of the Federal Joint Committee. The Administrative Council made clear its expectation for the scope for action of social self-government - as provided for in the Coalition Agreement - to be strengthened, and not restricted.

In defence of self-government

Only a few days after the visit by the Federal Health Minister, the plans for the reorganisation of the Administrative Council became known which the Minister presented with his draft departmental Bill of an Act for a Fair Selection of Health Insurance Funds in Statutory Health Insurance - later Fair Fund Competition Act (FKG). In a special session, the Administrative Council, together with representatives of the social partners, then publicly opposed the plans for the Administrative Council to be made up of full-time board members, thereby sending an unambiguous signal to the policy-makers. This was followed by numerous activities and measures at federal and Länder level, with which the Administrative Council, in cooperation with the social partners, fought against the reform project, which was seen as a general attack on self-government and social partnership.

After the planned organisational reform of the Medical Service (Medical Service Reform Act) became known, which also aimed to do away with self-government in the administrative councils of the Medical Services and at national level, the Administrative Council took up a clear position against this reform project. The fear was expressed in the public statements that the plans would lead to a change in the system of statutory health and long-term care insurance. The key word “professionalisation” and the alleged greater independence of the Medical Services merely served as pretexts to disempower social self-government.

The united approach of the administrative councils of the member funds and of the social partners was also clearly shown in an extraordinary Members’ Assembly at which Federal Health Minister Spahn answered questions posed by the delegates of the member funds and by the Administrative Council members. The criticism of the project was clearly expressed by the delegates and other invited guests. They called on policy-makers not to question tried-and-tested
decision-making structures. As a result of the massive resistance put up by self-government and the social partners, it was possible to prevent social self-government being done away with in the National Association of Statutory Health Insurance Funds in the further legislative procedure.

**Providing guidance for extensive legislature**

Despite the massive attacks on the self-government work of the National Association of Statutory Health Insurance Funds throughout the year, the Administrative Council lived up to its responsibility and made important decisions on healthcare. In addition to the planned organisational reforms enshrined in the Fair Fund Selection Act and in the Medical Service Reform Act, the five specialist committees of the Administrative Council also had to face the numerous legislative projects of Federal Minister Spahn - such as the Appointment Service and Care Act (Terminservice- und Versorgungsgesetz), the Act for More Safety in Medicinal Product Supply (Gesetz für mehr Sicherheit in der Arzneimittelversorgung), the Act to Reform the Training of Psychotherapists (Gesetz zur Reform der Psychotherapeutenausbildung), the Implant Register Act (Implantateregistergesetz), the Digital Care Act (DVG), and the Online Access Act (Onlinezugangsgesetz), as well as the discussion paper of the Federal Ministry of Health on the Reform of Emergency Care. Contrary to the criticism voiced by the Minister, self-government has certainly demonstrated its ability to act. It also proved that the existing committee structure and the established advisory processes have shown their value via the specialist level, the Specialist Advisory Council and the specialist committees up to the Administrative Council.

In the ongoing legislative procedure on the Appointment Service and Care Act, the Administrative Council has introduced political positions to improve dental care and to provide financial relief for insured persons. In addition to the increase in the fixed allowance from 50 % to 60 % provided for in the Act, the increase was brought forward to 1 January 2020. Further positions on cost limitation for insured persons were directed amongst other things at the permanent limitation of the increase rates in the Fee Schedule for Dentists, the delimitation of extra benefits and standard benefits, and the inclusion of fully-ceramic and metal ceramic crowns and bridges in standard care. These positions form the basis for a position paper to be introduced in the forthcoming legislature.

In accordance with the continuation of the Innovation Fund beyond 2019, as agreed in the Coalition Agreement between the CDU/CSU and SPD for the
19th legislative period, the Administrative Council adopted a position paper on the adaptation of the statutory provisions in a timely manner. The demands were largely incorporated into the Digital Care Act.

The Administrative Council also proved its ability to take action in the medicinal product sector. Against the background of the increase in high-priced medicinal products, especially for novel therapies, which are often approved without a sufficient data basis, the Council resolved on political demands to improve quality and affordability in this care segment.

Far-sightedness and initiative were shown by the Administrative Council in the establishment of a data collection point at the National Association of Statutory Health Insurance Funds that was provided for as part of the Digital Care Act. The Administrative Council approved the project at the recommendation of the specialist committees on fundamental issues and health policy and on digitalisation, innovation and benefits for patients which were addressing the topic. Furthermore, it advocated the use of the data collected via the data collection point by the National Association of Statutory Health Insurance Funds: for the statutory tasks to be performed in the framework of joint self-government on the one hand, and for care research on the other. The aim was to be to analyse developments in healthcare provision that are relevant to statutory health insurance.

**Position paper on the European elections 2019**

The elections to the European Parliament and the formation of a new European Commission were also scheduled in the year under report. In order to represent the interests of statutory health insurance vis-à-vis the European Union (EU), the Administrative Council contributed to the advance political debate at EU level by presenting a position paper. The focus was placed on cooperation between the Member States on important future topics such as the evaluation of medicinal products and medical devices, the use of digitalisation, or unified research efforts in order to jointly exploit the potential and make the healthcare systems future-proof.

In addition, the specialist committee on fundamental issues and health policy gathered information for its future work on the health policy priorities of the 9th legislative period of the EU in Brussels in order to be able to send out appropriate signals with a view to taking over the EU Council Presidency from 1 July 2020 onwards.
The long-planned change to the Board of the National Association of Statutory Health Insurance Funds took place in mid-2019. With this move, an experienced and passionate representative of statutory health insurance left the health policy stage with the retirement of Johann-Magnus von Stackelberg, Deputy Chairman of the Board of the National Association of Statutory Health Insurance Funds since 2007.

Johann-Magnus von Stackelberg began his career in statutory health insurance in 1982 at the AOK’s Scientific Institute. He was responsible from 1990 to 2007 for the contracts of the Federal Association of the AOK, most recently as Deputy Chairman of the Board. In July 2007, the Administrative Council elected him as a member of the Board and Deputy Chairman of the Board of the National Association of Statutory Health Insurance Funds. As a member of the founding board of the new association alongside Dr. Doris Pfeiffer and K.-Dieter Voß, Johann-Magnus von Stackelberg was initially responsible in the next year for the structural and personnel development of the departments of Out-patient Care, Medicinal products and Remedies, Hospitals and the Contract Analysis Staff Unit. After the National Association of Statutory Health Insurance Funds had taken over its statutory tasks as of 1 July 2008, Johann-Magnus von Stackelberg managed and shaped its contract policy.

Taking leave and praise
Numerous representatives from the healthcare system and from the political arena thanked Johann-Magnus von Stackelberg for his services to statutory health insurance. The Federal Minister of Health, Jens Spahn, also did not miss out on the opportunity to pay tribute to Johann-Magnus von Stackelberg in a very personal speech at the Summer Festival of the National Association of Statutory Health Insurance Funds.

Four decades at the service of statutory health insurance
Looking back, Johann-Magnus von Stackelberg counted among the most striking challenges the changes in the healthcare system which had to be mastered in statutory health insurance after 1990, with the achievement of German Unification. In his view, the Act on the Reform of the Market for Medicinal Products (AMNOG) has been particularly significant in recent times. He considered that it had been a groundbreaking and at that time overdue step to address the price monopoly of the pharmaceutical industry and to curb the increasing spending of the health insurance funds on medicinal products. Its implementation had however also required a large number of organisational measures and additional personnel resources at the National Association of Statutory Health Insurance Funds in
order to properly perform the new statutory tasks related to the negotiations on the reimbursement amount.

For almost four decades in the service of the community of solidarity, many of them in demanding positions, Johann-Magnus von Stackelberg has accompanied and been responsible for shaping change in the healthcare system in all its facets. In countless sets of negotiations held with the healthcare providers, he stood up unswervingly for quality and economic efficiency in healthcare with great clarity and clever analysis. His actions and his attitude were an impressive act of advocacy for the institution of joint self-government. With his departure, statutory health insurance loses not only an outstanding personality, but also one of its most distinguished experts in contract policy.

"I am at peace with myself." This was how Johann-Magnus von Stackelberg bade farewell to the staff of the National Association of Statutory Health Insurance Funds. A wonderful thing to say at the end of a long working life.

**The new Board of the National Association of Statutory Health Insurance Funds**

In the course of the reorganisation of the Board of the National Association of Statutory Health Insurance Funds, the Administrative Council elected Gernot Kiefer as Deputy Chairman of the Board in March 2019. He has been a member of the management of the National Association of Statutory Health Insurance Funds for roughly ten years. His responsibilities comprise the Divisions Central Services, with the Personnel and Finance sections, as well as the German Liaison Agency Health Insurance – International (DVKA). He is also responsible for the Health Division, which deals with the topics of long-term care insurance, benefit law, medical aids, and prevention. The Acts to Promote Long-term Care and the amendment of the definition of need for long-term care have constituted the most comprehensive reform of long-term care insurance since its introduction more than 20 years ago. Under the leadership of Gernot Kiefer, the National Association of Statutory Health Insurance Funds has created a solid foundation for action and provided important stimuli.

Stefanie Stoff-Ahnis joined the Board as a new member. She had already been elected by the Administrative Council in November 2018. The lawyer had previously been a member of the Executive Board at AOK Nordost, where she was responsible for the Care Division. She has been responsible at the National Association of Statutory Health Insurance Funds for the out-patient and in-patient care divisions, as well as for medicinal products and remedies, since 1 July 2019. Her goals are particularly to promote patient-friendly, sustainable, economically-efficient structures, and to secure and expand the quality of care - also by using innovative instruments.
Software_
The expansion of the digital infrastructure

The digitalisation of the healthcare system is contingent on connecting all healthcare providers to a secure data infrastructure, namely the Telematics Infrastructure (TI). Healthcare providers can use the correspondingly approved online applications as soon as they are connected to the TI. The first application that is already currently available is insured persons’ master data management. This means that insured persons’ master data can be checked online for their validity, and adapted if necessary. Further applications are currently being developed and tested.

**TI connection progressing only slowly**

The legislature’s aim was to connect all medical and dental practices to TI in 2019. As the number of products available for connecting practices (connectors) increased, the number of connected healthcare providers had already gone up by the end of 2018. In addition, the legislature set a deadline of 30 June 2019 for the connection, which provides for a reduction in remuneration in the event of non-compliance. It is nevertheless estimated that only 67% of out-patient healthcare providers were connected to the TI at the beginning of December 2019.

The Digital Care Act (DVG) is intended to further pursue the goal of linking all practices to the TI. To this end, the remuneration of contract doctors for services if the practice is not connected to the TI is to be reduced from its initial level of 1% to 2.5% from 1 March 2020 onwards. In addition, the legislature has introduced a new regulation in the Digital Care Act to extend the TI to other groups of healthcare providers.

It is estimated that only 67% of out-patient healthcare providers were connected to the TI at the beginning of December 2019.
Field test of emergency data management and electronic medication plan

In parallel, the industry is developing new applications for the TI and further developing the products for TI connection according to the specifications of gematik. The next stage will see the introduction of the specifically-addressed communication (“KOM-LE”) of the healthcare providers as a secure transmission procedure and the basic Qualified Electronic Signature (QES) service that is necessary for medical applications. In addition, the first manufacturer announced in mid-2019 that its connector would undergo approval tests at the end of 2019 for the first medical applications, emergency data management (NFDM) and the electronic medication plan (eMP), at gematik. When it has been successfully approved, the connector will be tested in a field test at selected practices and pharmacies, as well as in a hospital in a real environment for the NFDM and eMP applications. The first connector field test will launch in the first quarter of 2020. To use the medical applications, insured persons need a PIN for their electronic health cards (eGK). The National Association of Statutory Health Insurance Funds has informed its member funds in detail about the upcoming field test and the need to send out PINs/PUKs for a successful field test and for the use of the applications in the subsequent productive operation.

Electronic medical records and e-prescription in progress

The National Association of Statutory Health Insurance Funds is furthermore observing the development of further applications more closely. The necessary specifications for the development of electronic medical records (ePA) were published in May 2019, on the basis of which the industry can now develop them. The statutory deadline, subject to sanctions, after which the health insurance funds must be able to offer their insured persons electronic medical records by 1 January 2021, is highly ambitious. An advanced connector is also required for insured persons to use the electronic medical records. The deadline for electronic prescriptions (E-Rezept) is similarly ambitious. gematik must have published all the necessary documents for the development of the e-prescription by 30 June 2020, on the basis of which the industry can develop it.

Fundamental changes in the shareholder structure at gematik

The Appointment Service and Care Act (TSVG), which came into force in May 2019, legally regulated the acquisition of 51% of the shares in gematik by the Federal Republic of Germany, represented by the Federal Ministry of Health. The National
The role of statutory health insurance is to be limited in future to providing support, whilst at the same time expanding gematik’s competences.

Decision-making powers vs. payment obligations in gematik

Association of Statutory Health Insurance Funds now holds 24.5% of the shares in accordance with the Appointment Service and Care Act, as do the healthcare provider organisations as a whole.

The financing responsibility however remains solely with statutory health insurance. At the same time, its influence in gematik’s highest decision-making body, the shareholders’ meeting, was significantly reduced: A simple majority is sufficient here to pass resolutions.

The change in the shareholder structure was notarised during the shareholders’ meeting held in mid-May 2019. Under the chairmanship of the new chairman of the shareholders’ meeting, now appointed by the Federal Ministry of Health, it was decided that the statutory bodies of gematik should continue to exist as before. The special shareholders’ meeting in June 2019 then appointed Dr. Markus Leyck Dieken, with the vote of the Federal Ministry of Health and its majority of 51%, as the new managing director of gematik. The restructuring of the existing committees was continued at the shareholders’ meeting held on 2 October 2019. The previous expert committees were reorganised by merging or dissolving them. The importance of the shareholders’ specialist input was reassessed and limited in this process. Their role is to be limited in future to providing specialist support, whilst at the same time expanding gematik’s competences.
Health apps on prescription

The Bundestag adopted the Digital Care Act (DVG) in November 2019. The legislature’s declared aim is to take advantage of the many possibilities offered by digitalisation for improving healthcare. For the first time, insured persons will have a legal entitlement to receive medical care using digital health applications, parallel to the types of benefit listed in Book V of the Social Code (SGB V). The Federal Institute for Drugs and Medical Devices will examine the extent to which these actually have positive effects on care provision and, after successful examination, list them in an official register as reimbursable digital health applications. In this way, the legislature is transferring responsibility for shaping the system to a state institution instead of to joint self-government, as had previously been the case.

**Patient protection before speed**

The National Association of Statutory Health Insurance Funds argued in the discussion regarding the content of the test criteria and remuneration arrangements for digital health applications that the basic principles of patient protection and economic efficiency must also be observed here in the interest of the insured persons. Rapid approval must not be an end in itself. This concern was taken up at short notice in a motion for an amendment. The test criteria must now at least comply with the principles of evidence-based medicine. Positive healthcare effects are only to be established if either a medical benefit or a patient-relevant structural and procedural improvement has been proven. This is also significant for the price negotiations with the National Association of Statutory Health Insurance Funds. It will negotiate in future with the manufacturers of the digital health applications on the remuneration amounts that become valid one year after inclusion in the official list. Lower prices can be agreed if the manufacturers do not provide the necessary evidence, for example in the case of provisional inclusion in the directory for digital health applications for testing purposes. The principle of evidence-based medicine was however not yet appropriately implemented in the subsequent statutory ordinance.

**Electronic medical records and data protection**

From 1 January 2021 onwards, all health insurance funds must provide their insured persons with electronic medical records approved by gematik. Otherwise, massive financial sanctions may be imposed. The electronic medical records will be established as a central exchange platform between healthcare providers and insured persons. Electronic medical records are an application that is voluntary for insured persons which they must consciously opt to use. There is a transitional period until the beginning of 2022 for existing electronic health files to be migrated to the electronic medical records, whilst from April 2022 onwards, in accordance with the Digital Care Act, electronic medical records may no longer be financed by the funds.

The insured persons themselves have full data sovereignty. They can grant access rights for different areas of authorisation, or not allow any other person to access their own records. A fine-grained authorisation concept in this respect must be implemented from 2022 onwards. Until then, the first year of the introduction of the electronic medical records (2021) will therefore be subject to special duties of clarification and information. The electronic medical records initially provide for three authorisation areas:
1. documents of healthcare providers
2. documents of insured persons
3. documents of health insurance funds

If insured persons grant their health insurance fund authorisation to access the electronic medical records, health insurance funds can exclusively place documents in the area for health insurance funds. The health insurance funds cannot...
Inclusion in the directory for digital health applications (DiGA)
Remuneration agreements between the National Association of Statutory Health Insurance Funds and manufacturers

Manufacturer applies for inclusion in the DiGa directory in accordance with section 139e of Book V of the Social Code

Federal Institute for Drugs and Medical Devices examines and decides within 3 months

Temporary inclusion in the DiGa directory in accordance with section 139e of Book V of the Social Code

Evaluation

- 12 months’ trialling in standard care
- discount manufacturer’s price in first year
- remuneration of medical services

Direct inclusion in the DiGa directory

- manufacturer’s price in the first year
- remuneration of medical benefits

Inclusion in the DiGa directory in accordance with section 139e of Book V of the Social Code

Adjustment of the Schedule of Fees 3 months after inclusion in the directory for digital health applications

Price negotiations with National Association of Statutory Health Insurance Funds

Potentially Arbitration Office after 1 year of unsuccessful negotiations

The insured persons themselves have full data sovereignty regarding their electronic medical records.

Promoting digital care innovations
In order to improve the quality and efficiency of care, health insurance funds are given the opportunity to financially support the development of digital innovations. These can be: digital medical devices, telemedical or IT-based procedures, or the development of apps or procedures for the application of Artificial Intelligence. Support can be provided by health insurance funds in cooperation with third parties, or through an equity participation of up to 2% of the fund’s financial reserves. The new arrangement will enable the health insurance funds to be even more active in shaping healthcare in the future.

Data transparency is to strengthen care research
Another goal of the Digital Care Act is to be able to make better use of data for research purposes in future. The data of the morbidity-orientated risk structure equalisation have been made available to the insured persons themselves have full data sovereignty regarding their electronic medical records.

The Year’s Topics

The records log all access. These log entries cannot be deleted, and can only be viewed by the record owner. The authorisation concept will be designed in even greater detail in later expansion stages, for example by separately granting access rights for individual groups of doctors or documents and (confidential) subfolders.

Promoting digital care innovations
In order to improve the quality and efficiency of care, health insurance funds are given the opportunity to financially support the development of digital innovations. These can be: digital medical devices, telemedical or IT-based procedures, or the development of apps or procedures for the application of Artificial Intelligence. Support can be provided by health insurance funds in cooperation with third parties, or through an equity participation of up to 2% of the fund’s financial reserves. The new arrangement will enable the health insurance funds to be even more active in shaping healthcare in the future.

Data transparency is to strengthen care research
Another goal of the Digital Care Act is to be able to make better use of data for research purposes in future. The data of the morbidity-orientated risk structure equalisation have been made available to

Illustration: National Association of Statutory Health Insurance Funds
The reorganisation of data transparency now provides for additional accounting data of the statutory health insurance funds to be made available, on top of the existing data. The National Association of Statutory Health Insurance Funds, together with the health insurance funds, will take over the role of data collection. The highest priority attaches to the protection of the insured persons’ data. The data are already pseudonymised by the health insurance fund, and will not be passed on with the name or insured person’s number. Taking on the new role will enable the statutory health insurance funds and their associations to contribute their expertise to the design of the reorganisation at a central point.

available since 2014 as part of the accounting data of the persons with statutory health insurance for a defined group of authorised users, among others for care research and the health insurance funds and their associations, for further institutions of self-government, and for institutions of the health reporting of the Federation and of the Länder. Authorised users can submit an application for their projects. If the legally-permitted purposes of use are complied with, the applicants receive aggregated results. Both today and in the future, individual datasets remain under the control of the Research Data Centre, and will not be passed on to third parties.
The Year’s Topics

First digital care services

The self-government partners and policy-makers created a series of framework conditions in 2019 for the implementation of digital and telematic applications. The aim is to make the digital potential available to the community of insured persons, patients and contributors.

E-prescription underway
The Act on the Safe Supply of Medicinal Products is intended to enable persons with statutory insurance to use the telematics infrastructure (TI) to manage and redeem their prescriptions digitally in future. Three implementation steps are planned for this:

1. The National Association of Statutory Health Insurance Physicians and the National Association of Statutory Health Insurance Funds are to agree by 31 March 2020 on the arrangements necessary for the medical profession to use e-prescriptions.

2. The German Pharmacists’ Association and the National Association of Statutory Health Insurance Funds are to lay down all the necessary regulations for pharmacists to use the e-prescription in the framework agreement on the supply of medicinal products.

3. gematik has until 30 June 2020 to implement the measures necessary for an e-prescription to be sent via the TI. This data channel is to be gradually extended to include other prescriptions, and in future will also be possible without direct contact between physicians/dentists and insured persons.

In line with the three parties involved in the drug supply process - physicians, insured persons and pharmacies - the legislature has created a direct relationship of dependence between the contracts underlying the e-prescription. The contract between the medical profession and the National Association of Statutory Health Insurance Funds, on the one hand, and between pharmacists and the National Association of Statutory Health Insurance Funds, on the other, must be explicitly compatible with one another. Both contracts must provide for the use of the TI to transmit the e-prescription.

A digital channel for certificates for incapacity for work
The National Association of Statutory Health Insurance Funds already presented a concept for converting from the current roughly 77 million certificates of incapacity for work in paper form to an electronic procedure back in 2018, and made an active contribution to the political debate. The electronic certificate of incapacity for work was largely implemented by the legislature.

Digital transmission of data from electronic certificates of incapacity for work

Illustration: National Association of Statutory Health Insurance Funds
with the Appointment Service and Care Act and - in a second step - with the Third Act to reduce bureaucracy, especially for small and medium-sized enterprises. An electronic procedure for the transmission of data on incapacity for work by contract doctors and hospitals to the health insurance funds using the TI will be mandatory from 1 January 2021. Employers of persons with statutory health insurance are also to be integrated into the electronic procedure as of 1 January 2022. The health insurance funds will then be obliged to make the data on incapacity for work that they receive available in electronic form for electronic retrieval by employers or, in the case of insured persons in marginal employment, by the mini-job centre.

The National Association of Statutory Health Insurance Funds has actively accompanied the legislative procedures, and started early with the preparation of the implementation of the procedure for the electronic certificate of incapacity for work, so that it was already possible to initiate the required datasets (incl. dataset formats and contents) and procedural arrangements in 2019.

**Expansion and promotion of video consultations**

Video consultations have been part of standard care as benefits provided by contract doctors since 2017, but have so far only been provided on a small scale. However, increased take-up of video consultations in contract doctors’ care has considerable potential for increasing the range of services, making the treatment of persons with statutory health insurance more flexible, and reducing waiting times. In order to establish video consultations in contract doctors’ care, the National Association of Statutory Health Insurance Funds agreed with the National Association of Statutory Health Insurance Physicians on extensive adjustments to the Standard Schedule of Fees (EBM) as of 1 October 2019.

The adaptations aim on the one hand to abolish the previously planned restrictions on the billing of video consultations which were based on statutory and professional-law stipulations, and thus to give video consultation scope for broad application. In this context, in particular the originally-planned connections with indications (e.g. video consultations exclusively for checking wounds) were already abolished in the spring of 2019. In addition, as a result of the amendment of the ban on remote treatment by the German Medical Assembly, the Standard Schedule of Fees was adapted to also allow video consultations in future in the context of exclusively remote treatment of previously unknown patients. It is

**Video consultations have considerable potential for increasing the supply of care, making the treatment of persons with statutory health insurance more flexible, and reducing waiting times.**

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Video consultation

**Illustration: National Association of Statutory Health Insurance Funds**
therefore no longer a prerequisite for carrying out video consultations that patients have already been treated once in person. Rather, it is now up to the physician to decide for which (possibly unknown) patients it is sufficient and appropriate to carry out a video consultation instead of a personal consultation in the doctor’s practice.

Accompanying regulations were made for authentication in the sense of an identity check of insured persons by doctors’ practices in the case of exclusively remote treatment without presenting an electronic health card. In addition, extensive openings were implemented for video consultations in psychotherapeutic care and in the care of persons in need of long-term care.

Adjustment of the remuneration as an incentive
In order to encourage contract doctors to conduct more video consultations, various adjustments have been made to the remuneration for video consultations which are intended to provide targeted incentives. On the one hand, the previous remuneration for a video consultation via a single benefit has been abolished. Instead, contract doctors will be able to charge their basic lump sum for the exclusively remote treatment of patients within a quarter as a lump sum for remote treatment. Secondly, a start-up subsidy, limited to two years, was introduced for implementing video consultations at the initiative of the National Association of Statutory Health Insurance Funds. This provides that surgeries which regularly conduct video consultations are to receive an additional remuneration of 10 Euro per video consultation, up to a maximum of 500 Euro per quarter, in addition to their medical services and a remuneration for the technology. Statutory health insurance provides additional funds (outside of the budget) in order to finance this start-up support.

The measures that have been adopted have removed major limitations and created incentives to make video consultations an integral part of contract doctors’ care and to use them targettedly in the treatment of persons with statutory health insurance.

Electronic prescriptions: What will change for insured persons?

**Physicians**
- Status quo:
- digital prescriptions
- digital invoicing
- digital organisation of

**Insured persons**
- Status quo:
- Insured persons deliver an analogue prescription in person.

**Pharmacies**
- Status quo:
- digital invoicing
- digital inventory management
- digital organisation of

**Physicians**
- Insured persons use TI, for instance with a digital key to the server, to transmit and manage electronic prescriptions.
Promoting innovative forms of care

The Innovation Committee that is part of the Federal Joint Committee has been promoting innovative care models and application-orientated care research since 2016 with an annual funding volume of up to 300 million Euro. In the fourth year since the Innovation Fund was established, health insurance funds, physicians’ associations, university clinics and general hospitals, as well as universities and research institutes, have again submitted numerous funding applications to the Innovation Committee. The project proposals are evaluated in accordance with the funding criteria published in the respective promotion announcements. Selected projects can be funded for a period of up to four years. The decision of the Innovation Committee is also influenced by the funding recommendations of the ten-member Expert Advisory Council, which contributes its scientific and practical expertise to the assessment process.

Testing new forms of care

On 19 October 2018, the Innovation Committee published a call for proposals for new forms of care, both thematic and non-topic-specific. A total of 89 project applications were submitted by the deadline to test care innovations under everyday conditions and evaluate them according to scientific standards. The Innovation Committee selected 31 innovative projects for funding in the area of new forms of care, and these will receive 167.9 million Euro in financial support. This means that the Innovation Committee did not fully take up the available funding volume in 2019. The reason for this is the project selection, which is carried out strictly according to the funding criteria and does not allow any compromises at the expense of quality.

The National Association of Statutory Health Insurance Funds is pleased to see that health insurance funds are again involved in the majority (98 %) of the projects that have been selected. Member funds of all associations of types of health insurance fund are represented through many alliances across different types of insurance fund. As a rule, the care models are based on selective contracts, so that the respective projects are based on a stable legal framework and the care services can as a matter of principle be continued even after the funding has expired.

Care research

A total of 197 project proposals were submitted in response to the calls for proposals made on 19 October 2018 and 23 November 2018 in the funding area of care research. The main topics of the calls for proposals include

- the impact of evidence-based health information for patients
- processing and interlinking of health data at population level
- accessibility and improving the situation of people in need of assistance

The Innovation Committee has decided to support 59 projects. Of these, 19 projects belong to the thematic area, one project to the further development of telemedical cooperation networks of in-patient and out-patient institutions.

New forms of care by topical areas 2019

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<td>167.9 mill. €</td>
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Continuation and further development of the Innovation Fund

The Digital Care Act extends and develops the Innovation Fund with a reduced funding volume of 200 million Euro up to 2024. The new forms of care now account for 80 % of the funding volume, and care research makes up 20 %. In both areas, a maximum of 20 % of the funded proposals are to come from the thematically-open call for proposals. The number of projects funded in the new forms of care will be limited to 20 from 2020 onwards as a rule, and the applications will generally be evaluated in a two-stage procedure. The elaboration of the applications can be supported by financial resources from the Innovation Fund for up to six months. A new funding area will be added in care research: Guidelines setting out special care needs can be (further) developed with at least 5 million Euro. In addition, the ten-member Expert Advisory Council will be replaced by a broader pool of experts.

Once projects have been completed, the Innovation Committee, in accordance with the Digital Care Act, will make a recommendation for new forms of care within three months on the transition to standard care. In doing so, it submits a concrete proposal for the transition, and designates the competent organisations of self-government. In the case of care research, the Innovation Committee can make a recommendation for the transition to standard care.
Cookie
Taking stock of the digital healthcare market

In view of the ever-increasing prevalence of digital applications and devices in the healthcare sector, the National Association of Statutory Health Insurance Funds has commissioned a study to analyse the digital evolution in the healthcare system. The study focused on emerging structures, market participants, digital services and implications for the healthcare system and statutory health insurance.

The study addressed the following key questions:
1. Who are the new stakeholders on the healthcare market? Is a new class of “healthcare providers” emerging?
2. What business models are the new stakeholders such as Google and Co., as well as start-ups, pursuing?
3. What dynamics of change, and which challenges for statutory health insurance, result from this, especially with regard to benefit assessment and patient protection, as well as regarding options for regulating data flows?
4. What are the implications for the governance structures of statutory health insurance? Are the tools available to joint self-government optimally geared to this? What are the implications with regard to financing issues?

A stocktake at national and international level
When taking stock, relevant developments in the national and international context, as well as the local stakeholders, were analysed. The results showed that digital healthcare services are often software-based mobile applications, special computer programs, or combinations of hardware and software. They aim as a rule to bring about concrete improvements in care, and are characterised by agile product development cycles.

New players on the healthcare market
The providers of digital healthcare services have special characteristics. As new healthcare providers, start-ups provide important stimuli for the development of digital applications for the healthcare system. They are often established on the second healthcare market, but seek to become integrated into the first healthcare market. Global technology companies with correspondingly large financial, development and marketing resources wish to use the disruptive potential of digitalisation for themselves in order to change the structures of the healthcare market in the long term and open up market access. They focus on digital solutions for data aggregation and processing. Established players in the medical technology and pharmaceutical industries are supplementing their traditional products to include digital solutions, primarily in order to achieve an add-on to existing services.

An active steering role should be taken by statutory health insurance
The data-generating and data-based processes, which are becoming more significant in the course of digitalisation, enable extensive analysis and control possibilities in the healthcare system. They offer the potential to develop population-related care models, personalised treatment methods and predictive screening measures at patient level by aggregating and summarising data. The disruptive pressures that the new healthcare providers are bringing to bear on the second and first healthcare markets therefore necessitate a more active steering role on the part of the statutory health insurance funds, their associations, and the National Association of Statutory Health Insurance Funds.

Promoting insured persons’ media and digital literacy
Digital media and healthcare services are becoming increasingly important for insured persons and patients. The strong take-up is thanks to the increasing need for information on health topics. Due to the large number of
Implications for the statutory health insurance funds, their associations and the National Association of Statutory Health Insurance Funds

Source: Deloitte, illustration: National Association of Statutory Health Insurance Funds

Health policy significance

There is considerable pressure on the healthcare system in Germany to make the potential offered by digitalisation available to persons with statutory health insurance and to patients. The mission debate regarding digitalisation in the healthcare system is being conducted by many different stakeholders in Germany. The health insurance funds and their associations must take on an even better coordinated, more active role in shaping the healthcare system through digital applications in future. In general, considerable trust is placed in the institutions of statutory health insurance when it comes to the digitalisation process. Digital solutions must form an integral part of the objectives of the statutory health insurance funds, their associations and the National Association of Statutory Health Insurance Funds, and they must be integrated into the healthcare system.

It must be ensured that the same requirements as to effectiveness, safety and benefit are imposed on digital health services as they are for medicinal products or medical device innovations.

Autonomous management and organisational efficiency

New options of analysis and management with the potential to change the distribution of roles in healthcare.

Health policy significance

A large number of interest groups interpreting digitalisation in their own interest and claiming the right to interpret it as they see fit.

Patient protection and efficiency of care

Insured persons make use of digital services; this necessitates safeguarding quality, benefit and efficiency of care.

Implications for the statutory health insurance funds, their associations and the National Association of Statutory Health Insurance Funds

It must be ensured that the same requirements as to effectiveness, safety and benefit are imposed on digital health services as they are for medicinal products or medical device innovations.
What benefits do assistance technologies have for persons in need of long-term care? On behalf of the National Association of Statutory Health Insurance Funds, the Institute for Innovation and Technology (iit) conducted a stocktake of assistance technologies for long-term care which provides an overview of the state of development, benefit and potential for persons in need of long-term care. This makes it possible to derive a picture of the state of development and implementation of digital solutions.

**Systematic needs analysis**
This was the first time that information had been collected in a systematic, comprehensive manner on the benefits of assistance technologies. This was based on literature and document research, discussions and workshops with experts, as well as case studies. The focus was less on the technologies themselves than on the needs of people in need of long-term care in order to maintain or regain their independence in various areas of daily life.

**A benefit assessment model**
In order to classify the benefit ensuing from assistance technologies, a model has been developed which takes into account the needs of people in need of long-term care and those of people involved in the provision of such care, as well as aspects of the housing, living and care situation. This results in potential criteria for a benefit assessment in the respective long-term care context.

Promising assistance technologies the development of which is already advanced and for which there are indications of a benefit are available in particular in the areas of mobility, cognitive and communication skills, as well as social contacts. These are for example founded on game-based assistance technologies, applications from robotics, or app-based therapies. Further investigations are however necessary in order to make reliable statements on effectiveness and benefit.

The testing and market launch of the majority of the assistance technologies from the case studies examined are still pending. Questions still need to be answered regarding how assistance technologies can be integrated into existing long-term care processes and care structures, which business and financing models are suitable to establish the technologies on the market, but also which risks might exist, especially with regard to persons in need of long-term care.
Faster appointments and better care

The Appointment Service and Care Act (TSVG) entered into force in May 2019. It aims to provide equal access to out-patient medical care for all persons with statutory insurance by reducing waiting times for doctors’ appointments, extending the range of consultation hours, and improving the associated remuneration of contract doctors’ services related with this. The Act furthermore aims to improve care in rural and structurally-weak regions by further developing the basics of requirement planning and expanding the promotion and guarantee instruments of the Associations of Statutory Health Insurance Physicians.

Appointment service points reachable 24/7
The legislature has assigned extensive tasks to joint self-government in order to achieve these goals. The Associations of Statutory Health Insurance Physicians were thus obliged to set up appointment service points by early 2020 at the latest. These must be available 24 hours a day, seven days a week on a uniform nationwide telephone number. Their services for insured persons include
- arranging prompt treatment appointments
- providing support in finding a general practitioner
- arranging immediate medical care in acute cases on the basis of a uniform, standardised initial assessment procedure (to be implemented by early 2020 at the latest)

Adjustments to both the Standard Schedule of Fees (EBM), and to the Federal Skeleton Agreement for Physicians (BMV-Ä) were necessary for implementation, for which corresponding provisions were made by the end of August 2019.

Extrabudgetary remuneration
In order to give all persons with statutory insurance equal access to out-patient medical care, the Appointment Service and Care Act provides for a variety of remuneration incentives to motivate physicians to allocate appointments more efficiently. With effect from September 2019, a resolution of the National Association of Statutory Health Insurance Funds and the National Association of Statutory Health Insurance Physicians on the Evaluation Committee added the following extrabudgetary supplements to the Standard Schedule of Fees:
- percentage supplements for treating patients within a specific period of time where the appointment was arranged through the appointment service points
- supplement for promptly treating an acute case, i.e. treatment no later than the day after first contact by the insured person via the appointment service points
- supplements for general practitioners or paediatricians, provided that an appointment for specialist further treatment has been successfully arranged in cases of a medical emergency, i.e. no later than four calendar days after the need for treatment has been determined by the general practitioner or paediatrician.

According to the Appointment Service and Care Act, specialist physicians providing primary care near people’s homes must offer open consultations for at least five hours per week. The partners to the Federal Skeleton Agreement for Physicians agreed on selected groups of physi-

Illustration: National Association of Statutory Health Insurance Funds
Further provisions contained in the Appointment Service and Care Act

- expansion of the list of benefits of statutory health insurance to include benefits for the cryopreservation of egg or sperm cells or germinal cell tissue for subsequent artificial insemination
- expansion of the list of benefits of statutory health insurance to include HIV pre-exposure prophylaxis services
- expansion of the fixed subsidies for prosthetics (with effect from 1 October 2020) and a bonus scheme that constitutes a lesser burden on insured persons
- expansion of follow-up care after hospital treatment and rehabilitation to include specialised out-patient palliative care benefits, home help, as well as respite care
- obligation for contract doctors to examine gradual reintegration when issuing a certificate for incapacity for work of six weeks or more
- adjustment of self-help support to at least 70 % as part of the framework of lump-sum support across different types of insurance fund

Additional costs of roughly 500 million Euro per year will result, even if the volume of benefits remains unchanged.
Doctors’ fees up by almost one billion Euro

The negotiations on fees for registered doctors and psychotherapists for 2020 have been brought to a negotiated conclusion: The statutory health insurance funds will provide a total of around 995 million Euro in additional funding for the out-patient care of their insured persons. At the same time, the negotiating partners agreed to support video consultations.

**Difficult negotiations, but an amicable settlement**

The ideas of the National Association of Statutory Health Insurance Funds and those of the National Association of Statutory Health Insurance Physicians were initially far apart: Whilst the National Association of Statutory Health Insurance Funds sought to compensate for the general cost development in surgeries with an increase of 0.24 % (approx. 85 million Euro) in the orientation value, the National Association of Statutory Health Insurance Physicians demanded an increase of 2.67 % (approx. 950 million Euro). In particular, the National Association of Statutory Health Insurance Physicians wished to ensure that the hospitals’ salary agreements also applied to the out-patient sector for freelance physicians. This was rejected by the National Association of Statutory Health Insurance Funds in view of the increasing surpluses in doctors’ surgeries.

It was ultimately possible to reach a negotiated agreement once again. The National Association of Statutory Health Insurance Funds and the National Association of Statutory Health Insurance Physicians agreed that the orientation value was to increase by 1.52 %. This corresponds to a rise of 565 million Euro. As the burden of disease for persons with statutory health insurance is declining slightly, the treatment requirement for 2020 is by contrast expected to be reduced by 0.2 % (approx. 40 million Euro) nationwide.

**Rising statutory health insurance expenditure for extrabudgetary benefits**

The amount of services subsidised outside the budget, such as preventive check-ups, on the other hand, is growing steadily due to the high demand on the part of insured persons. It can be assumed that this increase will continue at around 3.0 % in 2020, which is why the fees are expected to rise by a further 470 million Euro. In total, registered doctors will therefore receive an additional approximately 995 million Euro in 2020.

The assessment committee has furthermore decided to remunerate “medical assessment and counselling services” in human genetics on an extrabudgetary basis from 2020 onwards - initially limited to three years. In addition, the existing extrabudgetary remuneration for services in tumour genetics was extended by three years.

**Additional income for doctors through the Appointment Service and Care Act**

In addition to the fee negotiations, contract doctors will also benefit financially from the Appointment Service and Care Act (TSVG), which was passed in early 2019. The Act will take full effect in 2020. Doctors can generate additional income in out-patient care, for example by treating patients in open consultations without appointments or in consultations arranged by an appointment service point. The National Association of Statutory Health Insurance Funds presumes that this Act will require the statutory health insurance funds to provide additional fees of at least 500 million Euro in 2020 alone.

Registered doctors will receive an additional roughly 995 million Euro in 2020 in total.
Finding a midwife online

There had previously been no systematic provision of information for pregnant women and young mothers with regard to freelance midwives in the local area and the services that they provide, given that many midwives had not published their contact details and activity profiles on the Internet or in other media. The Appointment Service and Care Act (TSVG) has now laid the foundation for a publicly-accessible register. The National Association of Statutory Health Insurance Funds has been commissioned to compile and publish a list of midwives on the Internet from which pregnant women and young mothers can obtain information regarding the services offered by all freelance midwives in Germany within a pre-selected radius.

The register lists more than 18,000 midwives

In order to implement this statutory obligation, the National Association of Statutory Health Insurance Funds has been able to draw on a list of contracting partners containing data on midwives which has been available to it for many years and is updated monthly. This list has been used by the health insurance funds in the past in order to verify midwives’ entitlement to charge. All freelance midwives who wish to settle accounts with the statutory health insurance funds have been legally obliged for many years to accede to the contract for the provision of midwifery services. This is possible either via the respective member association, the German Midwifery Association or the Federation of Freelance Midwives in Germany, or for non-associated midwives directly via the National Association of Statutory Health Insurance Funds. More than 18,000 midwives are currently listed in the list of contracting partners with their range of services. These services include:

- care for pregnant women and childbed care
- birth and postnatal exercise courses
- home birthing
- births in clinics, following care by the same midwife throughout pregnancy
- births in birth houses

It was possible to use the list of midwives as contracting partners to integrate the search for midwives into the Internet pages of the National Association of Statutory Health Insurance Funds within only a few weeks of the statutory arrangement coming into force. Anyone looking for a midwife now finds an overview of freelance midwives in the selected area. The complete range of services provided by each listed midwife is displayed in addition to the contact details. An FAQ list makes it easier to use. In addition, insured persons receive background information on the midwifery services provided under statutory health insurance.

If you are looking for a midwife on the homepage of the National Association of Statutory Health Insurance Funds, you will find an overview of freelance midwives in the selected area.

Midwifery services provided under statutory health insurance

Each insured person is entitled to receive midwifery services during pregnancy and birth, as well as after birth. These benefits include:

- individual advice and informative sessions
- antenatal classes for insured persons
- check-ups (such as blood pressure measurement, urine testing, necessary laboratory tests)
- support services in case of pregnancy-related symptoms or labour pains
- birth support in hospitals, in the birth house and at home
- childbed care up to twelve weeks after birth (midwifery services)

If the child cannot be cared for by the insured person after delivery, the insured child is entitled to the midwifery services which relate to him or her.
Reform of requirement planning for out-patient care

With the requirement planning guideline, the Federal Joint Committee defines the nationwide uniform planning framework for out-patient care within statutory health insurance. The possibilities for physicians and psychotherapists to set up practices in the respective Federal Länder are determined on this basis according to need. An amendment to the requirement planning guideline came into force in June 2019.

As a result, roughly 3,500 additional concessions will be put out to tender. This will create approximately 1,500 new doctors’ concessions for general practitioners, as well as 800 for psychotherapists, 400 for paediatricians, 480 for neurologists, 150 for ophthalmologists, and 100 for rheumatologists.

Adjusting the ratios and quotas
In the case of paediatricians, the planning structure and the level of care was adjusted. A uniform ratio of paediatricians per inhabitant under the age of 18 (ratio) will apply in future to all regions. A higher level of care will only be provided for core cities in order to take account of specialised paediatric care. The ratio of neurologists and psychotherapists per inhabitant in the different regions has been harmonised. The level of care has been adjusted for internists, thus reducing the very high levels of overcapacity.

The morbidity factor
Requirement planning will be orientated even more closely in future towards the development of the population. The previous demographic factor has been developed into a morbidity factor. The first step will be to develop the general ratios every two years on the basis of the nationwide demographic development. The population is divided into a total of eight age and gender groups for this purpose. A change in the population structure over time leads to an adjustment of the general ratios in the directive. In a second step, regional differences in the morbidity structure are also compensated for every two years. Patients are additionally classified according to the morbidity rate. If regional morbidity differs from the national average, the regional ratios are also adjusted.
Quality assurance in intensive non-residential long-term care

Insured persons who require non-residential long-term care around the clock due to a particular need for home care or a threat to their vital functions are to be able to rely on high-quality care. The National Association of Statutory Health Insurance Funds has agreed together with the national organisations responsible for representing the interests of nursing services on a uniform nationwide framework for the long-term care treatment of people with intensive nursing care needs.

Long-term care services which provide intensive non-clinic non-residential long-term care must meet comparable requirements throughout Germany. Particular attention was paid to the specific qualification requirements of the long-term care specialists deployed. This also created a uniform basis for the contractual regulations between the contracting partners at Länder level. The Framework Recommendations came into force as per 1 December 2019. The contracting partners at regional level now have the task of adapting the contents of the care contracts to the new Framework Recommendations.

Focus on overarching structural problems
The National Association of Statutory Health Insurance Funds also pointed to the need for legislative changes to remedy fundamental structural problems in non-clinic intensive long-term care. This concerns both hospital care and structured discharge, especially of patients requiring ventilation, as well as the professional assessment of the potential of weaning from mechanical ventilation during the qualified long-term care of insured persons in the non-residential and residential sectors. Against the background of the (mis-) incentives described above, such as the lack of incentives to wean from mechanical ventilation and high financial co-payments on the part of the insured persons, the National Association of Statutory Health Insurance Funds has advocated fundamental changes to the statutory framework and extended benefit entitlements for persons with statutory health insurance in residential long-term care. This is intended to eliminate the disadvantages of residential care that arise from high co-payments on the part of the insured persons. The focus of the National Association of Statutory Health Insurance Funds is placed on ensuring high-quality care for people with intensive long-term care needs in any setting and the elimination of dysfunction and misincentives in the care process.

The political debate gained momentum with the draft Act to Promote Rehabilitation and Intensive Long-term Care, which was already presented in the second half of 2019.

Long-term care services which provide intensive non-clinic non-residential long-term care must meet comparable requirements throughout Germany.

Proportion of intensive long-term care

<table>
<thead>
<tr>
<th>Service area</th>
<th>2018 in Euro</th>
<th>2019 in Euro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home care</td>
<td>6,436,813,216</td>
<td>6,872,475,450</td>
</tr>
<tr>
<td>of which</td>
<td></td>
<td></td>
</tr>
<tr>
<td>intensive residential long-term care under sec. 37(2) (3) SGB V</td>
<td>62,405,546</td>
<td>67,295,500</td>
</tr>
<tr>
<td>of which</td>
<td>1,854,557,874</td>
<td>2,003,305,429</td>
</tr>
<tr>
<td>intensive non-residential long-term care under sec. 37 SGB V</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: 2018: KJ 1, KV 45 1st-4th Quarters
Illustration: National Association of Statutory Health Insurance Funds
Hardware
The first stock-take after the introduction of lower limits for nursing staff

Lower limits for staff for long-term care have been in force in clinics since 1 January 2019 in order to promote high-quality, safe patient care. Lower limits for nursing staff prescribe a certain number of long-term care staff who have to care for a given number of patients. These limits are binding for the care-sensitive areas of geriatrics, intensive care, cardiology and trauma surgery. If the average monthly number of nursing staff is lower than the prescribed number, hospitals have to accept reductions in remuneration or reduce the number of patients to be cared for.

Data on nursing care staffing available for the first time

Data on nursing care staffing in hospitals have been collected for the first time since the lower limits were set. Initial evidence from approximately 800 hospitals indicates violations of the binding lower limits, but also shows a significant improvement in compliance. Whereas the monthly average for non-compliance was 12 % in the first quarter of 2019, this figure fell to only 3 % of around 21,000 shift- and ward-related reports on patient occupancy and nursing care staffing of hospitals in the fourth quarter of 2019. When looking at the individual shifts, however, it becomes clear that 11 % (66,000 shifts) of the approximately 600,000 day and night shifts were still understaffed in the fourth quarter of 2019.

It cannot be reliably deduced whether the data also actually prove improved patient care. One reason for the more frequent adherence to lower limits for nursing staff in the care-sensitive areas may be an actual increase in the number of nursing care staff. This may however also be caused by the merging of wards or the shifting of patients and nursing care staff at the expense of other areas in hospitals. The National Association of Statutory Health Insurance Funds considers that knowledge about nursing care staffing, and compliance with minimum requirements, are only the first important steps towards patient protection.

Further developments in lower limits for nursing staff

The German Hospital Federation is proving to be a difficult negotiating partner when it comes to nursing care staffing. No agreement was reached on the introduction of the first lower limits for nursing staff in accordance with the Ordinance on Lower Limits for Nursing Staff (PpUGV) of 28 October 2019.

<table>
<thead>
<tr>
<th>Intensive care</th>
<th>Geriatrics</th>
<th>Trauma surgery</th>
<th>Cardiology</th>
<th>Neurology</th>
<th>Stroke care unit</th>
<th>Neurological early rehabilitation</th>
<th>Heart surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. no. of patients per nursing carer</td>
<td>2.5*</td>
<td>3.5*</td>
<td>10</td>
<td>20</td>
<td>10</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Max. no of nursing assistants</td>
<td>8 %</td>
<td>0 %</td>
<td>15 %</td>
<td>20 %</td>
<td>10 %</td>
<td>15 %</td>
<td>10 %</td>
</tr>
</tbody>
</table>

* These ratios for the care-sensitive area intensive care apply to 2020. A 2:1 ratio will apply to the day shift from 2021 onwards, and 3:1 patients per carer will apply to the night shift from the same date onwards. Illustration: National Association of Statutory Health Insurance Funds
nursing staff as of 2019. Instead, the Federal Ministry of Health issued an ordinance setting lower limits. In accordance with the Act to Promote Nursing Staff, the self-government partners are responsible for the further development of these limits. The National Association of Statutory Health Insurance Funds and the German Hospital Federation were to agree on lower limits for the areas of neurology and heart surgery for the first time by 31 August 2019. These were determined in the negotiations on the basis of the evaluation results of the Institute for the Hospital Remuneration System (InEK). These results showed a necessary differentiation of lower limits for neurology, the neurological stroke unit and neurological early rehabilitation. The German Hospital Federation however once more declared that the negotiations had broken down. The lower limits were subsequently updated by the Federal Ministry of Health via an Ordinance on Lower Limits for Nursing Staff dated 28 October 2019.

Continuous expansion to the whole hospital
Further care-sensitive areas in hospitals are to be defined annually as of 1 January, and lower limits are to be agreed for the following year. The National Association of Statutory Health Insurance Funds has been committed to setting lower limits for nursing staff in internal medicine and surgery, as well as for purely paediatric areas. As the German Hospital Federation once again refused to come to an agreement, the Federal Ministry of Health was again called upon, and instructed the Institute for Hospital Remuneration System accordingly.

Precise recording of patient occupancy
How hospitals have to prove their nursing care staff deployment has been regulated since November 2018 in the agreement on proof of compliance with lower limits for nursing staff. The National Association of Statutory Health Insurance Funds and the German Hospital Federation have to update the agreement annually, for the first time in November 2019. The main concern of the National Association of Statutory Health Insurance Funds was to achieve more accurate recording of patient occupancy. Up to now, the average patient occupancy of a ward has been collected via the “midnight census”, which does not include short-stay cases. The National Association of Statutory Health Insurance Funds is in favour of taking all patients into account when calculating the lower limit - in the interests of patient protection.
New remuneration system for nursing staff in hospitals

The Act to Promote Nursing Staff, which came into force in early 2019, constituted an agreement to make fundamental changes to the remuneration system for hospitals. Nursing staff costs will be separated from the diagnosis-related group case flat-rates from 2020 onwards and reimbursed independently of them in the form of a long-term care budget. Until now, nursing staff costs have been reimbursed within the diagnosis-related group case flat-rates. Roughly one-fifth of the hospital costs will be removed from the diagnosis-related groups contained in the list of case flat-rates as part of the conversion of the reimbursement system. With expenditure amounting to approximately 75 billion Euro, this corresponds to an order of magnitude of 15 billion Euro.

Separation of nursing staff costs
The financing of the future long-term care budget is based on the principle of cost coverage, and thus takes into account, on a hospital-by-hospital basis, hospitals’ expenditure on patients’ direct long-term bedside care. The separation of nursing staff costs from the diagnosis-related group case flat-rates now proposed solves the problem of the earmarked financing of long-term care, since the agreement on the long-term care budget only finances nursing staff costs that have actually been incurred. Having said that, the misincentives associated with the cost coverage weigh heavily. A system that does not set a framework of needs cannot be a permanent solution. It is to be feared that the clinics will focus on maximising income, and not on improving long-term care.

Setting the course for the new remuneration system
The design of the new financing framework called for extensive coordination between the self-government partners at national level, including the German Long-term Care Council, the Federal Ministry of Health, and the Institute for the Hospital Remuneration System. A large number of agreements for the separation of long-term care had to be concluded in 2019.

First of all, the nursing staff costs included in the valuation ratios of the diagnosis-related group system had to be determined and separated from the diagnosis-related group system in early 2019. For this separation, the contracting parties had to agree on a uniform definition of nursing staff costs at national level, which in future will also be binding for the agreement on long-term care budgets at local level. Further open questions regarding the design of the future case flat-rate and long-term care financing system development were clarified as part of a basic agreement. Based on this agreement, the Institute for the Hospital Remuneration System was able to calculate the diagnosis-related group version for 2020.

Despite difficult negotiations, the German Hospital Federation and the National Association of Statutory Health Insurance Funds have agreed on the list (2020 list of diagnosis-related groups and long-term care revenue list) that is to be valid in the coming year. This created the necessary conditions for the agreement on hospital-specific long-term care budgets for 2020.

It is to be feared that the clinics will focus on maximising income, and not on improving long-term care.
Erroneous accounts from hospitals, and accounting audits by the health insurance funds, are an ongoing issue which has repeatedly been a concern for the Federal Court of Audit. The National Association of Statutory Health Insurance Funds has made proposals with an argumentation paper.

**Recommendations of the Federal Court of Audit**

Many of the recommendations published by the Federal Court of Audit are in line with the requirements of the National Association of Statutory Health Insurance Funds, and include:

- incentives for correct billing conduct
- legally-binding examination of structural features.

Both aspects have since been addressed by the Medical Service Reform Act, which entered into force on 1 January 2020.

**New provisions introduced by the Medical Service Reform Act**

The new statutory provisions for hospital accounting audits are much more far-reaching and consistent than in the past:

- The accounting of the hospitals is to be made binding.
- In the event of incorrect invoicing, surcharges will be payable to the health insurance fund in addition to the repayment of excess revenue.
- The number of audits will depend on the invoicing quality of the hospitals in future. The more often a hospital’s audited accounts are not objected to, the less frequently hospitals will be audited by the health insurance funds from 2021 onwards. The question of whether and to what extent surcharges on the repayment of excess revenue are to be paid to the health insurance fund is also determined by hospitals’ invoicing quality.
- Statistical evaluations published by the National Association of Statutory Health Insurance Funds ensure transparency in the accounting and auditing process.

The National Association of Statutory Health Insurance Funds is critical of the introduction of a maximum permissible audit quota. This could lead in practice to health insurance funds having to pay incorrect invoices without auditing them once this quota has been reached.

Some of the accounting audits will be omitted in future because the prerequisites for the provision of special complex services must be substantiated before the hospitals can provide these services. Hospitals will only be able to invoice the complex codes linked to specific services from 2021 onwards if they can provide evidence of confirmation via the Medical Service of the structural characteristics specified. The Federal Arbitration Committee will make a large number of decisions on coding problems within specified deadlines. The expanded list of out-patient services to be agreed on by the contracting parties at national level will, in the legislature’s view, help reduce the number of audits to primary misallocations. A modern further development of the examination procedure will potentially also include electronic data exchange between the Medical Services and the hospitals. Given that tight deadlines have been set for all new accounting audit arrangements, the National Association of Statutory Health Insurance Funds has initiated preparatory measures, in cooperation with the health insurance funds.
Promoting hospitals required in order to satisfy demand in rural areas

Hospitals that are required in order to satisfy demand in rural areas will receive a flat-rate subsidy of 400,000 Euro per hospital from 2020 onwards. This annual amount is paid as a supplement per fully- and partly in-patient case. In order to identify the hospitals that are entitled to receive the supplement, the German Hospital Federation and the National Association of Statutory Health Insurance Funds have been commissioned in the Act to Promote Nursing Staff to agree by 30 June of each year on a list of hospitals that meet the criteria set by the Federal Joint Committee for agreeing guarantee supplements. The Federal Joint Committee has defined
• when there is a threat to nationwide care provision,
• when reduced care needs are present,
• for which benefits the necessary reserves are to be maintained.

Funding for hospitals in rural areas is available to primary care hospitals that are required in order to satisfy demand and which have a department for internal medicine and for surgery, as well as hospitals that have a specialist obstetrics department. The contracting parties are to publish the list of hospitals that are required in order to satisfy demand on their respective websites so that it is available to all.

48 million Euro in support for hospitals in rural areas
The contracting parties have agreed that the supplement will be paid per hospital location, as the Federal Joint Committee’s criteria are also based on the location definition. A location which meets the criteria for both primary care and obstetrics

Rural hospitals required in order to satisfy demand

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Primary care hospitals</th>
<th>Hospitals with an obstetrics dept.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low demand for care</td>
<td>Pop. density under 100 per km²</td>
<td>Pop. density lower than 20 women aged 15 to 49 per km²</td>
</tr>
<tr>
<td>Necessary reserves</td>
<td>Specialist internal medicine dept. and specialist surgical dept. suited to care for primary and standard care emergencies</td>
<td>Specialist obstetrics dept. or gynaecological/obstetrics dept.</td>
</tr>
<tr>
<td>Risk to blanket coverage with care</td>
<td>At least an additional 5,000 residents would have to drive more than 30 mins. to the nearest primary care provider if a hospital closes.</td>
<td>At least an additional 950 women aged 15 to 49 would have to drive more than 40 mins. to the nearest birth clinic if a hospital closes.</td>
</tr>
</tbody>
</table>
can however only claim the 400,000 Euro supplement once. The contracting parties have included a total of 120 locations in the list of rural hospitals required in order to satisfy demand. This corresponds to a supplement volume of 48 million Euro for 2020. The supplement will be disbursed even if the hospitals in question do not have a financial deficit. However, only those hospitals which can still show a deficit in the balance sheet after consideration of the 400,000 Euro subsidy are entitled to an additional guarantee supplement.

Rural hospitals required in order to satisfy demand receiving a subsidy in 2020

Source: Agreement on list of hospitals under sec. 9 subs. (1a) No. 6 of the Hospitals Remuneration Act
Illustration: National Association of Statutory Health Insurance Funds
Reforming emergency care

The Central Contact Point as a One-Stop Shop

The Federal Ministry of Health first presented a discussion draft on the reform of emergency care in July 2019, followed in January 2020 by a draft departmental Bill which had been revised in some points. The background to this is that many people in Germany attend the emergency out-patient departments of the hospitals for regular out-patient care. On the one hand, the out-patient standby service of the registered doctors is relatively unknown, whilst on the other hand too many people seeking assistance go directly to the hospitals’ emergency out-patient departments, even on weekdays, and even with minor problems.

The draft departmental Bill of the Federal Ministry of Health essentially comprises the following reform projects:

1. A common emergency management system (GNL) is to be set up which can be reached via the numbers 112 and 116 117. The system is to guide patients to the right level of care on the basis of a standardised initial assessment.

2. Integrated emergency centres (INZs) are to be set up at selected hospitals under the professional direction of the respective Association of Statutory Health Insurance Physicians. These are to become a central contact point for all emergency patients at the hospital.

3. The rescue service is to become a separate medical service area in Book V of the Social Code. Care at the place where the emergency takes place, and the ambulance ride to a hospital, will be regulated as services of medical emergency rescue that are independent of one another. The available emergency resources of the hospitals are to be available to the common emergency management system and to the rescue service in digital form in real time.

An evaluation of the reform project from the perspective of the National Association of Statutory Health Insurance Funds

The National Association of Statutory Health Insurance Funds presented proposals for reforming emergency care back in 2017. Several central demands of the National Association of Statutory Health Insurance Funds are reflected in the draft departmental Bill of the Federal Ministry of Health. It is expressly welcomed that a central contact point will be created in future for all emergency patients, and that the Federal Joint Committee, in addition to the in-patient emergency level concept already established, will be commissioned to define uniform nationwide framework requirements for the provision of premises, staff and equipment, as well as the scope of services in out-patient emergency care. This will define for the first time which out-patient emergency structures must be provided in order to comply with the guarantee mandate and to ensure that hospitals’ accident and emergency departments are relieved of “minor cases”. The location selection of the INZ is to be carried out by the extended Länder committees on the basis of the planning specifications of the Federal Joint Committee that are uniform nationwide. This is in line with the proposals put forward by the National Association of Statutory Health Insurance Funds.
Funds, and is expressly welcomed. Another positive aspect is the fact that the emergency service is to be integrated into the healthcare system.

**Establishing a common emergency management system**

The common emergency management system, which is digitally networked with all healthcare providers involved in emergency care and has real-time access to the available capacities (rescue equipment, hospitals and INZ), is to have a real control function in future. Patient data are to be transmitted to the hospital in advance of the ambulance arriving there. In addition, a visiting telemedical standby service is to be integrated into the common emergency management system. This digitalisation offensive is to be expressly welcomed.

It is especially important for patients who are seriously injured or have life-threatening diseases to be taken to exactly the right place where they can receive appropriate medical assistance for their problem.

**Establishing the rescue services as a medical service area in Book V of the Social Code**

A new benefit area of statutory health insurance for the rescue service is introduced in Book V of the Social Code under the term “medical emergency rescue”. This takes into account the fact that emergency rescue has developed into preclinical medical care. At the same time, it enables insured persons to be entitled to medical emergency rescue without taking up other benefits under statutory health insurance. This can avoid medically unnecessary journeys to hospitals by the rescue service or hospital admissions in the future.

**Establishing a central contact point on a one-stop basis**

The idea of a central contact point for all emergency patients is evaluated positively. It is also a welcome development that no “third sector” is created as was set out in the discussion draft, but instead the focus is placed on close cooperation between the Associations of Statutory Health Insurance Physicians and the hospitals. The National Association of Statutory Health Insurance Funds considers that a one-stop arrangement, supported by the Associations of Statutory Health Insurance Physicians and the hospitals, should be established at each selected INZ location. Expert medical staff from both care areas decide on further care: Either patients are treated on an out-patient basis in the INZ managed by the Association of Statutory Health Insurance Physicians at the hospital location (emergency service practice of an Association of Statutory Health Insurance Physicians) or, in the case of medically-urgent problems, they are transferred to the central emergency admission of the clinic.
Quality controls in hospitals

A major instrument of quality assurance in hospitals is the regular review of compliance with statutory stipulations and regulations of the Federal Joint Committee. The basic principles for this were created with the Hospital Structure Act (Krankenhausstrukturgesetz – KHSG), and the Federal Joint Committee was commissioned to issue a guideline in which the nature, scope and procedures of quality controls are regulated by the Health Insurance Medical Service.

Given the broad scope of the Medical Service Quality Control Guideline, the general stipulations for the indications for controls, the commissioning bodies, and the nature, scope and procedures, as well as for handling the test results, are regulated in a General Part A. This has already been in force since December 2018. For the other objects of control stipulated by the legislature, the respective details of the procedures in individual sections are successively defined in the Special Part B of the Guideline.

Reviewing the documentation quality
On this basis, the quality assurance committees at national and Länder levels, and the statutory health insurance funds, can instruct the Medical Service to verify whether a hospital has documented its quality assurance data correctly. The correspondingly extended guideline has been in force since June 2019.

Reviewing requirements for structural quality
This Part of the Medical Service Quality Control Guideline defines the conditions for testing the minimum structural quality requirements set forth in the Federal Joint Committee’s guidelines. This enables the health insurance funds to have the implementation of the requirements resulting from the different structural guidelines verified, such as:

- the Quality Control Guideline on Premature Births and Births at Term
- the Quality Control Guideline on Abdominal Aortic Aneurysm
- the Guideline on Minimally-invasive Heart Valve Surgery

The checks are carried out annually on a sample basis, but can also be commissioned on the basis of concrete indications. In addition, there will be the possibility of carrying out regular checks on hospitals providing services relevant to the Guidelines for the first time. This will ensure that the prerequisites for the provision of services are demonstrated in advance.

The outlook
The implementation of the regulations on a tiered system of emergency structures in hospitals is to be discussed at the initiative of the National Association of Statutory Health Insurance Funds in order to enhance patient safety.
The Year's Topics

Binding staffing requirements for psychiatry and psychosomatics

2019, the Federal Joint Committee, with the approval of patient and Länder representatives, adopted the initial version of the Psychiatry and Psychosomatics Staffing Guideline (PPP Guideline), and submitted it to the Federal Ministry of Health for approval. The PPP Guideline entered into force in early 2020.

**Binding staffing stipulations from 2020 onwards**

With the introduction of the Guideline, all psychiatric, child and adolescent psychiatric and psychosomatic hospitals and departments will have to comply with binding minimum staffing stipulations for the first time by early 2020. This applies to all staff working in therapy: physicians, nursing staff, psychologists, specialised and movement therapists, as well as social workers. The minimum requirements apply per professional group. They have to be met quarterly at the level of the facility, and must be documented vis-à-vis the Länder associations of the health insurance funds. If the minimum stipulations for staffing are not met, the hospital’s entitlement to remuneration lapses.

The calculation of the specific amount of the loss of the entitlement to remuneration will be decided by the Federal Joint Committee by June 2020.

The National Association of Statutory Health Insurance Funds has advocated that the staff records of the facilities should also be kept on a ward-related and monthly basis. This is intended to create transparency with regard to the deployment of the staff in order to be able to verify whether particularly sensitive care areas such as dementia or acute care units are staffed according to need. These ward-related records will be evaluated in future by the Institute for Quality Assurance and Transparency in the Healthcare System.

**Supplementing the existing staff**

The new Guideline also adapts the staffing stipulations of the existing Psychiatric Staff Ordinance (Psychiatrie-Personalverordnung) to meet today’s specialist requirements. A 5% increase in staffing levels has been specified. The National Association of Statutory Health Insurance Funds believes that the additional staff is necessary in order to enhance psychotherapy in hospitals and to guarantee dignified care for acutely ill patients.

43% of the facilities did not comply with the previous staffing stipulations in the data year 2018. The new guideline means that the hospitals will therefore have to increase their staff significantly – a transitional period of four years is provided for this.

Degree of implementation of actual staffing in psychiatric hospitals

![Diagram showing the degree of implementation]

Degree of implementation = actual staffing/required staffing

Source: Proof of compliance with the requirements of the Psych Staffing Ordinance, evaluation results of the Institute for the Hospital Remuneration System, data year 2018, version September 2019.

Illustration: National Association of Statutory Health Insurance Funds
A nationwide directory of hospital locations

Hospitals and their locations must be unambiguously identifiable for the purposes of billing with insurance providers, for hospital planning or for quality assurance measures. This was not possible in the past due to the many levels of regulation and control. Different delimitations were therefore chosen in practice. Hospital locations and out-patient clinics have been recorded in a location directory with an identifier since January 2019.

Greater clarity regarding hospital locations
The legislature had already commissioned the German Hospital Federation and the National Association of Statutory Health Insurance Funds in the previous legislative period to ensure clarity with regard to the definition of a “location”, and to establish and continuously develop a nationwide directory of the locations and out-patient clinics of all hospitals. The development of the directory was started in 2018 as planned. The Institute for the Hospital Remuneration System was awarded the contract for the technical implementation and the organisational operation.

Hospitals have been able to register their locations and out-patient clinics via the website https://krankenhausstandorte.de/ since January 2019. They each receive unique location and out-patient clinic identifiers. It has been mandatory since 1 January 2020 to indicate this identifier in invoices. The identifier can potentially be used in further areas of application, e.g. in quality assurance or when calculating surcharges, for example for emergency levels or centres.

Approximately 1,600 hospitals had registered their locations and out-patient clinics by mid-December 2019 and received the corresponding identifiers. The list is therefore almost complete. The aim for 2020 will be to improve the quality of the data and to continuously track changes such as mergers or closures of hospitals or their locations. It has been mandatory since 1 January 2020 to indicate the location identifier in invoices.

Structure of the 9-digit location identifier

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Suffix for type of facility, e.g. University out-patient clinic (HSA = 04)

Illustration: National Association of Statutory Health Insurance Funds
Uniform standards for clinical centres

Centres are hospitals which are of particular significance for caring for patients, as they assume tasks for other hospitals, for example. These can include treatment recommendations for patients of other hospitals, or interdisciplinary case conferences for oncological patients. A centre within the meaning of the law on fees and charges is an institution that is particularly specialised in the relevant field and stands out from other hospitals due to its medical competence and equipment. The centre must differ from the hospitals which do not have a centre function in that it performs special tasks.

Special tasks and quality requirements
The Act to Promote Nursing Staff mandated the Federal Joint Committee to define centres' special tasks by the end of 2019, and to lay down uniform nationwide quality requirements for the performance of tasks for the first time. These can particularly include stipulations on the type and number of specialist departments, minimum case numbers and cooperation with other healthcare providers. The background to the Federal Joint Committee’s mandate was a decision taken earlier by the Federal Arbitration Office which had proved to be unworkable. According to this decision, only the designation as a centre in the hospital planning in the Länder was sufficient to finance special tasks. This resulted in a patchwork of implementation, and to disputes regarding the selection criteria per Federal Land.

Specific tasks of a centre may arise from
• tasks of a supra-local nature that involve more than one hospital,
• special equipment requirements in a hospital, especially in rare disease centres,
• the need to concentrate care at individual locations due to exceptional technical and personnel requirements.

The special tasks are to be financed via centre supplements, as these are benefits that are provided to patients of other hospitals, or overarching tasks (e.g. register maintenance and evaluation) which benefit in-patient care. These benefits cannot therefore be financed through the diagnosis-related group case flat-rate system.

Selection of the departments and decision-making
The deliberations on the Federal Joint Committee were concluded regarding the following areas in 2019:
• centres for rare diseases
• oncological centres
• trauma centres
• rheumatological centres
• cardiological centres
The arrangements are to be supplemented by further care-relevant centres in 2020.

The National Association of Statutory Health Insurance Funds expressly welcomes the fact that the regulations of the Federal Joint Committee on centres define for the first time uniformly at national level when outstanding expertise and equipment are available in comparison with other healthcare providers of top-level medicine which qualifies hospitals to take on special centre tasks.
Virus protection
The legislature carried out a comprehensive, far-reaching organisational reform of the Health Insurance Medical Service in 2019 with the Medical Service Reform Act.

**New composition of the administrative councils**
The administrative councils of the individual Medical Services in the Federal Länder and at national level will be completely restructured under the proposed regulations. The administrative councils are to therefore be composed of a total of 23 members. Of these, the health insurance funds will elect 16 representatives with voting rights. Five representatives with voting rights will be nominated by the Länder in future, on the basis of proposals made by the patients’ organisations. In addition, the Länder will appoint two representatives of the Land Long-Term Care Associations and of the Land Medical Associations, without voting rights.

The draft Bill initially provided for membership of the administrative council of a health insurance fund to be incompatible with being elected to the administrative council of a Medical Service. The National Association of Statutory Health Insurance Funds considered that this would have been tantamount to the de facto elimination of social self-government in the Medical Service. It therefore took up a clear position against this proposal. As a constitutive element of statutory health insurance, social self-government must also continue to be directly represented in the administrative councils of the Medical Services.

As a constitutive element of statutory health insurance, social self-government must also continue to be directly represented in the administrative councils of the Medical Services.

The legislature justified the reform of the Medical Services and of their administrative councils, which up to then had been staffed by the health insurance funds on their own responsibility, by claiming that the independence of the Medical Service would be enhanced. The National Association of Statutory Health Insurance Funds sees no reason for this. It is already impossible today for the administrative councils of the Medical Service to exert an influence on the original tasks of appraisal and advice.

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**Transitional process to the new corporations Medical Service and Medical Service of the Federation**

**2020**
- By 31 Dec. Election and nomination of the members of the new administrative councils of the medical services

**2021**
- By 31 Mar. Assembly of delegates to elect the members of the new Administrative Council of the Medical Service of the Federation
- By 30 Jun. decision of Land authorities on new Statutes of the Medical Services
- Medical Services fully established, after publication of the Statutes
- By 31 Dec. decision of Fed. Min. of Health on new Statutes for the Medical Service of the Federation

**2022**
- Medical Service of the Federation starts operations

Illustration: National Association of Statutory Health Insurance Funds
Incompatibility rule for social self-government averted

This provision was removed at the last minute in the legislative procedure in view of the strong criticism that had been voiced. Social self-government continues to be represented in the administrative councils of the Medical Service. The compromise reached between the parliamentary groups within the Government however weighs heavily: Those who are already volunteering in one Medical Service, or in more than one self-government body or association of an insurance provider, are not permitted to work in another Medical Service Administrative Council. In addition, the activity will be limited to two terms of office - stipulations which did not previously exist for corporations under public law. Special regulations are created for the Medical Service which are alien to the system and cannot be justified.

Potential for conflicts of interest through the further occupation of the administrative councils

The new composition of the administrative councils makes healthcare providers responsible for shaping the Medical Service - albeit without voting rights. This harbours potential for conflicts of interest. The administrative councils ultimately decide amongst other things on guidelines on the basis of which the provision of services is examined. The legislature's aim to ensure the independence of the Medical Service is counteracted by the involvement of the healthcare providers. The National Association of Statutory Health Insurance Funds therefore advocated that the professional groups be involved in advisory councils, but not in the Administrative Council.

Risks to the functionality of the Medical Service

The former Medical Service of the National Association of Statutory Health Insurance Funds (MDS) will be replaced in future by the new Medical Service of the Federation. It is to decide independently on the guidelines for the expert review. This will break up the well-functioning cooperation between the National Association of Statutory Health Insurance Funds and the MDS in developing medical-scientific positions and in representing them in the committees of joint self-government. As the Medical Service of the Federation will be financially supported by the Medical Services in future, and no longer by the National Association of Statutory Health Insurance Funds, the members of the Administrative Council of the National Association of Statutory Health Insurance Funds are no longer represented in the Administrative Council of the Medical Service of the Federation. In addition, the limitation to a maximum of two memberships of administrative councils of the health insurance funds and of the Medical Service cuts the transfer of knowledge at administrative council level between the health insurance funds, the Medical Service and the Medical Service of the Federation.

It is of fundamental importance for both the Medical Services and for the health insurance funds that the bases of the assessments should comply with the legal interpretation of the health insurance funds.

In addition to medical aspects, considerations related to benefit law also play an important role in a relevant number of guidelines when making expert decisions. It is of fundamental importance for both the Medical Services and for the health insurance funds that the bases of the assessments of the Medical Service should comply with the legal interpretation of the health insurance funds. The Guidelines provide an indispensable basis for both the Medical Service and the health insurance funds to act together. There is an urgent need for the expertise of the health insurance funds to continue to be directly involved. The National Association of Statutory Health Insurance Funds has therefore called for a consensus-based arrangement.
Mouse_
Priority for patient protection in medical devices

The legislature has launched two projects to improve patient safety in the supply of medical devices: The Implant Register Act (Implantateregister-Gesetz) and the Medical Devices Law Implementation Act (Medizinproduktrecht-Durchführungsgesetz). Are the two Acts achieving their objective?

The Implant Register Act brings progress
The central aim of the “Act Establishing an Implant Register” (Implantateregister-Er richtungsge setz – EIRD) is to enhance the safety and quality of implants. For the first time all over Germany, the Act creates a legal basis for all implants and all subsequent interventions in connection with the implant to be reported to the Register for specific product classes. This increases patient safety, as product defects can be detected earlier than was previously the case. However, the data must be valid in order for this to be achieved. The Implant Register is based exclusively on information provided by hospitals, surgeries and industry. The health insurance funds are to report the “vital status” of their insured persons to the Register. The limitation to this single parameter to be reported by the health insurance funds however falls short of the mark. The inclusion of further insurance fund data could effectively increase patient protection.

Using data from the funds’ accounting
Health insurance funds have audited accounting data. These data could be used to verify the hospitals’ implant data. As hospital invoices are prone to errors and are often incorrect, verification by the funds would significantly improve the quality of the Register.

Rapid contact with insured persons through correct contact details
If patients need to be contacted because of a problem with implants, this should be done quickly. It would therefore make sense for the health insurance funds to pass on the information, as they always have the current contact details of their insured persons. Unfortunately, however, the Act provides for the hospitals to be responsible. Any patient relocation therefore leads to delays, which in turn endanger patient safety.

The Register does not increase knowledge everywhere
Although the Register data are collected, health insurance funds are not informed as to which implants their insured persons have received. The health insurance funds are therefore unable to provide sufficient support to their insured persons in the case of a claim because they lack the data to do so.

Aligning the Medical Devices Act to the EU Regulation
The new EU Regulation on medical devices will apply from 26 May 2020 onwards. This requires amendments to the German law on medical devices. The corresponding draft Bill of a Medical Devices Law Implementation Act of the Federal Government was presented in the second half of 2019. The draft Bill contains some problematic provisions over and above German law being brought into line with EU law.

The Act provides for a considerable extension of "special approvals" for medical devices. Medical devices which have not completed a European conformity assessment procedure can thus be approved in Germany by the Federal Institute for Drugs and Medical Devices under certain conditions. The wording of the explanatory memorandum to the Act suggests that it is to be expected that considerably more medical devices can be approved via this special national route in future than has been the case to date.

For the first time all over Germany, the Act creates a legal basis for an obligation to report implants and subsequent interventions to the Register.
Avoiding national go-it-alone
This expansion of special approvals is viewed critically by the National Association of Statutory Health Insurance Funds because it allows the protection provisions of the EU Regulation to be deliberately circumvented. National special approvals on a go-it-alone basis should be avoided. If all the EU Member States were each to introduce far-reaching exemptions for national special approvals, this would undermine the actual protection objective of the EU Regulation. Instead, in the view of the National Association of Statutory Health Insurance Funds, it must be legally clarified that, outside of pandemics or other disasters, “special approvals” constitute exceptions as a matter of principle. They should only be granted for a limited period of time, and the approval decisions should be published with all the relevant information.

Changes to the method evaluation in the Federal Joint Committee
Other amendments to the Act relate to the procedure for method evaluation of new examination and treatment methods (NUB). The legislature deviates from recognised scientific practice at several junctures here. For example, the maximum duration of the procedure was reduced from three years to two without making any adjustments to the extensive consultation procedures. Carrying out the trial during this period contradicts the basic principles of scientific study planning, and will present the Federal Joint Committee with major challenges. Similarly, it is not clear why an NUB may be used in hospitals in the future if only the potential for it is available, but there are no reliable statements on the potential for benefit or harm. This is a step backwards in terms of evidence-based medicine. The power to revise the procedure is also to be criticised. This authorises the Federal Ministry of Health to prescribe to the Federal Joint Committee the rules of procedure for the method evaluation in future. It is to be feared that the evaluation standards, which up to now have primarily focused on patient safety, are to be relaxed.

Implant Register participants

The expansion of special approvals is viewed critically by the National Association of Statutory Health Insurance Funds, as it allows the protection provisions of the EU Regulation to be deliberately circumvented.
Implant Register participants

DIMDI (registry office)

RKI (trusted body)

Healthcare facilities (mandatory reporting of patient-related data and operation data)

Implant manufacturers (mandatory product registration)

Federal Institute for Drugs and Medical Devices (receives reports)

Existing registers (integration)

Health insurance funds, accident insurance, private health insurance (report of insured persons' vital status)

Professional associations (scientific evaluation)

Patient (receives implant pass)

Illustration: National Association of Statutory Health Insurance Funds

Implant register

Launched in 2021

- hip joints
- knee and endoprostheses
- breast implants
- others to follow

Server_
The results of the concerted action on long-term care (KAP) were presented to the public in early June 2019. This was preceded by a year of intensive consultations in five working groups in which the National Association of Statutory Health Insurance Funds was able to consolidate its positions as a central player. The agreed measures are intended to tangibly improve the working conditions of professional carers, enhance long-term care training, and implement further relief measures for carers. The Federal Ministries, the Länder, and the organisations involved in the concerted action on long-term care, have committed themselves to implementing this comprehensive package of measures.

A collective agreement on long-term care that has been negotiated by the trade unions and employers can be declared universally mandatory by the Federal Government.

Improving remuneration
The Act on Better Wages in Long-term Care was adopted in order to improve the remuneration of carers. It provides that a collective agreement for long-term care negotiated by trade unions and employers can be declared universally applicable by the Federal Government. If this fails, the Long-term Care Commission set up by the Government is to propose minimum wages for skilled workers too.

Promoting decision-making powers for carers
The aim is also to improve the decision-making skills of long-term care professionals. In particular, this involves optimising delegation procedures between medical and nursing staff, as well as substituting medical services for long-term care specialists in the sense of the transfer of medical tasks.

More long-term care professionals from abroad
In order to facilitate the recruitment of skilled long-term care workers from abroad, the Immigration Act for Skilled Workers (Fachkräfteeinwanderungsgesetz – FEG), which was adopted in 2019, will expand the legal framework. The Federation and the Länder in particular are responsible for setting up a central service point for the recognition of foreign long-term care training. In addition, a quality label is to be developed which, firstly, certifies private intermediaries of skilled foreign long-term care workers and, secondly, sets uniform standards for the specialist and language training of skilled foreign long-term care workers.

A financial and organisational tour de force
The measures that have been adopted will lead to higher co-payments on the part of those in need of long-term care, especially of home residents, according to the existing cost allocation. The National Association of Statutory Health Insurance Funds considers that the Federal Government must quickly develop a coherent overall financing concept. A situation must be prevented in which the investment costs and the additional costs incurred as a result of the KAP continue to be passed on to those in need of long-term care.

Central measures of concerted action on long-term care
• Recruit 10 % more trainees and training facilities
• Expand further training and retraining for long-term care
• Attract skilled workers from abroad
• Improve the working conditions of carers
• Expand decision-making powers for carers
• Facilitation through digitalisation
The Act to Promote Nursing Staff (PpSG), which came into force in 2019, aims to achieve tangible improvements in the daily lives of nursing staff through better staffing and working conditions. The Act provides that fully-residential long-term care facilities are entitled to receive supplemental payments to finance a total of 13,000 additional long-term care posts. Up to 100 million Euro per year will be made available in addition between 2019 and 2024 to promote measures in long-term care facilities aimed at improving the reconcilability of long-term care, family and work. Furthermore, digitalisation is to be promoted in long-term care. To this end, long-term care insurance will support the acquisition of the appropriate digital and technical equipment for long-term care facilities in 2019 to 2021 with a one-off grant of up to 12,000 Euro per facility.

The National Association of Statutory Health Insurance Funds has decided on the details of the requirements, contents and implementation of the financing and support projects in guidelines and specifications. These are binding on long-term care facilities and on the long-term care insurance funds that process applications, and ensure uniform funding procedures throughout Germany. In order to simplify the application process, the National Association of Statutory Health Insurance Funds has provided a sample application form for the respective funding measures. The long-term care funds have agreed on central responsibilities in order to make the procedures of application processing and approval efficient.

**Take-up of the funding**

The long-term care funding programme is taken up cautiously by the fully-residential long-term care facilities. Roughly 3,800 out of a total of 13,000 facilities had applied for funding for additional long-term care posts by the end of 2019; about 40 % of these applications were incomplete, and were merely submitted within the deadline. The long-term care funds had approved 2,223 applications by the end of 2019, and thus a total of 2,260 long-term care posts (full-time equivalents). Of these, 2,242 were skilled long-term care workers, and 18 were nursing assistants.

Only 1.3 % of the eligible long-term care facilities had taken advantage of the possibility to promote measures to improve the reconcilability of long-term care, family and work by the end of December. 201 out of a total of 356 applications were decided on by the end of December 2019.

Roughly 4 % of eligible long-term care institutions have applied for funding for digitalisation activities. Of the 3,487 applications that have been submitted, a total of 1,940 had been approved by the end of December 2019. The approval rate is 89.43 %, with 1,735 applications having been approved. Applications were for example rejected due to a lack of relief for nursing staff as the main purpose of the measure. 1,547 applications had not yet been finally processed within the first funding year 2019, mainly due to missing or unclear information.
A new quality system for residential long-term care homes

A completely reformed quality system for facilities was introduced in October 2019, a good ten years after the introduction of long-term care grades. This system focuses on the quality of care. The basis for this was formed by a scientific commission awarded by the long-term care quality committee to the Institute for Nursing Science at the University of Bielefeld and the aQua Institute in Göttingen. The final report, presented in September 2018, contains recommendations for 15 quality indicators to be used in the external quality audits by the Medical Services of statutory health insurance and the auditing services of private health insurance, and which concern the future quality presentation.

Fully-residential facilities have been required to collect quality data from their residents every six months since October 2019, and to transmit these data to the long-term care data evaluation centre (DAS). The data evaluation centre checks the data for completeness and plausibility. The evaluation is carried out in case- and institution-specific terms, on the basis of pseudonymised data. The results reflect the long-term care quality of a facility along the quality indicators, e.g. on the topics of maintaining mobility, frequency of pressure sores or use of restraining belts. They constitute an important foundation for the internal quality management of the long-term care facilities, and are incorporated into the public quality presentation for long-term care patients and their relatives.

New quality presentation
The extended Quality Committee on Long-Term Care agreed on the Quality Presentation Agreement for Fully-residential Long-Term Care (QDVS) in March 2019. QDVS replaces the long-term care transparency agreement (long-term care grades, "long-term care TÜV"), and defines the form in which the collected data for those in need of long-term care and their relatives are processed and published. Information will thus be available on the Internet portals of the long-term care insurance funds from the beginning of 2020, and this will differentiate better than previously according to differences in quality. The quality presentation includes the results of quality indicators and independent quality tests, as well as information on a wide range of features, including staffing.
Quality control in non-residential long-term care
At the same time, a new quality assurance procedure for non-residential long-term care was launched in 2017. The results of the study commissioned by Osnabrück University of Applied Sciences and the Institute for Nursing Science of the University of Bielefeld have been available since the autumn of 2018. The pilot phase will be carried out in 80 general and specialised long-term care services before the developed instruments and procedures for quality control and presentation are taken over into regular operation. The measurement-theory quality criteria, and the practicability of the instrument for quality assurance, will be tested. Furthermore, the suitability of the quality presentation and the practicability of the evaluation system will be tested. The results will be available in January 2020.

Non-residential caregiving services
With the Appointment Service and Care Act, the legislature has provided for the admission of non-residential caregiving services as healthcare providers in long-term care insurance. They are intended to increase the capacity to provide long-term care services, care and assistance in the management of the budget for persons in need of long-term care. In accordance with its statutory mandate, the National Association of Statutory Health Insurance Funds has adopted guidelines on the requirements for quality management and quality assurance for non-residential caregiving services. The guidelines set the standard for the content and scope of the quality management and quality assurance of caregiving services. On this basis, the National Association of Statutory Health Insurance Funds, together with the Medical Service of the National Association of Statutory Health Insurance Funds, has developed quality control guidelines for non-residential caregiving services, which came into force at the beginning of 2020.

Quality assessment indicators
1. General information regarding the facility
2. Equipment
3. Specialisation/main areas of care
4. Opportunities to get to know the facility
5. Group offers
6. Religious activities
7. Involvement of relatives
8. Contacts between the institution and the social environment/neighbourhood
9. Staffing (in nursing and care)
10. Cooperation agreements
11. Healthcare planning for the last phase of life
12. Additional chargeable services provided
The Year's Topics

The financial situation of social long-term care insurance

Numerous reforms have refined social long-term care insurance (SPV) since its introduction in 1995, and have expanded the group of beneficiaries. They have increased by roughly 70 % in the last ten years, from 2.2 million to more than 3.9 million in July 2019, but the benefits of long-term care insurance have also been significantly expanded, especially in the out-patient sector. Benefit expenditure has risen over a period of ten years from 19.3 billion Euro in 2009 to around 40.7 billion Euro at the end of 2019. In order to secure the funds available in social long-term care insurance, several contribution rate adjustments have been made since long-term care insurance was introduced. The contribution rate was most recently increased by 0.5 contribution rate points to 3.05 % of gross wages - 3.3 % for those without children - in 2019.

Rising costs for long-term care benefits
Further cost increases are expected in view of the demographic development and the measures planned in the concerted action on long-term care to improve working conditions in long-term care. According to a study commissioned by the Federal Ministry of Health, the planned nationwide increase in the wages of nursing staff alone, which was adopted with the Long-term Care Wage Improvement Act (Pflegelöhnerverbesserungsgesetz), will lead to additional expenditure.

Especially in the fully-residential sector, persons in need of long-term care are burdened with rising long-term care rates, and thus with increasing co-payments.

Financial burden on a person in need of long-term care in residential long-term care, in Euro, per month

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*Facility-specific co-payment for long-term care; unchanging for care levels 2 to 5
Source: vdek. Illustration: National Association of Statutory Health Insurance Funds
of around 1.4 to 5.2 billion Euro. In addition, cost increases running into billions are to be expected when implementing the introduction of an annual, flexibly-applicable "relief budget" (summary of the entitlement to day and night care, nursing where the carer is unable to attend, and respite care) as provided for in the Coalition Agreement. Further additional expenditure for better staffing of long-term care facilities is expected due to a personnel allocation procedure that is to be developed by 2020.

**Increasing co-payments on the part of those in need of long-term care**

The rising costs in long-term care benefits affect not only the contributors, but also those in need of long-term care and their relatives. Long-term care insurance is designed according to the principle of partial cost coverage. Especially in the fully-residential sector, persons in need of long-term care are burdened with rising long-term care rates, and thus with increasing co-payments. The average co-payment towards fully-residential long-term care was more than 1,940 Euro per month in January 2020. Of this, an average of approximately 730 Euro were accounted for by the care-related co-payment, more than 450 Euro by investment expenses, and roughly 760 Euro by room and board. Roughly one-third of those in need of long-term care in fully-residential facilities receive assistance for long-term care in accordance with Book XII of the Social Code.

**The need for reform**

Sound long-term financing of social long-term care insurance in order to cover the risk of the need of long-term care is indispensable. In order to provide direct financial relief to persons in need of long-term care and their families, and thus to limit their co-payments, the Länder must assume greater responsibility for financing. It is already provided by law that the savings made by the providers of social assistance through the introduction of long-term care insurance should be used to promote the investment costs in long-term care facilities. This is to be implemented by the Länder to a much greater extent than was previously the case.

Long-term care is a task for society as a whole. Therefore, besides those in need of long-term care, as well as the community of solidarity and the Länder, the Federation should also assume greater responsibility for financing. In order to stabilise the contribution rate in social long-term care insurance, it is necessary for at least the non-insurance benefits that are paid for by long-term care insurance to be covered by a tax-financed Federal subsidy.
A dialogue on the National Dementia Strategy

The figures from the German Alzheimer’s Society currently assume that 1.7 million people suffer from dementia. Some 3 million people could be affected by 2050. This poses considerable challenges in therapy as well as long-term care and support. This situation is made worse by the demographic development, in particular by the need to ensure sufficient qualified nursing staff and the loss of relatives providing care. Furthermore, the hoped-for breakthrough in the therapy of the disease syndrome is not yet in sight.

Improving the quality of life of those affected

The National Association of Statutory Health Insurance Funds actively supported the “Alliance for People with Dementia” from 2014 to 2018, for instance with a variety of measures and projects that directly improve the quality of life and the conditions of long-term care for people with dementia and their families.

This Alliance has been continued and developed since early 2019 as part of the National Dementia Strategy. The National Association of Statutory Health Insurance Funds is also a key player here. A strategy will be developed by early 2020, under the joint leadership of the Ministries of Family Affairs and of Health, and with the participation of the Federal Länder, local authorities and other stakeholders, such as the German Alzheimer’s Society. The following working groups are discussing the central issues:

• enhancing structures for the social participation of people with dementia
• supporting people with dementia and their families
• promoting the medical and long-term care of people with dementia
• promoting excellent basic and applied research on dementia

Designing care according to needs

The National Dementia Strategy is conceived as a dialogue that is conducted from the perspective of those affected, and the responsibility of the players involved is called upon. The results of the dialogue are to be presented to the Federal Government in May 2020.

Services must be geared to the special needs of people with dementia, and must be coordinated with one another.

The provision of healthcare and long-term care is of direct importance for the health and long-term care insurance funds. Most people would like to live in their own homes and be cared for there. This is often not possible without professional offers of therapy, care and nursing. These services must be geared to the special needs of people with dementia, and must be coordinated with one another. Long-term care provided in fully-residential long-term care is to be “dementia-sensitive”. In hospital care, the adaptation of the environment and of the work processes is crucial for people with dementia. The question moreover arises as to whether and within what framework rehabilitation measures for people with dementia can be considered.

The National Dementia Strategy is conceived as a dialogue that is conducted from the perspective of those affected, and the responsibility of the players involved is called upon. The results of the dialogue are to be presented to the Federal Government in May 2020.
Model projects for the further development of long-term care

How and under what conditions the care of those in need of long-term care and the support and relief of caring relatives can be further improved in future are central questions that are dealt with by the Research Unit on Long-Term Care Insurance. Numerous projects and studies have been funded in the year under report.

Disease prevention and health promotion in non-residential long-term care
In the study entitled “Taking stock of target group-specific disease prevention and health-promotion needs, potentials and intervention measures in non-residential long-term care”, which was completed in 2019, those who are at heightened risk of a deterioration of their functional health were to be identified from among the group of people in need of long-term care. Prevention measures should be deliberately expanded for this group of individuals. Furthermore, the effectiveness of target group-specific intervention measures should be evaluated. The results of the systematic literature search and of the evaluation of review data of the Health Insurance Medical Service show that no clear risk groups can be defined. Rather, resources and needs for health-promoting and preventive measures are to be determined individually, taking personal characteristics and life circumstances into account. The common practice of the determination of needs as part of the long-term care assessment in accordance with Book XI of the Social Code reveals potential for improvement in this respect. Further research is needed on the effectiveness of prevention measures.

Pain management in domestic care (ACHE)
The study entitled “Model development for pain management among elderly persons in need of long-term care in domestic care (ACHE)”, also completed in 2019, gives an insight into the pain process in long-term care and medical pain management among elderly people in need of long-term care who are cared for in their own homes. Based on interviews and tests with 355 elderly people in need of long-term care, as well as on interviews with relatives and analysis of documents, it has been established that the group of people studied suffer from considerable pain and resulting impairments. The results also show that long-term care and medical pain management has potential for improvement, e.g. with regard to the recording of pain, the documentation of long-term care pain management, and medicinal pain therapy.

Psychotropic drugs in residential and non-residential long-term care
The study entitled “Psychotropic drugs in residential and non-residential long-term care. Challenges in the handling and prerequisites for the implementation of alternative courses of action (PhasaP)” focuses on the use of psychotropic drugs in residential and non-residential long-term care facilities, and examines the handling of psychotropic drugs on persons in need of long-term care with and without cognitive impairments. The aim of the study is to support nursing staff in implementing and monitoring the use of psychotropic drugs. To this end, prerequisites and barriers for the dissemination and implementation of existing concepts will be analysed and, based on this, both recommendations for action for nursing staff, and an implementation concept, will be developed. The reduction of undesirable side effects is seen as a contribution towards improving the health situation and quality of life of persons in need of long-term care.

Hospice culture and palliative competence in residential geriatric care facilities
The Social Service Agency of Evangelical Churches in Lower Saxony developed a concept for the content, organisation and structure of palliative care in residential geriatric care facilities as part of its project entitled “Implementation of hospice culture and palliative competence in residential geriatric care facilities (ImPAct)”, and has been implementing this concept in a large number of
facilities since 2013. Based on this concept, the facilities are to develop and sustainably establish their own individualised approaches to the development of their own hospice culture. The factors for the improvement of palliative care in residential geriatric assistance are analysed as part of a process and result evaluation of the project. This is to identify the need for change and the conditions for implementing a hospice culture, on the basis of which a general concept for the content, organisation and structure of palliative care in residential long-term care will be developed.

Improving the quality of life of dementia patients
The model project entitled “Individual Music for People with Dementia” is being carried out in six Thuringian long-term care homes as part of a randomised controlled study. The subjects in the intervention group regularly listen to individually-selected music via headphones. The aim is to prove that the use of individually-preferred music - as a non-medicinal intervention - helps enhance the well-being, quality of life and social participation of people with dementia.

Another non-medicinal intervention is being tested by the project entitled “People with severe dementia in residential long-term care: randomised controlled study to prove the effectiveness of MAKS-s multimodal psychosocial intervention”. The project analyses whether the intervention can significantly reduce psychological symptoms and behavioural problems among severe dementia patients, thus improving the quality of life in the target group. Furthermore, it is examined whether, firstly, the practical everyday skills of the participants in the intervention group can be significantly improved, and secondly whether the stress burden on long-term care and support staff can be significantly reduced, which, thirdly, should result in a relevant reduction in the number of sick days.
Keyboard
New regulations on the supply of medicinal products

Several laws were introduced in the medicinal product sector in the year under report. The starting point for the legislature was serious deficiencies in the supply of medicinal products. It had previously become known that several blood pressure-lowering medicinal products were contaminated with potentially carcinogenic substances. Other incidences of misconduct concerned the distribution and manufacture of oncological medicinal products. In one case, the transfer of oncological medicinal products that had previously been stolen abroad took place in Germany. In another case, the cytostatic drugs produced by a pharmacist were wrongly declared, and were produced with too low a content of active ingredients. In view of the frequent occurrence of scandals related to medicinal products, the legislature felt compelled to take action. A further legislative procedure aimed to adapt national law to EU legislation and to reform pharmacy structures and remuneration. It came to a standstill in the parliamentary procedures, however.

The legislature is drawing important conclusions from the latest medicinal product scandals with the Act for More Safety in Medicinal Product Supply. The Act for More Safety in Medicinal Product Supply entered into force in August 2019. The legislature is thus drawing important conclusions from the latest medicinal product scandals. In particular, provisions are made regarding who is liable for material defects in medicinal products. In addition, unannounced inspections are to be carried out in pharmacies in future, e.g. if there is suspicion of falsification or there are indications of serious defects in medicinal products and active ingredients.

The Act also abolishes the existing special distribution channel for medicinal products for haemophilia. These had previously not been sold through pharmacies as standard, but were distributed directly to physicians and facilities. The National Association of Statutory Health Insurance Funds considers the abolition of this special arrangement to be appropriate. The extensive complex of new regulations ensures that the transfer of the products into supply via pharmacies is almost cost-neutral thanks to a two-year price reclassification process. New supply contracts between the health insurance funds and the healthcare providers ensure the financing of special forms of care in haemophilia for patients. A further new regulation furthermore ensures that the burden of co-payment on patients is limited.

Composition of pharmacists' remuneration on the basis of a fictitious example

Sales price of the pharmaceutical company 39.52 €

+ wholesale mark-up (3.15 % on sales price plus 0.70 € = max. 38.50 €) + 1.94 €

Pharmacy purchase price not incl. VAT 41.46 €

+ pharmacy mark-ups (3 % on sales price plus 8.35 €) + 9.59 €

+ mark-up for night and emergency service fund (0.16 €)* + 0.16 €

+ VAT on sales price and mark-ups + 9.73 €

Pharmacy sales price 60.95 €

* increased to 0.21 € as per 1 Jan. 2020.

Source: calculated on the basis of an arithmetically-average prescription acc. to national report of the statutory health insurance rapid medicinal product information system for Q4 2019, see https://www.gkv-gamsi.de/media/dokumente/quartalsberichte/2019/q4_2V Bundesbericht_GAmSi_201912_konsolidiert.pdf

Illustration: National Association of Statutory Health Insurance Funds
Draft Bill to promote local pharmacies

The legislature is pursuing two objectives with the draft Bill to promote local pharmacies. On the one hand, it was intended to respond to the case-law of the European Court of Justice (ECJ) of October 2016, according to which deviations from the Medicinal Products Price Ordinance (AMPreisV) in the form of bonuses to patients by foreign mail-order pharmacies are to be regarded as permissible. On the other hand, the pharmacy sector is to be further developed in terms of its structures and remuneration. The consultation was initially postponed, contrary to the original timetable. The reason for this is that an opinion of the European Commission is to be taken into account in the deliberations on the Act. The statement was delayed due to the lengthy process of constituting the new European Commission.

The National Association of Statutory Health Insurance Funds had repeatedly expressed its doubts regarding the compatibility of the Federal Ministry of Health’s plans with European law. The envisaged new provision de facto maintains the fixing of pharmacists’ uniform retail prices. From the point of view of European law, it is therefore comparable to the regulation which the ECJ, in its decision in October 2016, regarded as an interference with the free movement of goods that is enshrined in Article 34 TFEU. A violation of the new prohibition to grant discounts or bonuses is however now to be subject to contractual penalties. This is hardly feasible.

Moreover, the draft Bill provides for an additional fee for new pharmaceutical services, as yet undefined in detail. In the view of the National Association of Statutory Health Insurance Funds, additional expenditure can only be justified if it results in an additional benefit for patients. Moreover, an expert opinion by the Federal Ministry for Economic Affairs has come to the conclusion that the statutory health insurance funds are already paying pharmacists a total of around 1 billion Euro more for services today than would actually be necessary for cost-covering remuneration. It is urgent to ensure efficiency in this area.

In the view of the National Association of Statutory Health Insurance Funds, additional expenditure can as a matter of principle only be justified if it results in an additional benefit for patients.

Parts of the draft Bill to “to Promote Local Pharmacies” have been separated out in the current proceedings, and have now been regulated in the Measles Protection Act (Masernschutzgesetz). This concerns, amongst other things, the model project for flu vaccinations by pharmacists, as well as multiple prescriptions of medicinal products, where medicinal products can be dispensed several times on the basis of one prescription.
Taking stock of the Act on the Reform of the Market for Medicinal Products in 2019

The Federal Joint Committee initiated 547 sets of proceedings for the early benefit evaluation of medicinal products from the new and existing markets between January 2011 and January 2020, and conducted more than 1,625 sets of advisory proceedings. 27 out of 78 sets of exemption proceedings ended with the medicinal product being exempted from the benefit evaluation by the Federal Joint Committee. Refund amounts exist for a total of 233 active ingredients. 209 of these were concluded through agreement being reached between the contracting parties; 24 sets of proceedings were concluded with a ruling handed down by the Arbitration Office. Four active ingredients have so far been directly attributed to existing fixed-amount groups. A fixed amount for an active ingredient regulated by a refund amount became effective for the first time in 2019.

For the first time, a refund amount was agreed for an active ingredient that had initially been exempted from the benefit evaluation due to low turnover.

33 sets of refund amount negotiations, and no sets of arbitration proceedings, are pending as per 1 January 2020. 16 sets of pending refund amount negotiations constituted new negotiations that were necessitated by new resolutions of the Federal Joint Committee in conjunction with new areas of application, expiry of a deadline, or the termination of existing refund amount agreements. A refund amount was agreed for the first time in 2019 for an active ingredient that had initially been exempted from the benefit evaluation due to low turnover. This active ingredient became subject to dossier requirements as a result of exceeding the minimal level, which is 1 million Euro of turnover within twelve months.

Taking stock of the Act on the Reform of the Market for Medicinal Products

### 233 refund amounts

- **no additional benefit whatever**
  - 83
  - 46 of which medicinal products with several patient groups
- **mixed with and without additional benefit**
  - 67
- **definite positive additional benefit**
  - 83
  - 30 of which medicinal products with several patient groups
  - 11 of which mixed positive benefit

33 sets of refund amount negotiations, and no sets of arbitration proceedings, are pending as per 1 January 2020. 16 sets of pending refund amount negotiations constituted new negotiations that were necessitated by new resolutions of the Federal Joint Committee in conjunction with new areas of application, expiry of a deadline, or the termination of existing refund amount agreements. A refund amount was agreed for the first time in 2019 for an active ingredient that had initially been exempted from the benefit evaluation due to low turnover. This active ingredient became subject to dossier requirements as a result of exceeding the minimal level, which is 1 million Euro of turnover within twelve months.
30 years of medicinal product fixed amounts

For 30 years now, fixed amounts have successfully contributed to a good, affordable supply of medicinal products. As a control instrument that is close to the needs of the market, they develop their effect by combining competing medicinal products with identical or comparable active ingredients in groups. For these groups, fixed amounts are determined as maximum limits for reimbursement on the basis of existing prices. In addition, the National Association of Statutory Health Insurance Funds may exempt particularly low-priced fixed amount medicinal products from the statutory co-payment, which amounts to at least 5 Euro and at most 10 Euro.

Fixed amounts and prices
The pharmaceutical companies base their pricing on the fixed amounts. They frequently not only align their prices exactly with the fixed amount limit, but in fact undercut it. This illustrates that there is further potential for profitability, even below the fixed reimbursement level. The prices are even lower in about 65 % of all medicinal products sold on a fixed-amount basis, and they correspond exactly to the fixed amounts in about 35 % of cases. This applies regardless of whether or not the National Association of Statutory Health Insurance Funds has made arrangements for exemption from co-payment.

The relevant case-law
Fixed amounts have been repeatedly complained about by pharmaceutical companies since their introduction. All the higher courts which have jurisdiction, both at national and European level, have however now endorsed the fixed amounts system, which has worked well for 30 years, under constitutional, anti-trust and social law.

What is the secret of success?
The law clearly states how the fixed amount is to be determined. It is essential that at least 20 % of prescriptions and 20 % of the packages of a group are available at a fixed amount. On this basis, the National Association of Statutory Health Insurance Funds uses a transparent mathematical procedure to determine the exact fixed amounts, currently for 451 fixed-amount groups.

Milestones of the case-law on medicinal product fixed amounts

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2002</td>
<td>BVerfG 17 December 2002 The fixed amounts arrangement is constitutional.</td>
</tr>
<tr>
<td>2004</td>
<td>ECJ 16 March 2004 No violation of European competition law</td>
</tr>
<tr>
<td>2004</td>
<td>BSG 24 November 2004 Fixed-amount arrangement confirmed for medicinal products with the same active ingredient</td>
</tr>
<tr>
<td>2011</td>
<td>1 March 2011 Two landmark judgments on groups with several active substances and on comparative quantities</td>
</tr>
<tr>
<td>2012</td>
<td>3 July 2012 Costs of additional payments taken on by the health insurance funds only in atypical individual cases</td>
</tr>
<tr>
<td>2013</td>
<td>17 September 2013 Comparison method again confirmed</td>
</tr>
<tr>
<td>2018</td>
<td>3 May 2018 Three judgments: procedure of the National Association of Statutory Health Insurance Funds for determining fixed amounts confirmed</td>
</tr>
</tbody>
</table>

Key:
BVerfG = Federal Constitutional Court
BSG = Federal Social Court

Source and Illustration: National Association of Statutory Health Insurance Funds
The main reason for the continuing increase in expenditure on medicinal products by the health insurance funds is the constantly-rising prices of new patented medicinal products. Among these, Advanced Therapy Medicinal Products (ATMP), and orphan drugs, i.e. medicinal products for rare diseases, pose particular challenges for statutory health insurance. These medicinal products frequently reach the market for small patient populations after going through expedited approval procedures. Statutory health insurance, as well as the community of solidarity as a whole, are thus faced with the challenge of guaranteeing high-quality treatment and sustainable financing of care despite an undeveloped level of evidence.

**Advances therapies - complex new issues**

The National Association of Statutory Health Insurance Funds dealt intensively and nuancedly with the complex questions of quality and efficiency in the context of these therapies in 2019 in the exchange with its member insurance funds, and introduced the following policy demands in the form of a position paper:

- ATMPs are frequently created individually for one single patient. Uniform nationwide quality standards need to be required of healthcare providers in order to ensure the quality and safety of treatment.
- The undeveloped level of data on orphan drugs and ATMPs raises questions as to the benefits for patients where the risks are uncertain. From the patient’s point of view, authoritative studies are needed in comparison to the therapy standard.
- Treatment with ATMPs is partly out-patient and partly in-patient. This requires cross-sectoral coordination.
- Even with expensive medicinal products, the cost-benefit ratio must be suitable with regard to economic efficiency. Prices must reflect the uncertain state of knowledge regarding effectiveness and risks. Steps in the right direction have been taken with the introduction of data collections to accompany the application of medicinal products, including on orphan drugs, and the stipulation of quality requirements for the appropriate use of medicinal products for novel therapies.

### Requirements for a good, sustainable supply of ATMPs and orphan drugs

- Cross-sector supply chains ensure patients’ coordinated pre- and post-treatment.
- The evidence situation after approval - especially with regard to long-term effects - is improved as quickly as possible through patient-focussed data.
- Cross-centre documentation databases serve to generate comparative evidence according to uniform, binding guidelines on patient-relevant outcomes.
- The amount of the refund is retroactively linked to the actual duration and extent of the additional benefit, as well as to the generation of further evidence.
- The reimbursement amount for ATMPs or other one-off therapies applies retroactively from the first day on which the product is placed on the market.

**The challenge is to guarantee high-quality treatment and sustainable financing of care despite an undeveloped level of evidence.**
Reform in remedies

The Appointment Service and Care Act (TSVG) fundamentally reorganises the contractual remedies landscape. The National Association of Statutory Health Insurance Funds has been given numerous new tasks in this context:

• recalculation of the prices applicable nationwide for remedies with effect from 1 July 2019 onwards
• establishment of a joint approval agency for remedy suppliers per Federal Land as of 1 September 2019
• agreement on contracts and prices for remedies at federal level with the relevant national organisations of remedy suppliers by June 2020 and establishment of an Arbitration Office by November 2019
• establishment of healthcare provider-determined care levels by November 2020

Uniform nationwide prices set
The National Association of Statutory Health Insurance Funds has agreed with the relevant remedy associations on uniform national prices for remedies. The highest price agreed for the respective benefit item in a region within Germany was taken as a basis. The prices were published on www.gkv-heilmittel.de in good time and in accordance with the statutory obligation, and have replaced the prices for remedies previously agreed at the level of the health insurance funds since 1 July 2019.

Reorganisation of the approval procedure for remedies
The new working groups to be formed by each Federal Land for the approval of remedy practices were able to start work on time as of 1 September 2019. Remedy suppliers now only have to submit their application for approval to one body. The National Association of Statutory Health Insurance Funds has provided a technical procedure for the collection, acceptance and forwarding of registration data on schedule as a working basis for the working groups.

The selection of the members of the Arbitration Office
If disagreements arise during contract negotiations, they are to be settled by an Arbitration Office. The representatives of the remedy associations and of the National Association of Statutory Health Insurance Funds have agreed on the impartial members of the Arbitration Office.

Price and contract negotiations
The National Association of Statutory Health Insurance Funds was given the statutory mandate to agree on the remedy contracts in future, including prices for remedies, with the relevant national organisations of the remedy suppliers at federal level. The prices are to enable a performance-related, economic supply, and are to be calculated on a commercial basis. The development of the staffing and material costs for the provision of services, and the average running costs for the operation of a remedy practice, should particularly be taken into account. After the relevant remedy associations had been identified by the National Association of Statutory Health Insurance Funds, and extensive preparatory work had been carried out on a uniform draft contract and on pricing by the health insurance funds, it was possible to start the contract negotiations in the five remedy areas in the fourth quarter of 2019. They are to be concluded by 30 June 2020.
Hard drive_
Standardising the medical aid supply system

The National Association of Statutory Health Insurance Funds and the relevant national organisations of the healthcare providers at federal level are issuing joint framework recommendations to simplify and standardise the implementation and billing of the supply of medical aids.

Agreement was reached on various contents of this framework agreement:
- data protection
- standardisation of data collection forms
- documentation of advice to insured persons by healthcare providers
- establishment of a contract committee for questions of interpretation

The points on the electronic cost estimate and on the documentation of the insured persons’ co-payments remained contentious right up to the end. The negotiations were concluded by an arbitration award at the end of 2019. The proposal made by the National Association of Statutory Health Insurance Funds to improve the electronic cost estimation procedure was taken up in full. The call of the National Association of Statutory Health Insurance Funds for the documentation of the medical aids offered free of additional cost was not however included in the framework recommendation.

Rules of procedure for updating the medical aid directory
The Federal Ministry of Health has approved the Rules of Procedure of the National Association of Statutory Health Insurance Funds for the Preparation and Updating of the Medical Aids and Long-Term Care Aids List. This has created the framework for transparent, structured, comprehensible procedures and decisions. The medical aid directory is thus regularly adapted to the generally-recognised state of medical and technical knowledge, and the products can be introduced into the care system. This takes into account the dynamic medical aid market, and safeguards the high standard of care in Germany.

Updating the eligibility requirements for healthcare providers
The National Association of Statutory Health Insurance Funds has twice updated the recommendations for the uniform application of the requirements for the adequate, appropriate, functional manufacture, supply and adaptation of medical aids. These form the basis for the aptitude tests of the medical aids service providers by the prequalification bodies, or in individual cases by the health insurance funds. In particular, the recommendations were adapted to the completely revised medical aids directory. Moreover, further training courses were defined for the technical managers and employees of the companies in stoma management for the first time. This creates the basis for further quality improvements in the supply of medical aids.

The main legal framework in supply of medical aids

Framework recommendations have been established in order to standardise administrative procedures for the provision of medical aids.
The Year's Topics

Transparency on increased costs for medical aids

The overall update of the medical aids directory provided for by the Remedies and Medical Aids Supply Act (HHVG) was successfully completed as of the end of 2018. The numerous new regulations that this entails will ensure that persons with statutory health insurance receive medical aids of higher product quality, have access to product innovations, and have their individual care needs taken into account. When updating the 41 product groups of the medical aid directory, the focus was particularly placed on promoting insured persons’ rights and on the principle of benefits in kind. The newly-formulated service requirements stipulate comprehensive advice by the healthcare providers on needs-based care options that are free of additional costs. The National Association of Statutory Health Insurance Funds provided information on the results and details of the update project in a press briefing held in February 2019 on the occasion of the publication of the second update report. Over and above this, in accordance with the Rules of Procedure for the updating of the medical aids directory, the regular or ad hoc updating of nine product groups - including incontinence aids, hearing aids and insoles - was initiated.

Report on additional costs presented
The first report by the National Association of Statutory Health Insurance Funds on additional costs, published in July 2019, provides a comprehensive overview of the average additional costs paid by insured persons for medical aids, broken down by the product groups of the medical aids directory. It reveals all in all that 82 % of persons with statutory health insurance receive their medical aids free of additional costs. In 18 % of the cases examined, additional costs were documented, with two-thirds of the costs incurred being attributable to hearing aids.

Survey among insured persons on hearing aids supplied to them
The reasons for agreements on additional costs for supplying hearing aids were investigated in a representative survey among insured persons carried out by the National Association of Statutory Health Insurance Funds. A total of 3,457 adults with statutory health insurance took part in the largest survey of insured persons to date. 70 % of the respondents stated that they had made additional payments for their care. The analysis of the data shows that the level of the additional costs does not correlate with the level of satisfaction with the care provided: At 81 %, satisfaction with the hearing aid was almost as high for both the options with no additional cost, and where additional costs were paid. The survey furthermore showed that agreements on additional costs are mainly due to the very broad and technically diversified range of hearing aids available. It was however also shown that the level of the additional costs is influenced by the advice and services offered by the hearing care professional, as well as by the demand behaviour of the insured persons.
Zip_
The first report by the National Prevention Conference

The National Prevention Conference (NPC) submitted its first prevention report to the Federal Ministry of Health in June 2019. This is the first time that there has been a stock-take of the implementation of the National Prevention Strategy developed by the NPC and of other measures initiated on the basis of the Disease Prevention Act, which came into force in 2015.

**A considerable expansion of the commitment on the part of statutory health insurance**

The findings of the report show that the health insurance funds in particular have greatly increased their involvement: Of the total of 302.8 million Euro that the social insurance funds and the private health and long-term care insurers additionally mobilised for health promotion and primary disease prevention in 2016 and 2017, 201.5 million Euro (67 %) were accounted for by statutory health insurance.

**Statutory health insurance generated 201.5 million Euro out of the total of 302.8 million Euro that were additionally mobilised for health promotion and primary disease prevention in 2016 and 2017.**

A look at the individual service areas shows that the increase in statutory health insurance expenditure is attributable to those benefits to which minimum expenditure values have applied since 2015. For example, expenditure on health promotion and prevention in settings (section 20a of Book V of the Social Code) rose by 78.1 million Euro (+205 %) in 2016, and that on occupational health promotion benefits and on prevention of work-related health hazards went up by 70.7 million Euro (+93 %) (sections 20b and 20c of Book V of the Social Code). Even more funds were made available in 2017 than had been the case in the previous year: The additional expenditure amounted to 37.1 million Euro (+32 % for benefits in accordance with section 20a of Book V of the Social Code), and 11.2 million Euro (+10 % for benefits in accordance with section 20a and section 20b of Book V of the Social Code). Developments in expenditure on benefits in individual behavioural prevention (section 20 subsection (5) of Book V of the Social Code) are significantly weaker, having increased by 7.6 million Euro (+3.8%) in 2016, and even declining in 2017 (-3.2 million Euro). This is due to the shift in the commitments of statutory health insurance in favour of health promotion and prevention in settings, including the company setting.

**The need to set the course for action by society as a whole**

Even though the Disease Prevention Act (Präventionsgesetz) focuses closely on the social insurance agencies - and especially on statutory health insurance - significant factors that influence health status are beyond their control. This applies for example to living conditions, economic factors, educational opportunities, social networks and the natural environment. The aim should therefore be to reach agreements as part of the National Prevention Strategy which will help to move closer towards a pan-societal and cross-policy approach.
Overview of the National Prevention Strategy under section 20d of Book V of the Social Code

The institutions supporting the National Prevention Conference (NPC):
- National Association of Statutory Health Insurance Funds
- German Social Accident Insurance, national association
- Social Insurance for Agriculture, Forests and Gardening
- German Federal Pension Insurance

The National Prevention Conference (NPC)

The Year's Topics
Expansion of health promotion in the municipalities

The Statutory Health Insurance Alliance for Health is a joint initiative of the statutory health insurance funds for health promotion and disease prevention in settings. Based on scientific and practice-orientated findings, the Alliance promotes a wide range of activities from which vulnerable target groups in the municipalities are to benefit in particular. The statutory health insurance Alliance is making a total of 90 million Euro available for this commitment.

A municipal support programme
The Statutory Health Insurance Alliance for Health set up two support programmes for municipalities in 2019. Municipalities can receive funding for several years if the formal requirements and the criteria listed in the funding notices are satisfied.

Establishing structures
The programme entitled "Establishing health-promoting governance structures" aims to support municipalities in exercising their own responsibilities for shaping health promotion and disease prevention. Especially municipalities in socio-economically disadvantaged areas often lack the financial resources to establish mandatory structures for disease prevention and health promotion, such as health conferences. Such structures are however necessary so that measures can be planned and implemented as needed.

Submitting offers
Whilst only selected socially-disadvantaged municipalities can take advantage of this offer, the promotion of "target group-specific interventions" is open to all municipalities. This is intended to enable groups of individuals who are regarded as particularly vulnerable in terms of their health and social situation to benefit from health-promoting measures more than was previously the case. These groups of individuals include people with disabilities, children and juveniles from families with addiction problems, or people with a migration background. In this context, municipalities can work together with local cooperation partners such as sports clubs, counselling centres, neighbourhood facilities or welfare associations.

Municipal support programme of the Statutory Health Insurance Alliance for Health

<table>
<thead>
<tr>
<th>Support programme for enhancing municipal structures</th>
<th>Project support for vulnerable target groups</th>
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<tbody>
<tr>
<td>Eligible to apply</td>
<td></td>
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<tr>
<td>Municipal territorial authorities at the level of districts and of non-district towns where the social structure shows low socioeconomic values</td>
<td>Municipal territorial authorities at the level of districts and of non-district towns regardless of their social structure</td>
</tr>
<tr>
<td>Applications lodged by the most senior management of office or administration</td>
<td>Applications lodged by the most senior management of office or administration</td>
</tr>
<tr>
<td>Amount of support max. 210,000 € or 250,000 €</td>
<td>max. 110,000 €</td>
</tr>
<tr>
<td>Support period 5 years digressive support to ensure sustainability</td>
<td>4 years digressive support in the 4th year to ensure sustainability</td>
</tr>
</tbody>
</table>

1 Support is provided at district (Bezirk) level in the city states of Berlin and Hamburg, and in the city of Bremen.
2 The basis for the selection of municipalities is formed by the Robert Koch Institute’s German Index of Socioeconomic Deprivation.
Illustration: National Association of Statutory Health Insurance Funds
Projects for disease prevention and health promotion

The nationwide activities of the Statutory Health Insurance Alliance for Health focus on people in stressful life situations with special needs. The target groups include unemployed people, people with disabilities, and older people. These target groups can be reached with low-threshold health-promoting offers as part of the nationwide projects.

**Interlinking work and health promotion**
What began in 2014 as a small pilot project between the community of health insurance funds and the Federal Employment Agency, limited to six locations, was expanded significantly in 2019 through the systematic interlinking of employment promotion and health promotion. Broad-based cooperation between the Statutory Health Insurance Alliance for Health and the partners on the labour market, namely the Federal Employment Agency, the German Association of Rural Districts and the Association of German Cities, is now taking place at more than 200 locations. A steering group in each location identifies the health-related needs of unemployed people, plans appropriate offers for the target group, and implements them. The division of tasks between the partners follows the respective statutory responsibilities: The experts at the Job Centres and the Employment Agencies sensitise people to the topic of health in health-orientated counselling sessions. The Statutory Health Insurance Alliance for Health offers special health promotion and disease prevention measures for unemployed people, which they can use on a voluntary basis.

**Physical activity for people with disabilities**
Low-threshold physical activity and health promotion programmes for mentally-disabled people are being developed and tested at selected locations in Berlin, Brandenburg, Bremen, Saxony-Anhalt, Schleswig-Holstein and Thuringia, as part of the project entitled “Boosting Physical Activity and Health in Everyday Life”, which is being carried out with Special Olympics Germany. People with disabilities will be recruited as experts on their own merits for the implementation of the project.

**The experts at the Job Centres and the Employment Agencies sensitise people to the topic of health in health-orientated counselling sessions.**

**Active in old age**
The project by the name of “Remaining active and fit in old age in municipalities” seeks to help create an environment that is conducive to physical activity in the municipalities, and to increase the physical activity of older people. The German Gymnastics Federation is implementing the project together with the Rhine Hesse Gymnastics Federation, the Saxon Gymnastics Federation and the Land Gymnastics Federation of Saxony-Anhalt.

**More physical exercise in everyday life**
The “National Recommendations for Physical Exercise and Promotion of Physical Activity”, which were developed in 2016 on behalf of the Federal Ministry of Health, form the scientific basis for the project entitled “Municipal Promotion of Physical Exercise for the Implementation of the National Recommendations”. As part of the project, structures for the promotion of physical exercise are to be established in selected municipalities, which are geared to needs and practice-orientated.

You can find detailed information on these and other projects at:
https://www.gkv-buendnis.de/
buendnisaktivitaeten/bundesweite-aktivitaeten/
Hotspot_
Promoting family caregivers through rehabilitation

The Act to Promote Nursing Staff (PpSG) also reinforced the entitlement of family caregivers to receive medical rehabilitation benefits. This takes account of the special needs of family caregivers. Due to the long-term care situation of the family, they are often not able to avail themselves of non-residential rehabilitation services.

The new arrangement therefore gives family caregivers a choice between residential and non-residential rehabilitation. In addition, the person in need of long-term care can also be accommodated. The cost of care is covered by the health insurance fund of the family caregiver. If the person in need of long-term care is cared for in another institution (e.g. respite care) during the rehabilitation period, the health and long-term care funds will coordinate the care together if desired.

Setting the stage

With the aim in mind of ensuring the uniform application of the law, the National Association of Statutory Health Insurance Funds and the associations of the health insurance funds at federal level have issued recommendations to the health insurance funds for the implementation of the Act to Promote Nursing Staff with regard to medical rehabilitation benefits. Furthermore, the National Association of Statutory Health Insurance Funds, together with the Federal Association of Statutory Health Insurance Physicians, have created further prerequisites for the adaptation of the prescription model so that it can be enacted promptly following the necessary amendment of the Federal Joint Committee’s Guideline on Rehabilitation. The National Association of Statutory Health Insurance Funds, together with the German Hospital Federation, has integrated the special interests of family caregivers into the necessary application procedure for the area of follow-up rehabilitation.

The information on offer

The National Association of Statutory Health Insurance Funds and the associations of the health insurance funds at federal level have also created an information service in the form of the “Joint information of the health and long-term care insurance funds in accordance with section 12 of Book IX of the Social Code in support of the early recognition of needs”. In addition to general background information on medical rehabilitation, this includes specific information on rehabilitation for family caregivers.

It is made easier for family caregivers to take up residential and non-residential rehabilitation.

Rehabilitation for family caregivers

It is usually difficult for family caregivers to take advantage of necessary rehabilitation measures given the long-term care situation. At the same time, they frequently suffer from particular strain. Special framework conditions have therefore been created for this group of individuals, and these are intended to make it easier for them to make use of medical rehabilitation:

• Family caregivers can choose between residential and non-residential rehabilitation.
• Persons in need of long-term care can also be catered for in the rehabilitation facility. The costs are covered by the health insurance fund of the family caregiver.
• Persons in need of long-term care can also be accommodated in a respite care facility at the place of residence or near the rehabilitation facility during the rehabilitation measure. In this case, respite care and nursing where the carer is unable to attend can be taken up. The health insurance fund coordinates the care with the long-term care fund, with the consent of the persons in need of long-term care.
Structured discharge management after residential rehabilitation

Discharge management from residential rehabilitation and from hospital treatment was fundamentally redefined by the Care Improvement Act (Versorgungsstärkungsgesetz). The National Association of Statutory Health Insurance Funds, the National Association of Statutory Health Insurance Physicians, and the associations of rehabilitation facilities at federal level, were mandated to conclude the corresponding framework agreement on structured discharge management. A consensus was reached in January 2019 following intensive consultations. The framework agreement came into force as per February 2019 and, following the expiry of transitional periods, took full effect from August 2019 onwards.

The implementation of the contents of discharge management has made a significant contribution towards improving follow-up care from residential rehabilitation. The National Association of Statutory Health Insurance Funds and the associations of the health insurance funds at federal level will continue to closely monitor the implementation of discharge management and, where necessary, make adjustments with the involvement of the contracting parties.

Enhancing follow-up rehabilitation
In addition, in order to improve access to medical rehabilitation from in-patient hospital treatment, the National Association of Statutory Health Insurance Funds, the associations of the health insurance funds at federal level, and the German Hospital Federation, have agreed on a standard set of forms entitled “Application for follow-up rehabilitation”. This is an annex to the framework agreement on discharge management during the transition to post-hospital care, and is to be used in hospitals from 2020 onwards.

Elements of discharge management
• establishing and documenting the medical and long-term care needs existing post-rehabilitation
• introducing the medical and/or long-term follow-up care of the person undergoing rehabilitation, if necessary contacting the doctor or healthcare provider providing further treatment at an early stage
• prescribing benefits of the statutory health insurance funds
• assistance and advice when applying for health insurance and/or long-term care insurance fund benefits
• assistance in establishing contact with self-help groups
• identifying incapacity for work
• issuing a rehabilitation discharge report or a preliminary rehabilitation discharge report in order to ensure the flow of information

Other elements of discharge management can be:
• assistance in applying for necessary measures of participation in working life
• assistance in applying for necessary benefits for participation in life in the community
Net-based_
New regulations for midwifery and psychotherapists’ training

The training arrangements for psychotherapists, as well as for midwives, were revised by the legislature in 2019. The National Association of Statutory Health Insurance Funds welcomes the modernisation of professional training as a matter of principle. It is however critical of quality assurance and financing.

The reform of psychotherapists' training
The legislature has made an amendment to the Psychotherapists Act (Psychotherapeutengesetz) in the form of the Act to Reform the Training of Psychotherapists (Gesetz zur Reform der Psychotherapeutenausbildung). Two essential problems were to be solved by the reform:

1. The previous arrangements regarding training and qualification paths have been adapted in line with the Bologna Process in the interest of international comparability.
2. The financial situation of psychotherapists in training is improved by obtaining a licence to practice immediately after completing their studies and the possibility of treatment by psychotherapists who are undergoing further training.

Obtaining a licence at an early stage means that psychotherapists are entitled to practise treatment, even though they have had little opportunity to develop practical skills in the course of their studies. In addition, the field of activity is extended beyond medicine to include counselling, prevention and rehabilitation. It is therefore to be feared that seriously mentally ill insured persons will find it even more difficult to find a treatment place.

Obtaining a licence at an early stage means that psychotherapists are entitled to practise treatment, even though they have had little opportunity to develop practical skills in the course of their studies.

Reform of midwives' training
The Midwifery Reform Act (Hebammenreformgesetz) paved the way for all midwives to be higher education graduates. The Act will pose major challenges to the Federal Länder when it comes to creating sufficient study places. The National Association of Statutory Health Insurance Funds welcomes the mandatory university studies. It must however be ensured that midwives continue to perform tasks such as weighing and measuring the child, i.e. providing care in the childbed care period. The range of activities of academically-trained midwives must not be reduced to management and research tasks and birth care alone. The question will arise in this context as to how today’s midwives who have been trained at vocational school and those who will be trained at University will work together in future with their different levels of qualification.

A shortage of midwives must be expected to occur from a care perspective. A large proportion of those who have been able to learn this profession without obtaining a higher education qualification will not be able to gain access in future. Insured persons’ money from statutory health insurance is also partly used to finance the dual studies, even though education is a sovereign task of the Federal Länder. The National Association of Statutory Health Insurance Funds is critical of this financing of non-insurance benefits.
Back-up_
The Year's Topics

Fighting corruption in the healthcare system

The fight against misconduct and corruption in the healthcare system is a national as well as an international issue. Against the background of cross-border healthcare, there is an increasing need for an exchange of experience and networking with other countries. The aim is not only to coordinate measures better, but also to respectively further develop the legal framework to fight crime more effectively. The National Association of Statutory Health Insurance Funds organised two events in 2019 with the active promotion and advancement of these processes in mind.

A cross-organisational exchange of experience in Germany

The National Association of Statutory Health Insurance Funds organised a cross-organisational exchange of experience in May 2019 between the agencies responsible for combating misconduct in the healthcare system. An interim review was conducted three years after the Act to Combat Corruption in the Healthcare System (Gesetz zur Bekämpfung von Korruption im Gesundheitswesen) came into force. The impact and effectiveness of the new offences of taking and giving bribes in the healthcare system were also discussed.

The opening lecture by Prof. Michael Kubiciel from the University of Augsburg revealed perhaps the most important finding, drawing on the Federal Situation Report on Corruption published by the Federal Criminal Police Office: With only approximately 200 “corruption offences” registered nationwide, the new criminal offences of corruption in the healthcare system have not yet proven to be an effective basis for criminal prosecution. The actual practical test with the main criminal proceedings and the proceedings on appeal on points of law only is still to come. Having said that, the new offences are not toothless tigers, as the Act to Combat Corruption in the Healthcare System has a corruption-preventing effect.

The following contributions made it clear that the increased consultation by the Land Medical Associations and Associations of Statutory Health Insurance Physicians has contributed to the education and necessary sensitisation of the medical profession and helped in the systematic development of new compliance concepts. The accessory nature of the criminal offences contributes to this as follows: Cooperation which is permitted under the applicable professional and social law does not fall within the scope of the new criminal offences. In contrast, violations of existing prohibitions under professional and social law always carry a high risk of criminal liability.

Finally, the related findings from the practice of the law enforcement authorities were awaited with particular excitement by the approx. 150 participants. Several proven experts were welcomed from Munich I specialised public prosecution office, Frankfurt am Main chief public prosecution office, Celle chief public prosecution office, and Braunschweig public prosecution office. The abovementioned criminal prosecution authorities are already particularly specialised in combating property crimes and corruption in the healthcare system. The application of the new criminal offences to recurring case constellations was described in detail on the basis of initial investigation proceedings. The event was thus also able to make a significant contribution towards the exchange of experience between the public prosecution authorities of the different Federal Länder.

Cross-border cooperation in combating fraud and corruption

The European Healthcare Fraud & Corruption Network (EHFCN) organised the 13th two-day international conference in November 2019, this year for the first time in cooperation with the National Association of Statutory Health Insur-
ance Funds. Some 160 experts from 24 countries, most of whom were from the European Union (EU), took up the invitation to attend the conference on the topic of "Bytes without borders: preventing and countering healthcare fraud and corruption in the digital age".

In view of an open internal market and cross-border healthcare, going it alone in the fight against fraud and corruption does not seem to be expedient. In order to be able to meet the challenge successfully, closer cross-border cooperation in combating fraud and errors is needed in the procedure for electronic data exchange between the social insurance agencies throughout Europe, in accordance with the provisions contained in the regulations on the coordination of the social security systems.

The conference attendees described information and data analyses as key tools in the age of the digitalisation of the healthcare system. They have helped to develop innovative methods to detect accounting fraud. A focus of the conference was therefore placed on holding interactive practical workshops in which solutions that were already being successfully applied were presented along with ongoing practical projects.

“E-health, Big Data or Artificial Intelligence are already part of modern healthcare in the EU. Innovative approaches are however needed not only in patient care, but also when it comes to combating abuse and corruption. We can only be successful if we share experience and knowledge with other EU States, i.e. if we act in a network,” says Dr. Doris Pfeiffer, Chairwoman of the Board of the National Association of Statutory Health Insurance Funds.
Anonymisation_
Pseudonymisation_
A negative trend in statutory health insurance funding

The statutory health insurance funds will close the year under report 2019 with a deficit for the first time, after three years with positive financial results in the billions of Euros.* The anticipated deficit will amount to more than 1.5 billion Euro, and will outstrip the foreseeable increase in revenues of the Health Fund amounting to approximately 0.7 billion Euro. Consequently, the financial result of statutory health insurance in 2019 will be negative overall. A shortfall is expected to develop for 2020, for both the Health Fund and for the health insurance funds. This is despite the fact that the continued good employment and wage development led to a further significant increase in assessable income. The development of the deficit is therefore all the more worrying.

The vast majority of the health insurance funds were nevertheless able to keep their additional contribution rates stable at the turn of the year due to the gratifying reserve situation. The average additional contribution rate published by the Federal Ministry of Health, which must be calculated to cover expenditure, was raised from 0.9 % to 1.1 % for 2020 due to the fact that the expenditure prognosis was higher than the revenue forecast.

Financial development in 2019
The income subject to contributions of the statutory health insurance members (basic wage and pension total) increased in the year under report by 4.3 % year-on-year, to reach Euro 1,467.6 billion. A general contribution rate of 14.6 % hence resulted in income from contributions amounting to approx. 214.3 billion Euro. Factoring in contributions from marginal employment (approx. 3.2 billion Euro), and the contribution from the Federation reduced by the share of the Agricultural Health Insurance Fund (approx. 14.4 billion Euro), the total income of the Health Fund was about 231.9 billion Euro. This income enabled the Health Fund to fully finance the allocations of 231.1 billion Euro which had been assured to the health insurance funds for 2019. The excess funds are credited back to the liquidity reserve of the Health Fund. This increase in income will be around 0.7 billion Euro, once other statutory financial obligations of the Health Fund vis-à-vis the Innovation Fund and the Structural Fund, as well as the balance from the income equalisation of the additional contributions, have been taken into account. The Fund reserve will therefore be approx. 9.9 billion Euro as per 31 December 2019.

The statutory health insurance appraisers were unable to provide an agreed estimate regarding the expected expenditure of the health insurance funds. Whilst the Federal Ministry of Health and the Federal Insurance Office forecast an increase in expenditure by 11.3 billion Euro to around 245.7 billion Euro (+ 4.8 %), the financial experts of the National Association of Statutory Health Insurance Funds estimated an increase in expenditure of 11.6 billion Euro to around 246.0 billion Euro (+ 4.9 %). Given allocations of roughly 231.1 billion Euro from the Health Fund to the health insurance funds, the shortfall in fund-relevant expenditure was therefore approx. 14.6 billion Euro in 2019 according to the estimate by the Federal Ministry of Health and the Federal Office of Administration, and 14.9 billion Euro according to the estimate by the National Association of Statutory Health Insurance Funds. The additional contribution rates actually charged in 2019 in order to finance this shortfall varied between 0.3 % and 2.5 %, with the additional contribution rate averaging out at the rate of 0.9 % set ex ante by the Federal Ministry of Health. No health insurance fund was able to avoid charging an additional contribution in the year under report.

The financial forecast for 2020
The statutory health insurance appraisers clearly anticipate a further 3.8 % increase in income subject to contributions, which is thus set to reach 1,523.2 billion Euro in 2020. They estimate that income from contributions for 2020 will be approx. 222.4 billion Euro on this basis, plus contributions
from marginal employment amounting to approx. 3.3 billion Euro. Furthermore, the health insurance funds will receive a special one-off allocation of 225 million Euro from the reserve of the Fund for the calendar year 2020. This is intended to compensate for newly-introduced surcharges on invoices which the health insurance funds will have to pay to the hospitals in the event of the Fair Fund Selection Act (GKV-FKG) coming into force. Together with the contribution of the Federation amounting to approx. 14.4 billion Euro, and minus the expenditure of the Health Fund (20 million Euro), an allocation volume totalling approx. 240.2 billion Euro emerges. This amount is to be assigned as income to the health insurance funds for 2020. Because of the financial share that the Health Fund must also provide for the Innovation Fund and for the Structural Fund in 2020, and of the anticipated reduction in income resulting from the introduction of an allowance on company pensions (Statutory Health Insurance Company Pension Allowance Act [GKV-Betriebsrentenfreibetragsgesetz]) of 21 December 2019) amounting to approx. 1.2 billion Euro, which the statutory health insurance appraisers were not yet able to include in their income estimate, the Fund reserve will be reduced to an estimated level of approx. 7.8 billion Euro at the end of 2020.

Based on the expenditure estimate for 2019, the statutory health insurance appraisers were also unable to provide an agreed expenditure forecast for 2020. The Federal Ministry of Health and the Federal Office of Administration estimated the anticipated fund-relevant expenditure of the health insurance funds for 2020 at 256.8 billion Euro, the National Association of Statutory Health Insurance Funds at 258.6 billion Euro. This corresponds to an increase of 4.5 % (Federal Ministry of Health/Federal Office of Administration) or 5.1 % (National Association of Statutory Health Insurance Funds) compared to the previous year. In addition to the anticipated effects of the Appointment Service and Care Act (TSVG) and of the Act to Promote Nursing Staff, amongst other things the anticipated financial impact of the drafts of the Medical Service Reform Act, of the Digital Care Act, of the Measles Protection Act, and of Statutory Health Insurance Fair Fund Selection Act, are included in the estimate.

This results in an estimated shortfall in expenditure for the health insurance funds in 2020 of around 16.6 billion Euro (Federal Ministry of...}
The calculated additional contribution rate requirement is 1.1% and 1.2%, respectively. As had been anticipated, the Federal Ministry of Health, which is responsible for the definition, raised the average calculated additional contribution rate from 0.9% to 1.1% in October 2019. The average additional contribution rate serves on the one hand as a relevant additional contribution rate for the calculation of contributions for certain groups of members, e.g., for recipients of unemployment benefit II, and on the other hand as a benchmark for the price competition desired by lawmakers for health insurance funds. The National Association of Statutory Health Insurance Funds believes that the rate set for 2020 does not adequately reflect the actual financial needs of the health insurance funds.

Stable contributions as per the end of the year

Despite the negative financial development in 2019, 76 of the 108 health insurance funds financed by the Health Fund in 2019 were able to keep their additional contribution rate stable as of 1 January 2020, and five institutions were even able to reduce their rates. The additional contribution rates collected at the beginning of 2020 vary between 0.2% and 2.7%; one regional health insurance fund is able to dispense with collecting an additional contribution altogether. Contributions are expected to remain largely stable for 2020; the financial situation of the health insurance funds can however be predicted to be more critical from 2021 onwards. In addition to the already increased spending dynamic, many of the Federal statutes that have been passed since 2018 will successively lead to an additional spurt in expenditure. The cumulative expenditure impact of the legislation passed in the current legislative period, above all the additional expenditure resulting from the Act to Promote Nursing Staff and of the Appointment Service and Care Act, is estimated by the National Association of Statutory Health Insurance Funds at around 5.6 billion Euro for 2020. Since significant parts of this additional expenditure permanently increase the expenditure base, an increase in the future expenditure level, affecting the basis, of about 5 billion Euro is to be anticipated.

This calculation does not include those expenditure risks generated by new legislation which are evident but difficult to quantify, such as future additional expenditure on digital health applications. The financial dimension of these new benefits of statutory health insurance introduced with the Digital Care Act is currently still difficult to assess. It is however to be feared that it will further worsen the development of expenditure. There will however be no escaping contribution rate adjustments as soon as the reserves are reduced to the statutory minimum amounts.

*Because of the early publication of the Annual Report, the presentation of the financial situation of statutory health insurance in the year under report is essentially based on the results of the autumn forecast by the appraisers (table of estimates dated 11 October 2019); accordingly, the presentation of the financial data additionally arising at insurance fund level and shown in the official statistics at later dates, in particular the other income and expenditure of the health insurance funds, is omitted. The forecasts for 2020 presented here can no longer be regarded as valid at the time of publication as a result of the revenue and expenditure effects of the corona pandemic.
Financial and organisational reform in health insurance

The Statutory Health Insurance Fair Fund Selection Act (GKV-FKG) that was passed by the German Bundestag on 13 February 2020 readjusts the competition between the health insurance funds desired by the legislature in three regulatory areas. Firstly, the morbidity-orientated risk structure equalisation (Morbidity-orientated RSE) will be further developed after a long and intensive debate and accompanying scientific evaluation; secondly, the organisational law of the competing health insurance funds will be harmonised, and thirdly, the competition law applicable to the specific member competition of the health insurance funds will be reformed.

Morbidity-orientated RSE as a permanent building site
With the Statutory Health Insurance Fair Fund Selection Act, the legislature is fulfilling its statutory obligation to further develop the risk structure equalisation, taking into account the relevant opinions of the Scientific Advisory Board. At the same time, the Grand Coalition is working with the reform on a commitment contained in its Coalition Agreement, according to which the Morbidity-orientated RSE - in the political diction - should be further developed with the aim in mind of ensuring fair competition, and should be protected against manipulation.

The extensive changes to the financial equalisation system constitute the core of this reform Bill in terms of their scope and economic significance for the health insurance funds. The draft Bill takes up some of the reform proposals of the Scientific Advisory Board at the Federal Office for Social Security (BAS); these include in particular:

- introducing a model encompassing all diseases
- creating a risk pool
- introducing a regional component

The draft Bill also provides for the following changes as essential additional measures:

- introducing a lump sum for prevention in disease prevention
- establishing a “brake on manipulation”
- abolishing the criterion of reduced earning capacity

Due to its competition-neutral orientation and the diverging interests of its members in the further development of the Morbidity-orientated RSE, the National Association of Statutory Health Insurance Funds has deliberately not taken up a position on the necessity and appropriateness of the individual reform measures. The new requirements for the health insurance funds will take financial effect from the equalisation year 2021.

The extensive changes will tie up considerable resources in cooperation between the member funds and the BAS in order to ensure the timely, frictionless implementation of what the Act is designed to achieve.
Organisation law of the health insurance funds

The Statutory Health Insurance Fair Fund Selection Act also harmonises the organisational law of competing health insurance funds. The reform of the liability arrangements in the event of the closure or insolvency of a health insurance fund is essential in this process. Under the law as it stands, the health insurance funds of a type of health insurance fund (local, company, guild health insurance funds and substitute funds) are liable for the obligations of a dissolved, closed or insolvent health insurance fund of their type of health insurance fund (primary liability). Only in the event that the liable type of health insurance fund is unable to meet its obligations in economic terms are the other health insurance funds liable for the uncovered amount. The community of all health insurance funds will be directly liable in future for the obligations of a dissolved, closed or insolvent health insurance fund.

The National Association of Statutory Health Insurance Funds has spoken out in the legislative procedure against this abolition of primary liability. The background to this is that, in the view of the National Association of Statutory Health Insurance Funds, the primary aim of the liability system should be to prevent liability, i.e. to avoid closures and insolvencies. And it should be noted here that the previous liability system established the economic incentives in such a way that the community of liability concerned had a homogeneous interest in maintaining an endangered “sister fund”. The members of the joint liability scheme were always aware that closures would be more expensive than mergers - possibly also financially supported. Consequently, the practical experience of the National Association of Statutory Health Insurance Funds in the prevention of liability also shows that the association with primary liability played a major supporting role in the ability of the liability prevention system to function.

The legislature has nevertheless opted to abolish primary liability. This means that, with a view to liability prevention, the existing statutes of the National Association of Statutory Health Insurance Funds on voluntary financial assistance need to be adapted in line with the new legal situation.

The National Association of Statutory Health Insurance Funds believes that the design of the liability system should focus on avoiding closures and insolvencies.

Competition law

The new section 4a of Book V of the Social Code creates a specific foundation under social law for competition between members. Accordingly, competition between the health insurance funds serves the goal of improving the range of services and increasing the economic efficiency of care. The health insurance funds are expressly granted the right to advertise for members. At the same time, the principle is laid down that unfair commercial activities are not permissible, and thus directly result in claims for injunctive relief. It is also clarified that measures for risk selection are not permissible. The concrete framework for the admissibility of advertising measures will be laid down in a binding fashion in future in a legal ordinance.

This understanding of competition is by no means new; it is already being practised today, and is based on various individual standards and on the case-law of the social courts. The codification of this competitive framework in Book V of the Social Code is welcomed by the National Association of Statutory Health Insurance Funds as a first step towards a social competition law.
Trojan

Representation of interests at EU level

National Association of Statutory Health Insurance Funds

Associations of health and long-term care insurance funds at federal level

Accident insurance Pension insurance

Illustration: National Association of Statutory Health Insurance Funds
An appeal for cooperation within Europe

“The withdrawal of the United Kingdom from the EU is regrettable, but at the same time it sharpens the focus on what we have achieved together: Citizens benefit greatly from European integration.”

With these words, the Administrative Council of the National Association of Statutory Health Insurance Funds took up a position vis-à-vis the EU. European integration brings advantages, not lastly also in the healthcare sector - directly through functioning healthcare cover when staying in another EU State, and indirectly through the advantageous cooperation between the Member States, for example in the approval of medicinal products.

With the position paper entitled “Europe: joining forces, using potentials” that was adopted in March 2019, the National Association of Statutory Health Insurance Funds is taking part in the further development of health and long-term care policy in a European context, and formulates its requirements for the European Parliament that was elected in May 2019 and the new European Commission.

Taking advantage of potentials
Statutory health and long-term care insurance wishes to use and shape the opportunities and potentials offered by European integration. Already today, approximately 73 million persons with statutory insurance in the healthcare and long-term care sector in Germany can rely on receiving high-quality, economical care should they fall ill or need long-term care. Regardless of their financial capacity, they can share in medical progress, even beyond Germany’s borders. This is ultimately also true thanks to common arrangements within Europe.

What is more, quite a lot has been achieved for insured persons in recent years. The adoption of the Medical Devices Regulation is a step towards improving patient safety. Moreover, the further development of social security and the free movement of citizens is underway with the reform of the regulations on the coordination of the social security systems.

The National Association of Statutory Health Insurance Funds is actively involved in the further development of health and long-term care policy in a European context.

Representation of interests at EU level

Illustration: National Association of Statutory Health Insurance Funds
Enhancing patient benefit
The division of competences between the EU and its Member States allows the forces at European level to be usefully combined in many areas and on many future-orientated issues. Intensified European cooperation in the evaluation of medical devices and medicinal products can help bring about high-quality healthcare for patients with new products. Joint action is also expedient in digitalisation. Electronic medical records and prescriptions must be exchangeable across borders. Using big-data applications and artificial intelligence together can also improve the care of insured persons and optimise the underlying structures. The national healthcare systems benefit when research priorities are set jointly, and available data from different sources are compiled.

Securing mobility
Insured persons who are members of statutory health and long-term care funds are also well covered beyond Germany’s borders. The regulations on the coordination of the social security systems give them access to the healthcare systems of the host country when they are staying in a country belonging to the EU or to the European Economic Area, or in Switzerland. They must be constantly developed in order to guarantee the effectiveness of the coordination mechanisms. The National Association of Statutory Health Insurance Funds is committed to further enhancing this cross-border mobility and reducing obstacles.

Making use of strengths
Europe is united in diversity when it comes to healthcare and long-term care. The National Association of Statutory Health Insurance Funds also promotes the principle of self-government at EU level: This provides for the direct involvement of stakeholders through representatives of the insured persons and employers in the health and long-term care insurance funds and their associations. The principle of self-government in social insurance as an instrument of social policy control finds its equivalent at European level in social dialogue.
Getting ready for Brexit

It remained unclear for a long time in 2019 when and under what conditions the United Kingdom’s withdrawal from the European Union would take place. Statutory health insurance has therefore prepared for different scenarios and their consequences for insured persons. Changes to health and long-term care insurance would affect several groups of individuals, including workers with a connection to the United Kingdom, students enrolled in the United Kingdom, pensioners from Germany living in the United Kingdom and their family members, but also British people living in Germany.

**Withdrawal with an agreement**
A withdrawal agreement provides the basis for agreement to be reached between the withdrawing country and the EU, as provided for in the EU Treaty. It contains the conditions for the separation and the arrangements for a transitional period. The withdrawal agreement negotiated between the EU and the Government of the United Kingdom, which has been rejected by the UK Parliament on several occasions, provides for a transitional period until 31 December 2020 during which the regulations on the coordination of the social security schemes are to continue to apply. This applies for example to tourists, posted workers, pensioners and students. During this transitional period, insured persons would continue to have the same rights as before, i.e. they could for example use their European Health Insurance Cards (EHIC) to receive treatment in the United Kingdom or have their long-term care benefits transferred there. British people who are covered by the National Health Service could also continue to receive treatment.

**On the path to a new partnership**

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<td>End of transitional period (can be extended)</td>
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Negotiations on future partnership

As part of the withdrawal agreement concluded between the EU and the United Kingdom, the European social protection rules will continue to apply in full during a transitional period until 31 December 2020.

Future relations are to be negotiated during this transitional phase.

Illustration: National Association of Statutory Health Insurance Funds

The withdrawal agreement provides for a transitional period during which the regulations on the coordination of the social security schemes are to continue to apply.
in the EU on the basis of an EHIC issued in the UK or of a corresponding Provisional Replacement Certificate.

A disorderly withdrawal
If withdrawal takes place without such a withdrawal agreement, that is without rules for the separation and for a transitional period, neither the European coordination rules in health and long-term care insurance, nor the Directive on the application of patients’ rights in cross-border healthcare, will be applicable. The Agreement between the Federal Republic of Germany and Great Britain, dated 20 April 1960, relating to social security, might have to be applied again. Although it contains rules on the applicable law, e.g. for postings or exceptional exemption agreements, it is not identical to the existing coordination law. For instance, it does not cover long-term care insurance.

In order to avoid contractual loopholes, the Federal legislature has additionally adopted an Act on Transitional Arrangements in health and social affairs following the withdrawal of the United Kingdom (Brexit Social Security Transition Act - BrexitSozSichÜG). The aim is to provide short-term legal security and protection of the acquired rights and legitimate interests of those particularly affected by the withdrawal, and to avoid social hardships.

This means in concrete terms that insured persons who are or have been permanently resident in the United Kingdom do not lose their health and long-term care insurance cover or have to take out double insurance as a result of Brexit. It should still be possible to take account of membership issues and contribution periods related to the United Kingdom.

Since assistance in terms of benefits in kind will cease to apply in relation to the United Kingdom in the event of a no-deal withdrawal, rules on the reimbursement of costs for persons who are permanently resident in the United Kingdom and have declared that they would like to join statutory health insurance under the Brexit Social Security Transition Act are intended to remedy this situation.

The National Association of Statutory Health Insurance Funds has issued numerous circulars informing the statutory health and long-term care insurance funds regarding the impact of the United Kingdom’s withdrawal and the provisions contained in the Brexit Social Security Transition Act on insurance and contribution law, and on the benefit law of health and long-term care insurance. Furthermore, the National Association of Statutory Health Insurance Funds has prepared a joint statement together with the national organisations of social security on the impact of a no-deal Brexit in insurance and contribution law for employees and employers, which will be published shortly in the event of a disorderly withdrawal.

Information available
The National Association of Statutory Health Insurance Funds has made information on Brexit publicly available at www.dvka.de. It presents the potential impact of Brexit on different groups of people such as employers and employees, insured persons, British citizens in Germany, students, and healthcare providers.
The World Social Security Forum is held in rotating venues, taking place in Brussels in October 2019. The World Forum is considered to be the largest and most important international event for social security in the world, and offers those attending a good platform for networking, knowledge transfer and an international exchange of experience. It is organised by the International Social Security Association (IVSS), in which Germany is represented by the National Association of Statutory Health Insurance Funds, Pension and Accident Insurance, and the Social Insurance for Agriculture, Forests and Gardening. The National Association of Statutory Health Insurance Funds is represented on the Board of the IVSS by Manfred Schoch, member of the Administrative Council of the National Association of Statutory Health Insurance Funds.

The international search for solutions

Well over 1,200 representatives from more than 150 countries attended the 2019 World Forum, including ministers and leading experts from a wide range of social security fields and areas of work. The content focus was placed on the topic of “Social Security in the Digital Age”. Technological innovation and digitalisation place economies, labour markets and societies under considerable pressure to transform, e.g. with regard to appropriate financing and benefit structures, service provision and new forms of work. How can social security continue to be guaranteed under these new conditions? To what extent can social security systems benefit from this? Which systems are proving to be particularly adaptable, and what difficulties do they face? Approaches and solutions to these and other questions were discussed on a cross-country basis, findings were presented and experiences shared.

The National Association of Statutory Health Insurance Funds is a popular port of call for long-term care

The National Association of Statutory Health Insurance Funds was a much sought-after partner at the World Forum, especially on the topic of long-term care insurance and long-term care. This is not surprising, given that there has been growing international interest in the German long-term care system for about two years now, as Germany introduced an independent long-term care insurance system as long ago as in 1995, earlier than other countries did. With its comparatively long history and experience in the international arena, many countries regard social long-term care insurance in Germany as a blueprint for the implementation of a system of their own to protect people in need of long-term care and their relatives.
The Year's Topics

The European Representation of the National German Social Insurance Associations

The German Social Insurance Working Group Europe e.V. (DSVVAE) continues to represent the interests of German social security in Brussels in the new legislative period. Elections to the European Parliament took place at the end of May 2019, and the new European Commission, headed by Ursula von der Leyen, took up its work at the beginning of December. The European Representation of the National German Social Insurance Associations is also well positioned in staffing terms.

**New deputy Director**
The European Coordination Committee, which is headed by Ilka Wölfe as Director, has appointed Ulrich Mohr as deputy Director of the DSVVAE for six years. One Managing Director, or a member of the Board, from each branch of social security is appointed as a full member of the Coordination Committee, which in turn acts as a Board. It is currently represented by Gundula Roßbach, President of the German Federal Pension Insurance, Dr. Edlyn Höller, Deputy Managing Director of the German Social Accident Insurance, and Dr. Doris Pfeiffer, Chairwoman of the Board of National Association of Statutory Health Insurance Funds. The European Representation has been representing the interests of the national organisations of German social security vis-à-vis the European institutions since 1993. It analyses and monitors the development of European health and social policy and other policy areas, and informs its members. It bundles the European policy interests of statutory accident, pension, health and long-term care insurance, and is actively involved in policy-making at EU level.

**The National Association of Statutory Health Insurance Funds also a member of ESIP**
Membership of DSVVAE also makes the National Association of Statutory Health Insurance Funds a member of the European Social Insurance Platform (ESIP). It represents the interests of approximately 40 statutory social security organisations from all over Europe. The National Association of Statutory Health Insurance Funds is involved in the Health Committee of the ESIP, the professional body for the health insurance sector, and has held its alternating chair since 2014. The Director of the European Representation has also been President of the ESIP since December 2019.

**ESIP's organisational chart**

Illustration: National Association of Statutory Health Insurance Funds
The Year’s Topics

The potential of digitalisation for the DVKA

Particular importance for the member funds and the German Liaison Agency Health Insurance - International (DVKA) attaches to the exchange of news and data across national borders. At the same time, the growing networking that accompanies the technological development forms the basis for the extensive automation of business processes and procedures, both within the DVKA and in communication with partners. The increasing networking in social security also creates a tangible benefit for both employers and employees. Administrative processes are faster, more cost-effective, and more efficient.

**Reduction of the processing effort by the example of Insurance Services - International**

The corresponding specialist application “Insurance Services - International/Processing and Information System” (VIBA) has been connected to the EU’s EESSI system (Electronic Exchange of Social Security Information) since November. The information can also be provided to the competent foreign authorities electronically in both areas. This has made it possible to decouple the personnel requirements from the number of applications to be processed. Unexpected increases in volume, as were repeatedly observed in the past, no longer have a directly proportional effect. The processing time for an application is reduced significantly. As a result, more time is available for the consultation.

**Digital is faster**

Increasingly powerful systems allow processes and process steps to run simultaneously. Parallel processing is limited by analogue sub-processes, amongst other things. For example, the paper-based issuing of the A1 certificates currently still required by the legislature requires them to be printed and physically transported to the applicant. This process could already be implemented digitally today from a technical point of view. The legislature however needs to pass a corresponding legal amendment for this, and the standard procedures of statutory health insurance must provide the required functionality. For example, the final A1 certificate issued should be sent to the employer in an unalterable graphic format, and the finished certificate should be handed over to the employee. The A1 posting certificate could be made available to the applicant at any time in the future, directly and on an app-based basis. Simplifications through automated and paperless application procedures are essential for this.
Focus of communication in 2019

The National Association of Statutory Health Insurance Funds was faced with the challenging task in 2019 of bringing across the consequences of the legislature’s plans to weaken self-government in terms of both content and personnel in the shape of the Statutory Health Insurance Fair Fund Selection Act. One focus of the press and public relations work was therefore placed on this topic. In addition, the National Association of Statutory Health Insurance Funds took up a public position on a large number of topics in the interest of statutory health and long-term care insurance, thus setting a clear course. The breadth of the topics ranged from the supply of medical aids, the new evaluation system for long-term care quality, ideas for the reorientation of emergency care, or criticism of the legislature’s plans for the method evaluation of new treatment and examination procedures, through to the finances of statutory health insurance.

**Statutory health insurance debating:**

**Statutory health insurance live**
The series of events entitled “GKV Live” (“Statutory health insurance live”) focused in March on the importance of self-government. Administrative Council Chairmen Uwe Klemens and Dr. Volker Hansen debated with representatives from the political arena under the title “Strong self-government for a strong healthcare system”. Dr. Hansen warned that weakening self-government would have dramatic long-term consequences. With an urgent plea, Klemens advocated the preservation of self-government, greater scope for action, and the promotion of the idea of subsidiarity - as provided for in the Coalition Agreement.

Current legislative projects were discussed at other events. “Statutory health insurance live” dealt in January with the Appointment Service and Care Act. Another draft Bill was on the agenda in October which assigns an important role to the National Association of Statutory Health Insurance Funds in particular: the Digital Care Act.

**Portal to the German medicinal product market**
The statutory health insurance rapid medicinal product information system (GAmSi) portal received a new web design in the middle of the year at www.gkv-gamsi.de, and was supplemented by additional services. It is now one of the few publicly-accessible statutory health insurance portals with interactive analysis options for the German medicinal product market. The quarterly figures for the medicinal product market were previously only available as PDF documents to interested professionals. Since the relaunch, the desired analyses for selected quarterly figures can be compiled individually and interactively. Users can obtain an overview of the existing GAmSi offers more quickly than was previously the case, and can prepare interesting figures in graphic form themselves.
Cloud_
The budget and personnel work of the National Association of Statutory Health Insurance Funds

**The annual financial statement for 2018**
The annual financial statement of the National Association of Statutory Health Insurance Funds for 2018 was drawn up in April 2019. The audit, including the departmental budget of the German Liaison Agency Health Insurance - International (DVKA), was carried out by the KPMG AG firm of auditors. The “Travel expense accounts of self-government of the National Association of Statutory Health Insurance Funds” and the “Signature regulations and processes of the invoicing and payment runs of the National Association of Statutory Health Insurance Funds according to the dual control principle” were also audited. The firm of auditors issued an unqualified audit report. At its session that was held on 26 June 2019, the Administrative Council thereupon approved the activities of the Board and approved the 2018 annual financial statement.

**The Association's budget for 2019**
The 2019 budget plan of the National Association of Statutory Health Insurance Funds shows an overall budget of 192.2 million Euro. This includes the contribution towards the budget of the National Association of Statutory Health Insurance Funds, as well as the following pay-as-you-go financing arrangements:

- DVKA departmental budget
- the Medical Service of the National Association of Statutory Health Insurance Funds (MDS)
- the Federal Centre for Health Education (BZgA) in accordance with section 20a of Book V of the Social Code
- the guarantee supplement for midwives in accordance with section 134a subsection (1b) of Book V of the Social Code
- the promotion of special therapy facilities in accordance with section 65d of Book V of the Social Code
- the Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH (gematik)

### Elements of the overall budget 2019

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<tr>
<th>Element</th>
<th>Cost</th>
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<tr>
<td>Core budget sum</td>
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<tr>
<td>DVKA</td>
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<td>Medical Service (incl. Competence Centres)</td>
<td>11,196,000 €</td>
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<tr>
<td>Federal Centre for Health Education</td>
<td>34,946,000 €</td>
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<td>Guarantee supplement midwives</td>
<td>10,156,000 €</td>
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<td>Support for special therapy facilities</td>
<td>3,200,000 €</td>
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<tr>
<td><strong>Contribution of the National Association of Statutory Health Insurance Funds</strong></td>
<td><strong>145,076,000 €</strong></td>
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<tr>
<td>gematik</td>
<td>36,884,000 €</td>
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<td>UPD</td>
<td>9,651,000 €</td>
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<td>Data transparency</td>
<td>642,000 €</td>
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<td><strong>Allocation of further budget elements</strong></td>
<td><strong>47,177,000 €</strong></td>
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<tr>
<td><strong>Overall budget</strong></td>
<td><strong>192,253,000 €</strong></td>
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</table>

Cost per insured person 1.99 €

Cost per member 0.83 €
• the promotion of facilities for consumer and patient advice (UPD) in accordance with section 65b of Book V of the Social Code
• data transparency in accordance with sections 303a to 303f of Book V of the Social Code

The budget for 2020
The budget plan for 2020 that was drawn up by the Board on 29 October 2019 was unanimously adopted by the Administrative Council of the National Association of Statutory Health Insurance Funds on 27 November 2019. The Association’s overall budget was set at 230.1 million Euro. It hence rose by 37.9 million Euro year-on-year. This is partly a result of the higher pay-as-you-go arrangement to fund gematik, of the guarantee supplement for midwives, and of the promotion of facilities for consumer and patient advice, as well as of the higher contributions towards the budget of the National Association of Statutory Health Insurance Funds and of the departmental budget of the DVKA.

Staff development up to 2019
(not including the DVKA department)

The personnel work of the National Association of Statutory Health Insurance Funds
The staff budget for 2019 totalled 497.42 established posts. 377.56 target posts were accounted for by the Berlin location, and 119.86 target posts by the DVKA. The Administrative Council decided at its meeting in June to create two additional permanent posts in Berlin for the financial year 2019.

480.48 posts were occupied on 1 October 2019, 363.12 of which at the Berlin location and 117.36 at the DVKA. The occupancy rate is 96.6 % for the Association as a whole. The occupancy rate at the Berlin location is 96.2 %, and 98.0 % at the DVKA.

Source and illustration: National Association of Statutory Health Insurance Funds
The members of the National Association of Statutory Health Insurance Funds 2019

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<tr>
<td>1</td>
<td>actimonda BKK</td>
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<td>AOK – Die Gesundheitskasse für Niedersachsen</td>
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<td>AOK – Die Gesundheitskasse in Hessen</td>
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<td>7</td>
<td>AOK Nordost – Die Gesundheitskasse</td>
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<td>AOK PLUS – Die Gesundheitskasse für Sachsen und Thüringen</td>
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91. Novitas BKK
92. pronova BKK
93. R+V Betriebskrankenkasse
94. Salus BKK
95. SECURVITA BKK
96. SIEMAG BKK
97. Siemens-Betriebskrankenkasse (SBK)

98. SKD BKK
99. Sozialversicherung für Landwirtschaft, Forsten und Gartenbau (SVLFG)
100. Südzucker BKK
101. Techniker Krankenkasse
102. TUI BKK
103. VIACTIV Krankenkasse
104. Wieland BKK
105. WMF Betriebskrankenkasse

cut-off date: 1 January 2020

Mergers

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* cut-off date: 1 January 2019
** cut-off date: 1 January 2020
# Ordinary members of the Administrative Council in the 3rd period of office (2018-2023)

## Representatives of insured persons

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<tr>
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<td>BKK Pfalz</td>
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### Representatives of the employers

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Deputy members of the Administrative Council in the 3rd period of office (2018-2023)

**Representatives of insured persons**

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<td>Name</td>
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The table below lists the representatives of the employers and their respective health insurance funds:

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Ordinary and deputy members of the specialist committees of the Administrative Council

Specialist committee on fundamental issues and health policy

Chaired by: Stephan Jehring/Hans-Jürgen Müller (alternating)

**Ordinary members**

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<tr>
<td>1. Jehring, Stephan (AOK)</td>
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**Deputy members**

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Specialist committee on organisation and finance

Chaired by: Dr. Wolfgang Schrörs (†)/Andreas Strobel (alternating)

**Ordinary members**

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Specialist committee on disease prevention, rehabilitation and long-term care

Chaired by: Dietrich von Reyher/Eckehard Linnemann (alternating)

Ordinary members

**Employers’ representatives**

1. Parvanov, Ivor (AOK)
2. Ropertz, Wolfgang (AOK)
3. Söller, Wolfgang (AOK)
4. Thomas, Dr. Anne (EK)
5. Reyher, Dietrich von (BKK)
6. Kastner, Helmut (IKK)

**Representatives of insured persons**

1. Date, Achmed (EK)
2. Holz, Elke (EK)
3. Gosewinkel, Friedrich (EK)
4. Düring, Annette (AOK)
5. Kolsch, Dieter (AOK)
6. Kloppich, Iris (AOK)
7. Linnemann, Eckehard (Kn)
8. Schoch, Manfred (BKK)

Deputy members

**Employers’ representatives**

Nobereit, Sven (AOK)
Heß, Johannes (AOK)
Gemmer, Traudel (AOK)
Fitzke, Helmut (EK)
Franke, Dr. Ralf (BKK)
N. N. (BKK)
Wadenbach, Peter (IKK)
Wollseifer, Hans Peter (IKK)

**Representatives of insured persons**

Aichberger, Helmut (EK)
1st deputy on the list for insured persons 1-3
Hauffe, Ulrike (EK)
2nd deputy on the list for insured persons 1-3
Brück, Peter (EK)
3rd deputy on the list for insured persons 1-3
Lambertin, Knut (AOK)
1st deputy on the list for insured persons 4-6
Firsching, Frank (AOK)
2nd deputy on the list for insured persons 4-6
Wiedemeyer, Susanne (AOK)
3rd deputy on the list for insured persons 4-6
Brendel, Roland (BKK)
1st deputy on the list for insured persons 7-8
Römer, Bert (IKK)
2nd deputy on the list for insured persons 7-8
Scholz, Jendrik (IKK)
3rd deputy on the list for insured persons 7-8
Specialist committee on contracts and care

Chaired by: Martin Empl/Angelika Beier (alternating)

Ordinary members

**Employers' representatives**

1. Avenarius, Friedrich (AOK)
2. Söller, Wolfgang (AOK)
3. Vahle, Torben (EK)
4. Bley, Alexander (BKK)
5. Leitl, Robert (IKK)
6. Empl, Martin (SVLFG)

**Representatives of insured persons**

1. Lohre, Dr. Barbara (EK)
2. Katzer, Dietmar (EK)
3. Weber, Roman G. (EK)
4. Schröder, Dieter (EK)
5. Beier, Angelika (AOK)
6. Wiedemeyer, Susanne (AOK)
7. Brendel, Roland (BKK)
8. Römer, Bert (IKK)

Deputy members

**Employers' representatives**

Gemmer, Traudel (AOK)
Schirp, Alexander (AOK)
Parvanov, Ivor (AOK)
Wegner, Bernd (EK)
Reyher, Dietrich von (BKK)
Wadenbach, Peter (IKK)
Lunk, Rainer (IKK)
Heins, Rudolf (SVLFG)

**Representatives of insured persons**

Breher, Wilhelm (EK)
Plaumann, Karl-Heinz (EK)
Aichberger, Helmut (EK)
Nimz, Torsten (EK)
Lersmacher, Monika (AOK)
Tölle, Hartmut (AOK)
Hindersmann, Nils (KN)
Karp, Jens (IKK)
Schoch, Manfred (BKK)

1st deputy on the list for insured persons 1-4
2nd deputy on the list for insured persons 1-4
3rd deputy on the list for insured persons 1-4
4th deputy on the list for insured persons 1-4
1st deputy on the list for insured persons 5-6
2nd deputy on the list for insured persons 5-6
1st deputy on the list for insured persons 7-8
2nd deputy on the list for insured persons 7-8
3rd deputy on the list for insured persons 7-8
Specialist committee on digitalisation, innovation and benefits for patients

Chaired by: Nikolaus Chudek/Jochen Berking (alternating)

**Ordinary members**

**Employers' representatives**

1. Wegner, Bernd (EK)
2. Meinecke, Christoph (AOK)
3. Söller, Wolfgang (AOK)
4. Dohm, Rolf (BKK)
5. Chudek, Nikolaus (IKK)
6. Heins, Rudolf (SVLFG)

**Representatives of insured persons**

1. Berking, Jochen (EK)
2. Hoof, Walter (EK)
3. Vieweger, Birgitt (EK)
4. Kloppich, Iris (AOK)
5. Lambertin, Knut (AOK)
6. Hamers, Ludger (BKK)
7. Krause, Helmut (IKK)
8. Hindersmann, Nils (Kn)

**Deputy members**

**Employers' representatives**

Vahle, Torben (EK)
Landrock, Dieter Jürgen (AOK)
Selke, Prof. Dr. Manfred (AOK)
Ries, Manfred (BKK)
Leitl, Robert (IKK)
Empl, Martin (SVLFG)

**Representatives of insured persons**

Mirbach, Helmut (EK)
1st deputy on the list for insured persons 1-3
Decho, Detlef (EK)
2nd deputy on the list for insured persons 1-3
Brück, Peter (EK)
3rd deputy on the list for insured persons 1-3
Löwenstein, Katrin von (EK)
4th deputy on the list for insured persons 1-3
Roloff, Sebastian (EK)
5th deputy on the list for insured persons 1-3
Keppler, Georg (AOK)
1st deputy on the list for insured persons 4-5
Wiedemeyer, Susanne (AOK)
2nd deputy on the list for insured persons 4-5
Strobel, Andreas (BKK)
1st deputy on the list for insured persons 6-8
Grellmann, Norbert (IKK)
2nd deputy on the list for insured persons 6-8
Linnemann, Eckehard (Kn)
3rd deputy on the list for insured persons 6-8
### Ordinary members and personal deputies of the Specialist Advisory Council 2019

**cut-off date: 1 January 2020**

<table>
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<tr>
<th>Members</th>
<th>Deputies</th>
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<tbody>
<tr>
<td><strong>AOK</strong></td>
<td>1. Martin Litsch</td>
</tr>
<tr>
<td></td>
<td>2. Dr. Irmgard Stippler</td>
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<td></td>
<td>(since 9 April for</td>
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<td></td>
<td>Dr. Christopher Hermann)</td>
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<td></td>
<td>Jens Martin Hoyer</td>
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<td>Dr. Jürgen Peter</td>
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<tr>
<td><strong>BKK</strong></td>
<td>1. Franz Knieps</td>
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<tr>
<td></td>
<td>2. Andrea Galle</td>
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<tr>
<td></td>
<td>Verena Heinz</td>
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<td>Lutz Kaiser</td>
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<td><strong>Ersatzkassen</strong></td>
<td>1. Ulrike Elsner</td>
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<tr>
<td></td>
<td>2. Dr. Jörg Meyers-Middendorf</td>
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<td>Boris von Maydell</td>
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<td></td>
<td>Oliver Blatt</td>
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<tr>
<td><strong>IKK</strong></td>
<td>1. Jürgen Hohnl</td>
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<tr>
<td></td>
<td>2. Uwe Schröder</td>
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<td>Frank Hippler</td>
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<td>Enrico Kreutz</td>
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<tr>
<td><strong>KNAPPSCHAFT</strong></td>
<td>1. Bettina am Orde</td>
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<tr>
<td></td>
<td>2. Gerd Jockenhöfer</td>
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<td></td>
<td>Dieter Castrup</td>
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<td></td>
<td>Jörg Neumann</td>
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<tr>
<td><strong>Landwirtschaftliche Sozialversicherung</strong></td>
<td>1. Claudia Lex</td>
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<tr>
<td></td>
<td>2. Gerhard Sehnert</td>
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<td>Dirk Ender</td>
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<td>Jürgen Helfenritter</td>
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Organisational chart
Administrative Council

Board Member 2000
Stefanie Stoß-Ahns

Staff Unit 4300
Self-Government
Elke Niederhausen

Staff Unit 2010
Contract Analysis
Thomas Staffeldt

Subject Group
Analysis of Out-Patient Care
Andreas Bomke

Division 2000
Out-patient Care
Dr. Thorsten Fürstenberg

Section 210
Doctors’ Remuneration
(Standard Schedule of Fees)/Quality Assurance
Stephan Feldmann

Section 2120
Hospital Remuneration
Johannes Wolff

Section 2200
Hospital Quality Assurance
Dr. Mechtild Schmedders

Section 2310
Medicinal Products
Frank-Ulrich Schmidt

Section 2320
Medicinal Product Data
Christina Bode

Section 2330
AMNOG
Federal Joint Committee
Dr. Thomas Mayer

Section 2340
AMNOG
Standard Schedule of Fees
Dr. Anja Tebinka-Olbrich

Section 2350
Research Unit on Long-Term Care Insurance
Dr. Eckart Schnabel

Section 3120
Medical Aids
Carla Meyerhoff-Grienberger

Section 3140
Long-Term Care Insurance
Ulrike Bode

Section 3160
Demography/Long-Term Care
Klaus Dumeier

Section 3170
Disease Prevention
Jens Hupfeld

Board Member 3000
Gernot Kiefer

Secretariats of the Arbitration Units
Antje Bernhardt
Konstantin Stölze

Staff 31020
Combating Misconduct in the Healthcare System
Dr. Stephan Meseke

Staff 4500
Internal Audit
Wolfgang Rehberg

Staff 4600
Contract-Awarding Unit

Divisions

Division 2100
Out-patient Care
Dr. Thorsten Fürstenberg

Division 2200
Hospitals
Dr. Wulf-Dietrich Leber

Division 3100
Health
Dr. Monika Kücking

Division 3200
German Liaison Agency Health Insurance –
International Hans-Holger Bauer
(Managing Director)

Division 3310
General Administration
Gabriele Fink

Division 3320
Human Resources
Susanne Taps

Division 3330
Finance
Frank Tietz

Division 3340
IT Service
Peter Müller

Staff Unit 2200
Self-Government
Elke Niederhausen

Staff Unit 4400
Self-Government
Elke Niederhausen

Staff Unit 4500
Self-Government
Elke Niederhausen

Staff Unit 4600
Self-Government
Elke Niederhausen

Subject Group
Analysis of Out-Patient Care
Andreas Bomke

Section 2110
Doctors’ Remuneration
(Standard Schedule of Fees)/Quality Assurance
Stephan Feldmann

Section 2120
Hospital Remuneration
Johannes Wolff

Section 2130
Hospital Quality Assurance
Dr. Mechtild Schmedders

Section 2140
Hospital Medicinal Products
Frank-Ulrich Schmidt

Section 2210
Hospitals
Dr. Wulf-Dietrich Leber

Section 2220
Hospital Remuneration
Johannes Wolff

Section 2230
Hospital Quality Assurance
Dr. Mechtild Schmedders

Section 2240
Hospital Medicinal Products
Frank-Ulrich Schmidt

Section 2310
AMNOG
Federal Joint Committee
Dr. Thomas Mayer

Section 2320
AMNOG
Standard Schedule of Fees
Dr. Anja Tebinka-Olbrich

Section 2330
Research Unit on Long-Term Care Insurance
Dr. Eckart Schnabel

Section 2340
Research Unit on Long-Term Care Insurance
Dr. Eckart Schnabel

Section 3120
Medical Aids
Carla Meyerhoff-Grienberger

Section 3140
Long-Term Care Insurance
Ulrike Bode

Section 3160
Demography/Long-Term Care
Klaus Dumeier

Section 3170
Disease Prevention
Jens Hupfeld

Section 3210
Benefit Law/Rehabilitation/Self-Help
Gerd Kußla

Section 3220
International Data Processing
Markus Weyres

Section 3230
Insurance Services - International
Franz-Peter Kampmann

Section 3240
International Data Processing
Markus Weyres

Section 3250
International Health Insurance Law
Thomas Kreutzer

Section 3260
International Health Insurance Law
Thomas Kreutzer

Section 3310
General Administration
Gabriele Fink

Section 3320
Human Resources
Susanne Taps

Section 3330
Finance
Frank Tietz

Section 3350
Management of Holdings/Clearing Procedures
Sven Schulze

Section 3360
International Claims Management and Accounting
Burchard Osterholz

Section 3370
Disease Prevention
Jens Hupfeld

Section 3380
International Health Insurance Law
Thomas Kreutzer

Section 3390
International Health Insurance Law
Thomas Kreutzer
## Publications

### Position papers

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<td>GKV-Spitzenverband</td>
<td>Europa: Kräfte bündeln, Potenziale nutzen</td>
<td>March 2019</td>
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<tr>
<td>GKV-Spitzenverband</td>
<td>Europe: Pooling Strengths, Utilising Potentials</td>
<td>March 2019</td>
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<tr>
<td>GKV-Spitzenverband</td>
<td>Zukunft des Innovationsfonds</td>
<td>March 2019</td>
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<td>2. Bericht des GKV-Spitzenverbandes zur Fortschreibung des Hilfsmittelverzeichnisses gemäß § 139 Abs. 9 Satz 3 SGB V</td>
<td>February 2019</td>
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<td>Erster Präventionsbericht nach § 20d Abs. 4 SGB V</td>
<td>June 2019</td>
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<td>GKV-Spitzenverband</td>
<td>Imagebroschüre „Verantwortung für die Gesundheitsversorgung“ (aktualisierte Fassung)</td>
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<td>Präventionsbericht 2019 Berichtsjahr 2018</td>
<td>November 2019</td>
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<td>GKV-Spitzenverband</td>
<td>Report from the Board to the Administrative Council: The work and results of the Anti-Misconduct Office for the Healthcare System</td>
<td>November 2019</td>
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<td>GKV-Spitzenverband</td>
<td>Ergebnisse des Modellprogramms zur Weiterentwicklung neuer Wohnformen für pflegebedürftige Menschen nach § 45f: Zusammenfassende Bewertung der Forschungsstelle Pflegeversicherung</td>
<td>December 2019</td>
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<td>GKV-Spitzenverband</td>
<td>Schriftenreihe Modellprogramm zur Weiterentwicklung der Pflegeversicherung, Band 15: Digitalisierung und Pflegebedürftigkeit – Nutzen und Potenziale von Assistenztotechnologien</td>
<td>September 2019</td>
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