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**Comments of the German Social Insurance on
the Standardisation of Health Services and
Social Services**

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The German Social Insurance is a statutory insurance system which plays a major role in Germany's social security. Based on the principle of solidarity, health insurance, long-term care insurance, pension insurance, insurance against work accidents and occupational diseases and unemployment insurance provide effective protection against the consequences of major life risks.

The German Statutory Pension Insurance Scheme (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the Federal Associations of Statutory Health and Long-Term Care Insurance Funds act jointly to promote their interests when dealing with the bodies of the European Union and other European institutions.

Summary:

In recent years, the focus of standardisation organisations has not only been on products, for example medical products, but also on health and social services. Efforts to standardise health and social services are being increasingly fostered by the European Commission (EU Commission), national agencies and interest groups across Europe. One of the aims of this is to promote the highest possible quality for health services and social services.

Generally speaking, this aim is welcomed by the German Social Insurance because it serves to safeguard patients and beneficiaries. However, the Member States themselves are the ones best suited to develop appropriate mechanisms as part of their national health and social systems. This particularly applies to guaranteeing a high level of quality that is sustainable. The procedures and the provision of services in social insurance systems depend on the characteristics and traditions of each of the health and social insurance systems. These differ between the individual Member States.

European treaties recognise these national differences in social and health policies (e.g. Article 153 TFEU). The design of social security and health systems is largely left up to the Member States. The German Social Insurance wishes to point out that European and international initiatives must not interfere with the core areas of the national social insurance systems and their statutory responsibilities.

Therefore, the German Social Insurance calls for:

- the German, European and international standardisation organisations DIN, CEN and ISO¹ to cease considerations and activities related to the standardisation of health services and social services. This especially applies to services that are provided by statutory social insurance.
- the EU Commission to clearly state in its work programme or in a commitment that it does not support the standardisation of health services and social services.
- the German federal government to ensure that the financial aid which they indirectly provide to the CEN will not be used to develop standards for health services and social services.
- the German Institute for Standardisation (DIN) to change the current *Standardisation Roadmap for Services* to the effect that the standardisation of personalised social services, particularly with regards to statutory and regulated procedures, will not take place.

¹ References to DIN, CEN and ISO here and hereinafter also include the electrotechnical standardisation organisations DKE, CENELEC and IEC

I. Background and Issues

The German Social Insurance is greatly concerned with the increasing political interest and willingness to push for the standardization of health services and social services, particularly by the EU Commission as well as national bodies and interest groups across Europe. This applies to national, European and international projects and initiatives.

Since coming into force, Regulation (EU) No 1025/2012 on European Standardisation has provided the EU Commission with the possibility of a standardisation mandate to commission the creation of standards not only for products but for services as well. The EU Commission has highlighted the importance of standardisation, particularly for health services, in its 2013, 2014 and 2015 work programmes for standardisation. They refer to standardisation as a means of supporting the quality of health services for the safety of patients.

In addition, the EU Commission, in its Digital Single Market Strategy [(COM)2015, 192), has declared its intention to establish an integrated standardisation plan with standardisation priorities whose focus includes standards for healthcare (telemedicine, mHealth). According to the EU Commission, standards are a key tool for improving the interoperability of new technologies which in turn is a crucial prerequisite for securing Europe's competitiveness.

The International Organization for Standardisation (ISO) and the European Committee for Standardisation (CEN) has concerned themselves for some time with a series of specific standardisation projects that have been called for by interested parties. The standardisation initiatives that have been undertaken include health and care services in an ageing society (ISO) as well as homeopathy and aesthetic surgery (CEN). The German Institute for Standardisation (DIN) is involved in the work done by CEN and ISO.

Furthermore, as part of activities carried out by the European Commission, there have been efforts to define and develop an evidence-based European concept for medical care of breast cancer, which also takes into consideration the possibility of European standardisation. The results are intended to flow into a general concept for using European standards in the field of health services.

II. Health and social services as the focus of standardisation

1. Standardisation of medical products and equipment

The German Social Insurance considers standards to be useful in many areas. This applies particularly to areas where standards assist with the safety of products that are used in health care and thus, serve patient safety. Standards that are uniform and offer a high level of safety for medical products and equipment are very important for the safety and health of medical practitioners, nursing staff and patients. For example, the ergonomic design of hospital beds or the safe technical fit-out of laboratories not only increase safe usage (by doctors and nursing staff) but also quality and this ultimately benefits patients.

2. Standardisation of health services

However, the German Social Insurance does not consider that the standardisation of products is in any way comparable to the standardisation of health services.

Although the German Social Insurance acknowledges that it can be beneficial to standardise some services, it does not believe that this is the case for all types of services. Health services have unique characteristics. Unlike purely commercial services, health services are provided to human beings and should be individually tailored to the person and their situation.

The German Social Insurance appreciates that European institutions have recognised the special nature of health services as shown by their exclusion from the scope of application of the EU Services Directive. However, the German Social Insurance observes with concern that the EU Commission increasingly wants to push for the standardisation of health services. The EU Commission sees standards as a tool to support the quality of services in the health sector. However, in Germany, this responsibility is met by the social insurance institutions as outlined in the following.

a) Health services of the social insurance institutions

The statutory social insurance institutions in Germany provide numerous services in the health sector; therefore, they would be affected by the standardisation of health services in many different areas. From the perspective of the German Social Insurance, standardisation initiatives could affect both health care services of a preventive nature (e.g. screenings) as well as services provided by the statutory insurance institutions following a risk event (e.g. illness, accident, disability). This would impact not only medical treatment but also preventive measures such as screenings (including OSH) as well as medical rehabilitation.²

Health insurance funds fulfil their statutory mandate by offering appropriate services for early detection, for treatment of illnesses and for medical rehabilitation. Their quality and effectiveness correspond with the generally accepted state of medical knowledge and take into account medical progress. Furthermore, the quality of medical care is ensured by a variety of tools and instruments that work in conjunction with one another. Self-government plays a particularly important role here. In the German Federal Joint Committee, representatives from health insurance funds, physicians and hospitals issue directives for medical care and quality assurance. Guidelines are developed by the self-government, professional associations or medical-scientific societies. These are intended to show what options are available for decisions and actions based on reliable evidence and multidisciplinary consensus.

Institutions in the statutory accident insurance system are required to take all measures necessary to ensure that proper medical treatment and rehabilitation occurs as early as possible following an insured event. In order to do this, they can specify the requirements that doctors and clinics must meet in terms of professional competency, equipment, personnel, and duties to be undertaken. They can also specify which specific medical treatment should be provided to the patients insured by them. Standards of quality for outpatient, inpatient and rehabilitative care of people injured in workplace accidents are developed in dialogue and cooperation with the medical community and medical professional associations. These are adjusted to new requirements when necessary. This ensures that services related to medical

² The remarks made on health services, such as those by the EU Commission in its annual work programmes, are understood by the German Social Insurance in a broad context.

treatment always conform to the generally recognised state of medical knowledge and take into account advances in medicine.

The German Statutory Pension Insurance Scheme has established a dense network of medical and vocational rehabilitation facilities. All of these facilities are subject to comprehensive and continuous quality assurance by the German Statutory Pension Insurance Scheme. Part of this quality assurance is the internal Quality Management (QM) of the facilities with regular certification cycles. This internal QM is continuously supplemented by regular, comprehensive external quality assurance of all aspects of quality (structures, procedures and results) which allows the German Statutory Pension Insurance Scheme to provide rehabilitation of the highest medical and professional standard.

Thus, the aim of the German Social Insurance is to ensure the highest quality of health services possible and has developed numerous tools and instruments to this purpose.

b) Patient safety

It is the opinion of the German Social Insurance that attempts to further increase patient safety through standards is the wrong path to take. This approach is much more likely to be counterproductive and result in a drop in the quality of health care and patient safety.

Due to the different standards for medical and rehabilitative care in the various Member States, it can be assumed that the development of a standard, for example, a standard for a specific medical treatment at European level, would have minimum consensus. Over the medium term, the German Social Insurance believes that there would be a drop in quality due to “downward pressure to adjust”. Today’s quality standards, which are the result of a high level of technical and professional competence within the self-government in social insurance and the medical profession, could be undermined by competing standards.

Furthermore, patient safety is already a part of quality assurance with comprehensive activities such as Critical Incident Reporting Systems (CIRS). Provisions which contradict one another, for example, guidelines and EU standards, could jeopardise patient safety rather than improve it.

Finally, the German Social Insurance wishes to point out that the aim of the EU Commission to improve access to safe and high quality health care through the cross-border provision of services as part of the EU Patient Mobility Directive (2011/23/EU) will be achieved through existing instruments such as the specially established national contact points. These provide relevant information to patients about national health systems.

c) Competitiveness

Finally, it should be noted that the aim of European standardisation to promote the competitiveness of companies and to simplify the trade in services cannot fully apply to the health sector. Unlike the trade in products, health services provided as part of a social insurance system are only partially subject to free market conditions. The trade in such services can be limited by national provisions within the Member States. This applies even more so when a social insurance system provides benefits in kind, as is the case in Germany.

In this respect, there is the danger that standardisation of health services in the way of a “soft instrument”, similar to the open method of coordination in the health sector, will increasingly exercise influence on an area whose arrangement is a matter for the individual Member States.

Standardisation projects in the health sector, such as that for aesthetic surgery, can come into conflict with national regulations, laws and guidelines. This is even more so the case when it comes to a European standard which the Member States must add to their national standards without the ability to make changes.

The DIN has already taken the first step in the right direction by highlighting in the first German standardisation roadmap for services that the standardisation of health services would not be expedient. The DIN rightly points out that there is a lack of market relevance and added value in the standardisation of health services. Standardisation is neither a necessary nor suitable tool for ensuring or improving the quality of services provided. In addition, services relating to individual patients cannot be standardised because they are not objects that can be standardised but rather they become a part of the health service.

The EU Commission should also send a clear message in its work programme that it is against the standardisation of health services. Finally, it is the opinion of the German Social Insurance that the German federal government should take action to ensure that the funds it provides to CEN must not be used to develop standards for health services and thus, undermine the skills and competencies of Member States.

The German Social Insurance also recalls the feasibility study on the standardisation of health services which the EU Commission proposed but which failed due to resistance from the Member States. The way that service providers are intertwined and integrated into each national health and social security system shows that competition and patient safety are heavily dependent on national characteristics and the attributes of social insurance and health systems. To this extent, competition and patient safety cannot be subject to European standards. In particular, there is the danger that national legislation and the regulatory scope of self-government can be circumvented without the intervention of the institutions responsible for this.³

For this reason, the German Social Insurance is particularly critical of the standardisation processes for health services which have been initiated by the standardisation organisations from the Member States. Ultimately, if privately-organised standardisation organisations and their members start to influence national social insurance systems and encroach on their competencies then the question arises whether this type of action falls within the scope of European treaties and whether it is in accordance with the EU Acquis which all Member States have agreed to and which is the basis for European cooperation and the principle of democracy.

³ See also the decision of the 87th Conference of German Health Ministers on 26-27 June 2014 in Hamburg, Agenda Point 13.1. Standardisation in medicine through the European Committee for Standardisation (CEN) <https://gmkonline.de/Beschluesse.html?id=204&jahr=2014>

3. Standardisation of social services

The German Social Insurance is also critical of efforts to standardise social services as these can also affect the areas of responsibility covered by the social insurance institutions. In addition to health services, the social insurance institutions also provide other services such as long-term care, social and occupational reintegration services, and participation services which, like medical and rehabilitative services, are adapted to each individual person.

Within this context, the German Social Insurance observes with concern the recommendations in the DIN's standardisation roadmap on social services. It mentions the provision of personalised services. However, it sees standardisation as adding value when referring to information services or procedures for the interface between service provider and service user. It also refers to a standardisation project that is already running. Wherever services are directed by statutory provisions and are provided according to specific procedural principles there is a danger that the development of parallel structures will ultimately lead to legal uncertainty or the danger that legal requirements will be circumvented. In particular, standardisation cannot be reconciled with the statutory accident insurance's approach to social and occupational reintegration by using all appropriate means to assist a person return to their working life and community life. Here, the statutory accident insurance uses a needs-based approach to rehabilitation which is tailored to the individual. This individualised approach is not compatible with the aims of standardisation. From the perspective of the German Statutory Pension Insurance Scheme, the same applies to its endeavours to reduce incapacity to work by using medical rehabilitation and workplace participation programmes. In terms of statutory long-term care insurance, this also affects the right to individual counselling and help with selecting and using social services and assistance. Individual care counselling provides a tailored care plan with the preventive, curative, rehabilitative and medical care services that are needed to promote good health in each individual case.

It is the opinion of the German Social Insurance that the DIN's standardisation roadmap falls short of the mark. It should clearly state that the standardisation of personalised social services, particularly in terms of statutory and regulatory processes, does not make sense and, therefore, should not take place. Such additions or revisions to the DIN's German standardisation roadmap for services are all the more urgent because this is intended to be used as a blueprint for a European roadmap.

The German Social Insurance urges the German Institute for Standardisation (DIN) to amend the current standardisation roadmap to the effect that standardisation of personalised social services, particularly with regards to statutory and regulated processes, should not take place.

What are standards?

Standards specify technical or quality specifications. They reflect the current state of technology and economic situation at a particular point in time. They are developed by standards organisations. In Germany, this is the German Institute for Standardisation (DIN), in Europe the European Committee for Standardisation (CEN) and internationally the International Organisation for Standardisation (ISO). The DIN is mandated to involve all stakeholders in the standardisation process. Depending on the particular sector or area, this includes manufacturers, users, employers and employees, government agencies, statutory social insurance institutions, trade bodies, tradespeople, testing institutes, consumers, associations and the scientific community. Participation is possible by either becoming a member of a committee or by submitting a written comment on a standard. At European and international level, the national standardization bodies, including the DIN, are involved in the standardisation process.

Standards are private technical rules in the form of recommendations. Therefore, the use of standards is essentially voluntary. National regulations remain binding and take priority. However, a standard can become mandatory as a result of legislation, administrative provisions or contracts. A European standard that has been ratified must be adopted as a national standard.

**These comments are supported by the members of the
Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e.V.**

Members from health insurance

- GKV-Spitzenverband
- AOK-Bundesverband (AOK-BV)
- BKK Dachverband (BKK DV)
- Gemeinsame Vertretung der Innungskrankenkassen e.V. (IKK e.V.)
- Sozialversicherung für Landwirtschaft, Forsten und Gartenbau (SVLFG)
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