



## GVG EU Committee

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Position of  
"Standardisation of healthcare services"



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## Table of Contents

1	Summary	7
2	STATEMENT OF POSITION	11
3	What is standardisation?	13
3.1	Standardisation of products	14
3.2	Standardisation of services	14
3.3	Objectives of standardisation	16
4	Professional norms in the medical sector – guidelines versus standards	18
4.1	Directives	19
4.2	Guidelines	19
4.3	Standards	20
5	Healthcare services are professional services	23
6	Standards threaten legal certainty and the enforceability of patient claims	24
7	The CEN's lack of legitimacy	26
8	European standardisation of healthcare services does not lie within the EU's competences	28
9	Glossary	31



## 1 Summary

We observe with great concern the efforts at the European level on the subject of standardising medical treatments and other healthcare services, whether with regard to curative healthcare (e.g., occupational therapy, speech therapy, physiotherapy) or with respect to preventive and rehabilitative medical care. The current activities of the European Committee for Standardisation (CEN) in the development of standards for healthcare services are superfluous and inexpedient. Rather, there is a danger that individualised patient treatment based on a physician's therapeutic freedom is at risk, and that legal certainty as well as the enforcement of patient claims may be undermined. In addition, the ambitions and deliberations of the European Commission in this regard represent a massive intervention in the national competences of the member states as laid out in the European treaties.

In this regard, both the healthcare and other social-security systems are affected. Their organisation and financing lie within the competences of the member states, which are also responsible for the provision of healthcare services, whether in the form of preventative measures (screening), or in relation to medical treatments or rehabilitative measures such as the reintegration of people into working life.

In this regard, the organisation of an adequate healthcare system for all of a member state's citizens is a particular responsibility of the individual member states according to the European treaties. Germany fulfils this requirement in a widely accepted manner. All people in Germany have access to adequate care and participate in medical progress.

The quality of medical care is ensured through diverse yet coordinated instruments. Currently, an independent scientific institute is being founded on statutory grounds, which will address quality issues that cut across areas of care on behalf of the Federal Joint Committee.

The federal government, state governments, and the self-governing bodies of the health professions and the social insurance institutions, each in their re-

spective areas of responsibility, bear responsibility for ensuring that the overall healthcare environment is continuously adapted to current requirements. In this way, one of the world's best healthcare systems is reliably organised.

Caring for acutely or chronically ill people demands not only good medical knowledge, but also empathy and a consideration of individual circumstances. In this regard, individualised patient care necessarily comes to the fore. The desire to improve the quality of healthcare services in Europe, as well as to make such services more generally comparable and transparent, represents a legitimate goal for the European Commission, insofar as it is carried out within the context of the competences allowed to it by the European treaties.

However, the desire to standardise, harmonise and simplify on the basis of standard specifications misconstrues the needs of patients and limits the possibilities for medical care. In addition, the goal of improving patient safety cannot be better achieved by taking the path towards European standardisation. Instead, it is to be feared that European standards would not be as extensive as existing and established medical standards, and would thus jeopardise the quality of healthcare.

Instead, the European Commission should provide information about other provisions already in place in the member states, such as the clinical guidelines available in Germany. This would allow interested member states to use this information to strengthen their own healthcare systems. In addition, the reference network newly created in the context of the Patients' Rights Directive 2011/24/EU could make a contribution in this regard.

If – as is emphasised from many corners – one regards the general advantage of a European standard to be the ability “to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation”,<sup>1</sup> then the members of the GVG must clearly reject this idea in relation to healthcare services.

<sup>1</sup> EU regulation on standardisation 1025/2012  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>



This is because patients above all need assured care locally. General practitioners and specialists, dentists, psychotherapists, hospitals and other providers of healthcare services ensure this at a high level as part of their duties within Germany's individual branches of social insurance. The fact that not every service is suitable for standardisation is shown by the example of occupational health and safety protection, which is expressly excluded as a subject of standardisation in relation to the standardisation of services on the basis of a voluntary agreement by the CEN, made with reference to existing European and national regulations.<sup>2</sup> The same must apply to healthcare services, particularly with relation to public healthcare systems, which are subject to national regulations.

While European standardisation in the product realm is in fact helpful and desirable, it is wholly unsuitable in the context of medical treatment for people. CEN as a private standards-setting body is neither scientifically suited nor carries sufficient legitimacy to intervene in decisions reserved to self-administrating bodies in this area.

<sup>2</sup> CEN Guide 15, Guidance document for the development of service standards: Version dated 2012-02-01, 7.2.3, page 18/19 [http://boss.cen.eu/ref/CEN\\_15.pdf](http://boss.cen.eu/ref/CEN_15.pdf)



## 2 STATEMENT OF POSITION

The members of the Gesellschaft für Versicherungswissenschaft und -gestaltung (GVG) reject the development of European and international standards for healthcare services as unnecessary and unsuitable for the posited goal, and asks for the suspension of related activities on the part of the European Committee for Standardisation (CEN) as well as the deliberations on this topic by the European Commission. In addition, the GVG urges the German federal government to work within the scope of its capabilities to ensure that the financial support it provides to CEN is not used to develop standards for healthcare services in such a way as to undermine member-state competences. Instead, CEN is encouraged to adhere to the self-imposed obligation that “European standards shall not cover those subjects that clearly belong to the domain of regulation of the Member States, under the principle of subsidiarity, unless this is explicitly supported by the national authority”.<sup>3</sup>

The development of European standards for healthcare services:

- is incompatible with national healthcare systems, whose health services range from prevention to medical treatment to rehabilitation
- threatens the individualised treatment of patients
- inappropriately affects the medical profession’s therapeutic freedom
- threatens legal certainty and the enforceability of patient claims
- is unsuitable to the achievement of the associated goals, simply by virtue of the chosen procedure and approach

<sup>3</sup> CEN Guide 15, Guidance document for the development of service standards: Version dated 2012-02-01, 5.2, page 13 [http://boss.cen.eu/ref/CEN\\_15.pdf](http://boss.cen.eu/ref/CEN_15.pdf)

- constitutes an inadmissible interference in the national competences of the member states to “[lay] down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare”<sup>4</sup> [4]
- and is thus outside the competences of both CEN and the EU.

<sup>4</sup> DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 9 March 2011 on the application of patients’ rights in cross-border healthcare (recital 42)  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>

### 3 What is standardisation?

“Standardisation is the systematic process by which tangible or intangible subjects are reduced to a desired degree of order by the joint efforts of the interested parties.”<sup>5</sup> It is primarily used when the same or similar subjects are used in different contexts in different places by different groups of people. Though a unique, unmistakable and understandable description, the suitability of products and processes for their intended purposes should be improved, the substitution of goods and services supported, and technical cooperation and communication facilitated. By this means, the functioning of the economy and in particular free movement within markets is supported and promoted. Or, as expressed by the European regulation on standardisation: “The primary objective of standardisation is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply. Standardisation can cover various issues, such as standardisation of different grades or sizes of a particular product or technical specifications in product or services markets where compatibility and interoperability with other products or systems are essential.”<sup>6</sup> Standards are developed at the national level by the German Institute for Standardisation (Deutsches Institut für Normung, DIN) among others, at the European level by the European Committee for Standardisation (Comité Européen de Normalisation, CEN), and at the international level by the International Organisation for Standardisation (ISO) (for additional information on the issue of standardisation, see Glossary).

<sup>5</sup> German Institute for Standardisation (DIN). DIN 820-1:1994-04. DIN’s Goals. <http://www.din.de/cmd;jsessionid=HP79D2NF9EWCOSNADWMJKFS5.2?cmsrubid=59362&level=tpl-unterrubrik&menurubricid=59362&cmssubrubid=59365&menuid=47560&languageid=en&menusubrubid=59365&cmsareaid=47560>

<sup>6</sup> REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardization  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>

### **3.1 Standardisation of products**

The standardisation of products that serves the safety of patients and users, even and indeed especially in the healthcare sector, is to be welcomed and supported. Uniform safety standards and specifications, for instance for medical products and devices, but also with regard to the ergonomic design of (for instance) hospital beds or the safe technical equipping of laboratories increase patient safety as well as users' health and safety protections. To this extent, they pursue aspects of the issue in a way that from the point of view of the GVG members is to be welcomed.

### **3.2 Standardisation of services**

Like the standardisation of products, standards in the service sector serve the economy through the development of national and international markets, thus facilitating a liberalisation of trade in services. However, determining unified specifications is increasingly difficult as a service and its associated processes becomes more complex. This is especially true if it is a personal service that is performed on or with the person, as, for example, are most medical, dental or psychotherapeutic services. Among the typical features of such personal services, for example, is the fact that the objectives are subject to discussion between service providers and customers, as are the necessary related processes or measures.

To date, standards at the European level have primarily been in the areas of goods and product processes. For some time, a worrisome trend has been evident towards an increasing standardisation of services as well. To be sure, this can also be useful in individual cases, for instance if these European standards were to codify previously unregulated activities such as the "tourist guide training" (DIN EN 15565) or set requirements for the cleaning of school buildings (DIN 77400 "Cleaning services – School buildings – Requirements for cleaning") at the national level.

However, this does not apply in the case of healthcare services. The European Committee for Standardisation (Comité Européen de Normalisation, CEN) is currently developing standards for various physician-provided and other healthcare services. For example, the standards developed for services in cosmetic surgery stipulate which competences the doctor must hold (basic, advanced and further training), and how the management of and communication with the patient must proceed (including consultation with and evaluation of patient, consent, documentation, testing, post-operative care, as well as publicity and advertising, opportunity for complaints, insurance, etc.). Moreover, requirements for facilities (treatment rooms, procedure rooms and operating chambers) are regulated. In addition, they set special requirements for medical services themselves. Additional issue areas including treatment of cleft lips, jaws and palates, as well as areas such as Traditional Chinese Medicine, homeopathy, osteopathy and chiropractic services remain under development.

Neither the Commission nor CEN can demonstrate that there is added value associated with the standardisation of healthcare services. Rather, standardisation – with regard to conditions in Germany – is “not an essential instrument in ensuring or improving the quality of medical services provision”.<sup>7</sup> The fact that other member states also fail to recognise any such added value is attested to by the fact that a feasibility study planned by the European Commission for 2014 has been blocked by the opposition of the member states. This study is intended to establish the state of international and national standards, ascertaining the extent to which these standards are used and fulfil the needs of healthcare systems. In addition, the study is conceived as establishing further conditions that could apply to the development of standards for healthcare services, with additional reference to clinical standards and the inclusion of affected stakeholders in the standards-development process.

<sup>7</sup> Bundestagsdrucksache 18/1684 6.06.2014 Written correspondence (questions) including the German federal government’s responses during the week of June 2, 2014, question 56 (in German).  
<http://www.bundesanzeiger-verlag.de/fileadmin/Betrifft-Recht/Dokumente/edrucksachen/pdf/1801684.pdf>

### 3.3 Objectives of standardisation in the field of health services

In the view of the Commission, the standardisation of healthcare services should establish unitary quality standards within the EU. The service itself and its level of quality should be made comparable (benchmarking), in order to improve patient safety. Standards should additionally help to improve effectiveness and provide transparency.

From the perspective of the GVG members, none of these goals can be achieved through the instrument of standardisation. In order to avoid conflict with national provisions, European standards are fundamentally conceived as minimum benchmark standards or minimum requirements. A benchmarking system based on compliance with or oversight of minimum requirements therefore offers no added value for the German healthcare system and its patients, because for the overwhelming majority of German patients, with exception of a small number in border regions, the free, cross-border exchange of healthcare services is not practically relevant. The routine care of acute and chronic conditions takes place through outpatient care provided by local general practitioners and specialists, supplemented as necessary by in-patient care. This also applies for the special care of people injured in work-related accidents, which for the vast majority of cases in Germany is carried out following specified treatment-procedure and quality requirements. It can be assumed that the focus of healthcare for the average citizen of the European Union too is located in that person's own individual living environment.

Because of the development of specific features and the reference to minimum requirements, standards are also unsuitable to improving the quality of specific measures or procedures within the German healthcare system. This is particularly true for integrated and highly complex care such as that for severely injured patients after work-related accidents. Instead, standards could lead to a lowering of quality standards, legal uncertainty and problems in the enforcement of patient interests. Ultimately, proven and established systems such as the statutory accident-insurance scheme, which are grounded in a statutorily regulated, integrated and high-quality approach to care using all appropriate means could be shaken to their very foundations. For example,



a lowered level of performance could also affect issues of diminished liability through the sole financing of the system by employers. A competition or a “creeping adaptation” through rival standards that could be variously applied by service providers would be diametrically opposed to the health- and social-policy goals of the Social Code.

The standardisation of healthcare services is unsuitable to the achievement of the process’ stated objectives!

#### 4 Professional norms in the medical sector – directives, guidelines versus standard specifications

In order to improve the quality of medical care, there are – in addition to programmes of thorough and stringent basic, advanced and continuing-education training – proven instruments such as scientifically based (evidence-based) clinical guidelines, which are significantly better adapted to the specific features of medical or healthcare services than would be a set of standards. There is no need for standardisation, because there are already specific instruments established within the healthcare sector that support appropriate and high-quality healthcare, while at the same time doing justice to the field's complexity and the needs of patients. Medical professional societies along with self-governing medical and social institutions develop the norms for service provision while taking account of current medical and scientific knowledge. Thus, specific procedures involving all relevant parties have been developed for accident insurance, for example. In this way, it is assured that the benefits of medical treatment always correspond to the generally accepted state of medical knowledge, and take account of medical progress. At the same time, the needs of accident-insurance providers with regard to case management and the fulfilment of their insurance contract can be taken into consideration.

By contrast, standards are an unsuitable means of defining scientifically derived norms for medical treatments, and with regard to conditions in Germany, are “not an essential instrument in ensuring or improving the quality of medical services provision”.<sup>8</sup>

<sup>8</sup> Bundestagsdrucksache 18/1684 6.06.2014 Written correspondence (questions) including the German federal government's responses during the week of June 2, 2014, question 56 (in German). <http://www.bundesanzeiger-verlag.de/fileadmin/Betrifft-Recht/Dokumente/edrucksachen/pdf/1801684.pdf>

## 4.1 Directives

DIN/CEN standards must be distinguished from directives or guidelines. Directives in the area of healthcare are in accordance with the regulations on activities or forbearances contained in social legislation, are set by legally legitimated institutions and are thus independent sources of law (“legal duties”). For example, the Federal Joint Committee used directives to define the catalogue of services of the statutory health-insurance scheme (GKV) for more than 70 million insured individuals (e.g., the remedies directive in accordance with § 92 para. 6 Social Code V), thus determining what medical care services will be refunded by the GKV.

## 4.2 Guidelines

Scientific guidelines typically describe a medical norm that is constituted by “treatment and decision corridors”, and thus represents “good medical practice”. They are systematically developed so as to reflect the current state of scientific knowledge, and are regularly updated or adapted to scientific progress. They are created by established experts who (at least in Germany) are named by the relevant professional societies of the Association of the Scientific Medical Societies in Germany (AWMF), under a closely specified general framework. As a rule, they are based on a systematic search of the relevant literature and evidence, as well as an evaluation of the literature found in this previous process. The underlying process of creation is open, and the persons involved are named, with potential conflicts of interest disclosed.

Guidelines, which in normal cases can be used without paying a fee, thus have the character of a decision-oriented treatment recommendation with a corridor for deviation. They include recommendations that affected parties should follow or deviate from only in well-justified cases. The gradation of recommendations is based on identified evidence, clinical expertise and patient preferences, and in this regard involves explicitly subjective elements.

It is to be expected – as will be later explained – that conflict exists between areas covered by standards and guidelines. The resulting lack of clarity contributes neither to the optimisation of care nor to the improvement of quality.

In the area of social insurance too, guidelines form the basis of medical services provision. Thus, for example, the definition of quality standards in the statutory accident insurance scheme is carried out in dialogue between accident-insurance carriers and medical professional societies through the integration of scientific guidelines and evidence. This is particularly true for the recommendations governing assessments of occupational and work-related diseases.

### 4.3 Standards

Standard specifications, by contrast, are mere recommendations that interested parties can voluntarily employ. However, they can then become binding if – for example – relevant laws make reference to “the accepted state” of knowledge.

Standards are based on expert opinion (so-called interested parties), in which the circle of persons and institutions involved should insofar as possible reflect the entire available spectrum of opinions. However, the persons involved are not named in public documents and their interests or potential conflicts of interests are not disclosed.

Standardisation by CEN therefore raises serious concerns with regard to legitimacy and the preparation process. The members of the GVG regard this as a significant problem. It has become apparent that in practice, “only” interested parties active in the preparation of pertinent standards participate in the CEN processes. However, these interests are not exclusively oriented towards the common welfare, and can pursue other motives as well. “Standardisation is also extremely relevant for the individual participants in economic processes, since whoever makes the standards controls the market.”<sup>9</sup>

<sup>9</sup> German Institute for Standardisation “The German Standardization Strategy” (Opening Statement) [http://www.din.de/sixcms\\_upload/media/2896/DNS\\_english%5B1%5D.pdf](http://www.din.de/sixcms_upload/media/2896/DNS_english%5B1%5D.pdf)

As standards are additionally subject to a fee, there is conceivably an economic interest associated with the production of further such “products”.

This stands in sharp contrast to the basis of legitimation for guidelines. For the AWMF, “all parties involved in writing the guideline shall disclose their conflicts of interest at an early stage and a procedure for managing conflicts of interest shall be put in place. Ensuring transparency in collecting and recording conflicts of interest builds trust and protects the group from any charges of bias or impartiality.”<sup>10</sup> For the participants in the sub-committees of the Federal Joint Committee, the sub-statutory standardisation legislative body in Germany that broadly determines benefits entitlements and the regulatory framework for the provision of medical diagnostic and therapeutic procedures, it is a matter of course for participants to disclose their individual interests. Furthermore, the experts active in this body are mandated by health-sector or patient organisations, and are thus legitimised.

European standard specifications with rigid provisions not only interfere in an unacceptable manner in the medical profession’s therapeutic freedom, they are also an obstacle to patients’ claims to individualised medical treatment and rehabilitation. In this regard, European standards could also be contrary to the provisions of the U.N. Disability Rights Convention, according to which disabled people are entitled to healthcare and rehabilitation services oriented to their individual needs, taking into account their particular type of disability. It is extremely doubtful that a highly detailed set of standards could do justice to the particularities of each individual case.

To be sure, within the context of CEN standardisation deliberations, public consultations are carried out, giving third parties the opportunity to take a position. However, whether and to what extent these position statements are considered in the course of editorial development by the standards-setting organisation’s delegates at the CEN level remains uncertain. For this reason, standards are not suited to the formation of an expert consensus in the same manner as clinical guidelines. Rather, they create a parallel structure next to the proven and established structures within the self-governing bodies of phy-

<sup>10</sup> <http://www.awmf.org/leitlinien/awmf-regelwerk/ll-entwicklung/awmf-regelwerk-01-planung-und-organisation/po-interessenkonflikte.html>

sicians and social-insurance carriers, which by producing legal friction associated with professional and liability law, creates fundamental questions of legitimacy. Thus, as one serious concern, competing due-diligence standards for medical treatments could be created, endangering the coherency of professional and liability law (see also section 6).

**Standardisation processes are not suitable for establishing and defining scientifically derived norms for medical treatment!**

## 5 Healthcare services are professional services

Healthcare services are not typically market-based services in which service providers and consumers face one another in a commercial sense. Rather, health services are overwhelmingly professional services characterised by individuality, personal engagement, empathy, therapeutic freedom and expert knowledge. In this regard, these are complex services that must take account of individuals and the specific treatment situation, and which are thus by definition excluded from a standardisation model used for reproducible products.

Standardisation would not take sufficient account of the specific features of health services, particularly of medical treatments with their professional and social complexity and importance to the individual. Instead, there is a risk that highly specific and individualised patient-related services would be devalued through inadequate harmonisation. This can lead to improper patient treatment and endangers the relationship of trust between patients and the professional groups providing treatment.

**The standardisation of health services impinges in an inappropriate way on individualised patient treatment and the medical profession's therapeutic freedom!**

## 6 Standards threaten legal certainty and the enforceability of patient claims

Standards can lead to legal uncertainty and a lack of legal transparency, particularly when they occur in parallel with directives and guidelines. This is because standards, guidelines and directives can contribute to the concretisation of due-diligence standards associated with medical treatments.

For the medical treatment, the doctor is legally obligated to apply the professional standard of care generally accepted at the time of the treatment, unless a different approach has been agreed.<sup>11</sup> This professional standard represents the prevailing state of scientific knowledge and medical experience in the relevant technical field necessary to achieve the objective of the treatment in question.<sup>12</sup> This means the legal standards for a medically due service need to be interpreted relative to the patient, and must be concretised and derived for each individual case. This concretisation is typically done by a medical expert. In addition to the very complex jurisprudence in this area of the law, additional sources from the professional medical literature, guidelines or directives can come into play. In this way, standards, guidelines and directives can on the one hand be used to inform the content of a concretisation of legal liability standards, or on the other, can be directly agreed as a contractual benchmark of liability between physician and patient.

The CEN standardisation of healthcare services threatens to create a juxtaposition of different assessment standards. This can have serious consequences for the legally enshrined quality standards that have existed to this point. On the one hand, this represents an acute threat to the protection of the patient's trust. Up to now, within the context of medical care, a patient has been able to trust that all medical treatments will be assessed on the basis of the same high standards; in the future, he or she must instead expect different standards varying by treatment provider or the treatment context. Particularly in view of the objective of the CEN standardisation process (a European harmonisation of quality standards), it is to be expected that the standards created would lag behind the existing norms of most member states in order to ensure

<sup>11</sup> cf. § 630 Para 2 of the German Civil Code for all treatment contracts

<sup>12</sup> cf. Palandt / Weidenkaff German Civil Code Commentary, § 630, margin number 9ff



that all members have the opportunity to comply. In addition, the national historically developed health systems are very different, and thus a unitary standardisation would be accessible to only a limited degree (e.g., the range of activity pursued by midwives and their interaction with gynaecologists is regulated very differently in the various member states). In this sense, the standards created would not be sufficiently calibrated to the particular features of different systems, or could lead to a deterioration of existing norms.

On the other hand, the coexistence of different high due-diligence standards threatens to endanger existing high standards of quality, such as was the case with Germany's recent Patients' Rights Act, which sought broad-ranging legislative reform. In this regard, different liability standards could be applied in the context of a treatment. In the context of an assessment of treatment errors, this could mean that a patient would risk having less protection against medical malpractice if lower standards came into use. This could particularly apply in the case of cross-border treatments (for instance, in telemedicine) with multiple treatment providers and different liability standards. In such cases, the doctor with higher due-diligence requirements risks assuming liability for the failures of the others in the context of overall damages, because the others can invoke a lower standard of liability. As an economically relevant burden, this could lead to an erosion of today's due-diligence practices.

The European standardisation of health services can have legal implications that could threaten legal certainty and the enforceability of patient claims!

## 7 The CEN's lack of legitimacy

CEN is a private European standards-setting body. CEN is organised in the legal form of an association under Belgian law. As CEN standards are drafted, interested parties can participate through national member organisations (paying fees, if applicable).

In the area of healthcare services, these private organisations can therefore in principle also set requirements for medical treatment within social security systems, if the standards acquire sufficient support from the member states' standards-setting organisations.

In Germany, regulations in the healthcare sector are determined in a constitutionally anchored, well-defined cascade through the federal level, federal states, the self-governing medical profession and the corporate self-governing bodies of health professionals, hospitals and health-insurance carriers and other social-insurance carriers. In this regard, all participating levels are democratically legitimised. The subsidiarity principle is a matter of everyday practice. Thus, for example, the rules governing professional practices for academic health professionals are set by the practitioners themselves. In the context of statutory accident insurance, legislatively legitimised accident-insurance carriers determine standards and quality requirements for the treatment of work-related accidents or occupational diseases through the development of appropriate requirements. For the members of the GVG, it is inconceivable to place standards resulting from the work of a private association next to these established, well-functioning and constitutionally derived procedures.

In addition to the lack of legitimacy, the professional/technical competence of the "interested parties" (which in some cases have paid to be included) on the CEN committees is open to question. The composition of the working groups is arbitrary, non-transparent, and thus does not ensure a representative or high-quality composition. Particularly in areas that from legal requirements onward demand high quality and individualised care (e.g., for seri-

ously injured patients), the question arises whether the appropriate expert knowledge, which must always correspond to the latest science and research, is in fact present.

The financing of the CEN standards-setting process must additionally be deemed extremely questionable from the point of view and the self-conception of the self-governing actors in the German healthcare and social-insurance sectors. Operational funding for technical committees is provided not only by the Commission, the standardisation institute and its members, but also in some cases by third parties.

CEN is neither a legitimate actor nor qualified for the development of standards for healthcare services!

## 8 The European standardisation of healthcare services does not lie within the EU Commission's competences

Article 10 of the Regulation on Standardisation (EU) No. 1025/2012 stipulates that European standards and documents of European standardisation must be market-oriented, in the public interest, take account of the policy objectives clearly set out by order of the Commission, and be based on consensus. To this end, the Commission makes clear that it places its emphasis on the standardisation of services covered under the Directive on Services 2006/123/EG. However, healthcare services have been removed from the scope of the Services Directive on the grounds that a health service is a particularly sensitive protected good associated with the general welfare, and is not to be equated with a market-oriented service.

Moreover, Art. 168 Para. 7 TFEU makes clear that in the activities of the European Union, the member states' responsibility for their health policies and the organisation of their health sectors and medical care is to be preserved. The same applies to the field of social policy in relation to the area of rehabilitation (Art. 153 TFEU).

This is also addressed in recital 12 of the EU Regulation on European Standardisation. "The legal framework allowing the Commission to request one or several European standardisation organisations to draft a European standard or European standardisation deliverable for services should be applied while fully respecting the distribution of competences between the Union and the Member States as laid down in the Treaties." According to the regulation, "it remains the exclusive competence of the Member States to define the fundamental principles of their social security, vocational training and health systems and to shape the framework conditions for the management, financing, organisation and delivery of the services supplied within those systems, including ... the definition of requirements, quality and safety standards applicable to them."<sup>13</sup>

<sup>13</sup> REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardization  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>

The member states' responsibility includes the management of the social-insurance systems and the healthcare sector, including preventative, medical and rehabilitative care, as well as the allocation of the funding made available for these purposes. The practice of the medical profession as well as all regulatory elements that affect activity within the medical profession fall under the management of the healthcare sector and are therefore governed by the member states' responsibility. Accordingly, the European Patients' Rights Directive (24/2011/EU) provides no means of standardising ethical requirements or professional rules across the EU, but concentrates instead on the creation of information structures and reimbursement mechanisms. The project of a European standardisation of healthcare and rehabilitation services calls into question member states' rights to "[lay] down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare".<sup>14</sup> This is particularly true for the definition of professional capabilities, as well as for the definition of ethical standards and rules of professional conduct.

The standardisation of health services at the European level interferes with the competences of the member states to define and shape their healthcare systems. It is therefore impermissible and must be avoided!

<sup>14</sup> Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, recital (42) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>



## Glossar

### Standardisation:

“Standardisation is the systematic process by which tangible or intangible subjects are reduced to a desired degree of order by the joint efforts of the interested parties for the benefit of the entire community. It is not to result in individual interests gaining a special economic advantage. It enhances efficiency in industry, technology, science and government. It serves to safeguard people and property and to improve quality in all areas of life. It further serves as an instrument with which a given field of standardisation can be effectively organised and facilitates the exchange of information in it. Standardisation is carried out at national, regional and international levels.”<sup>15</sup>

One of the best-known examples of a generally used standard is probably that of the standardised formats for writing paper, such as the A4 format, often referred to as DIN A4. Most file folders, binders and other such goods, as well as printers and photocopiers, are adapted to this format. Unitary requirements for products and services at the national, international and European level promote the free movement of goods and services, and should at the same time lead to a high level of protection and quality.

### Standards creation

There are generally accepted practices and procedures for the development of standard specifications and their use. “Through standardisation, tangible or intangible subjects are reduced to a desired degree of order by the systematic joint efforts of the interested parties, for the benefit of the entire community. It is not to result in individual interests gaining a special economic advantage. It enhances efficiency in industry, technology, science and government. It serves to safeguard people and property and to improve quality in all areas of life”.<sup>16</sup> (DIN 820-1: 2009-05 “Standardisation Part 1: Principles”). The use of standards is voluntary in nature; standards are binding only if they are the subject of contracts between parties or if the legislature mandates that they be

<sup>15</sup> Standard DIN 820-1:1994-04

<http://www.din.de/cmd?level=tpl-unterrubrik&cmssubrubid=48549&languageid=de>

<sup>16</sup> ibid

observed. As standards represent clear (acknowledged) precepts of practice within a field, reference to standards in contracts provides legal certainty. In order that standards can be applied across borders to the greatest degree possible, they should not conflict with national regulations.

### **Standardisation procedures and activities at the EU level**

For standardisation at the EU level, two approaches are possible in principle: either top-down or bottom-up.

#### **Top-down process:**

Standards can be commissioned by the European Commission on the basis of the Regulation on European Standardisation (EU) No. 1025/2012 (“Standardisation Regulation”), which provides the legal basis for European standardisation. Relatively new – along with the expansion of the scope of the services standardisation projects – is the fact that going forward, the European Commission can commission standards within a specified time limit from the European standards-setting bodies (particularly the European standardisation committee “Comité Européen de Normalisation” (CEN)), if the area demonstrates a market need and holds public interest. Healthcare services, in spite of intense German efforts, are not explicitly excluded from the scope of the Standardisation Regulation, as they are from the Services Directive. However, a reference to member states’ reserved powers in the healthcare sector was included in recital 12. The interpretation of this recital has been contentious, with the Commission’s legal service currently engaged in producing a binding interpretation.

To this point, the EU Commission has issued no mandates to CEN to develop standards in the area of healthcare services. However, on 31 July 2013, the European Commission did present a communication to the European Parliament, the Council and the European Economic and Social Committee containing its annual work programme for European standardisation (COM (2013) 561), in which healthcare services – including rehabilitation services in this context – were specified. In its 2015 annual work programme for



European standardisation, presented on 30 July 2014, the Commission takes the approach of further pursuing the development of standards in the area of healthcare services, and of participating in this process. The 2015 work programme contains a call to pool knowledge about the development of healthcare-services standards.<sup>17</sup> The Commission is holding open the option of commissioning standards from CEN on certain cross-cutting aspects within the framework of its competences.

### Bottom-up process

Standards can also arise in the context of so-called bottom-up projects. In such a case, a national standards-setting institute initiates a standardisation project on behalf of the public or of “interested parties”. Among these “bottom-up” projects are, for example, the above-mentioned standardisation projects for cosmetic surgery (CEN/TC 403), homeopathy (CEN/TC 427), osteopathy (CEN/TC 414), and the treatment of cleft palates (CEN/TC 424).

### Standards-setting institutions

- Germany: In Germany, bodies concerned with the creation of standards include the German Institute for Standardisation (Deutsches Institut für Normung, DIN), the German Commission for Electrical, Electronic & Information Technologies (Deutsche Kommission Elektrotechnik Elektronik Informationstechnik, DKE; an organ of DIN), and the Association for Electrical, Electronic & Information Technologies (Verbandes der Elektrotechnik, Elektronik und Informationstechnik, VDE).
- Europe: In Europe, the European Committee for Standardisation (Comité Européen de Normalisation, CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) are both active. The CEN is a private organisation that aims to support European economy, protect citizen welfare and promote environmental protection. The CEN is responsible for European standards in all technical fields except electrical engineering and telecommunications. The 33 CEN members consist of the

<sup>17</sup> COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE The annual Union work programme for European standardisation for 2015, 3.2.23 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0500>

standards-setting institutions of the EU member states, members of the European Free Trade Association (EFTA) and countries that will in the future join the EU or EFTA.

- International: The equivalent at the international level is the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC).

## The objective of standards

Standards support the economy in the development of national and international markets, thereby facilitating a liberalisation of trade in products and/or services. Or, as expressed by the EU Regulation on European Standardisation (1025/2012): “European standardisation also helps to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation. Standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved supply conditions. Standards thus normally increase competition and lower output and sales costs, benefiting economies as a whole and consumers in particular. Standards may maintain and enhance quality, provide information and ensure interoperability and compatibility, thereby increasing safety and value for consumers.”<sup>18</sup>

## Healthcare services

Health services (and pharmaceutical services) are services “provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the member state in which the services are provided”.<sup>19</sup>

<sup>18</sup> REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardization  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>

<sup>19</sup> EU Directive 2006/123/EG services in the internal market, recital 22  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:376:0036:0068:en:PDF>

## Therapeutic freedom

Every patient has the right to individualised and skilled medical treatment. The decision on the selection and concrete implementation of the therapy fundamentally lies with the doctor, dentist or psychotherapist, taking into consideration the patient's right of self-determination. To this extent, the practitioner has a therapeutic freedom, which is an aspect of his or her profession and is fundamentally protected under the German Basic Law's Art. 12 on occupational freedom. "Therapeutic freedom is an essential element of medical professionalism. The physician always has a duty to the individual patients whose particularities he must respect; he can also have serious objections to the established methods. However, therapeutic freedom never means therapeutic arbitrariness; the doctor is subject to a due-diligence requirement inherent in the profession. He must be guided by the current standards of medical excellence, and act according to the best of his knowledge and conscience."<sup>20</sup>

The relationship with the patient is based on a special relationship of trust. The medical professional is thus subject to special professional duties to protect the patient, such as the treatment principles and rules of conduct that constitute medical ethics, disclosure obligations, and confidentiality and documentation requirements. In the area of social insurance, there are also special legislatively mandated requirements, as in relation to medical procedures' implementation and quality requirements, as well as in the area of rehabilitation and in relation to preventative examinations in the area of occupational health protection.

Members of the health profession have a duty to observe quality standards in the context of an individual patient treatment.

## Medical profession regulations

In Germany, regulations governing practice in the medical professions, including professional duties and continuing education, are subject to the

<sup>20</sup> Kienle, G. S. Evidenzbasierte Medizin und ärztliche Therapiefreiheit: Vom Durchschnitt zum Individuum Dtsch Ärztebl 2008; 105(25): A-1381 / B-1193 / C-1161

constitution under state law. The legal basis lies in the medical-profession and chamber laws of the individual federal states, which are adopted by the state legislatures. However, the states' chamber laws authorise the chambers to enact statutes governing professional discipline and training procedures. The chambers are public corporations and are subject to the legal supervision of the federal states. They are not subject to technical supervision, as they are organisations in a system of self-government.

Moreover, the medical profession's self-government is responsible for the assurance and further development of the quality of work within the academic medical professions, as well as for the directives and decisions of the Joint Federal Committee – all of which are important preconditions for establishing a level of care in Germany that takes into account patient needs, is professionally skilled, is economical and takes place at a high level of performance.

### **Liberal profession**

In general, the liberal professions provide personal, autonomous and professionally independent services of a high order in the interest of clients and the general public, on the basis of special professional qualifications or creative talent.

According to the definition of the European Court of Justice, “the liberal professions mentioned ... are activities which, inter alia, are of a marked intellectual character, require a high- level qualification and are usually subject to clear and strict professional regulation. In the exercise of such an activity, the personal element is of special importance and such exercise always involves a large measure of independence in the accomplishment of the professional activities.”<sup>21</sup>

<sup>21</sup> C-267/99 Adam./Administration De l'enregistrement et des Domaines de Luxemburg  
<http://curia.europa.eu/juris/document/document.jsf?text=&docid=46273&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1>



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