

## Comments

of the German Insurance Association (GDV)

ID-Number 6437280268-55

**on standardisation of medical treatments and other  
healthcare services at EU level**

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The German Insurance Association (GDV) is the federation of private insurers in Germany. Its 470 member companies offer comprehensive coverage and provisions to private households, trade, industry and public institutions, through 460 million insurance contracts. As a risk taker and major investor (with an investment portfolio of about 1,390 billion EUR), the insurance industry has outstanding significance in connection with investments, growth and employment in our economy.

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## **Summary**

German insurers believe that standardisation of healthcare services undermines quality of healthcare and, ultimately, patient safety. Therefore, any intentions to standardise these services have to be critically questioned and assessed with utmost care.

The European Commission's consideration to issue a mandate to CEN for the standardisation of healthcare services and current projects in this field are seen with great concern by German insurers for several reasons, the most important being:

1. While standardisation of processes and products is easily feasible, standardisation of services, especially in the health sector, fails because of a lack of unified criteria.
2. A patient's treatment is usually determined by individual factors (a patient's individual symptoms, individual characteristics and the specific circumstances). A simplified and general standardisation would therefore jeopardise proper treatment.
3. Standardisation of healthcare services result in legal insecurity and unpredictability legal standards of medical treatment.
4. All legal uncertainties or irritations of the trustful relationship between patients and doctors can provoke additional conflicts and increase the number of claims, which could impede the market and the availability of insurance cover for liability insurances for doctors and hospitals.
5. For top-down as well as for bottom-up procedures (initiated by the private sector), authorities and competences of EU institutions and Member States have to be respected.

The GDV pleads for restricting European standardisation in the field of services to those issues/subjects which are within the competence of the Union. At the same time we would like to suggest to take into consideration whether there should be implemented a legal definition for appropriate matters which can be subject to standardisation.

## Comments

German insurers observe with great concern a number of initiatives and further considerations at European level to standardise medical treatments and other healthcare services. This development could seriously threaten existing quality standards of healthcare and establish unsuitable criteria for evaluation of healthcare services. Existing national standards might be undermined by lower EU standards. A simplified and general standardisation would jeopardise proper treatment and patients' safety.

The insurance industry would be strongly affected by legal uncertainties with regard to liability criteria that can derive from EU standardisation in this field. Moreover, it could cause conflicts between patients and doctors about the extent of duties to take care in medical treatment. This might have serious consequences particularly for professional liability insurance for doctors or for hospital liability insurance.

### 1. Current relevance and occurrence of the issue

A number of current and planned activities in the field of standardisation of health services give reason to concerns:

- The **European Committee for Standardisation CEN** (Comité Européen de Normalisation) is currently conducting various projects of standardisation of healthcare services based on private initiative (so called bottom-up-procedure) on:
  - aesthetic surgery
  - homoeopathy
  - osteopathy
  - jaw-palate-cleft
- The **annual Union work program for European standardisation for 2015** stipulates that in order to manage "healthcare systems in a consistent manner, specific horizontal aspects could be subject to standardisation requests to CEN in line with relevant Union legislation and policies on healthcare"<sup>1</sup>.
- In 2013, the European Commission conducted a **public consultation on patients' safety and quality of care**. According to the summary of the contributions published in 2014<sup>2</sup>, **standardisation of healthcare services** was mentioned as a tool to improve patients' safety.

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<sup>1</sup> For healthcare services see cp. 3.2.23 on page 11: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0500&from=DE>

<sup>2</sup> For the Report on The Public Consultation on Patient Safety and Quality of Care see [http://ec.europa.eu/health/patient\\_safety/docs/pasq\\_public\\_consultation\\_report.pdf](http://ec.europa.eu/health/patient_safety/docs/pasq_public_consultation_report.pdf)

## **2. Impact of standardisation of healthcare service on the insurance industry**

The insurance industry fears a **strong negative effect on professional liability insurance** and hospital insurance through standardisation of healthcare services.

Insurers give cover for claims against doctors or hospitals in cases of mal-treatment. This contractual obligation could contain payments of compensation for negligence as well as conducting law suits against unjustified claims on behalf of the insured (doctor/hospital). The very core of this business therefore is strongly related to negligence law and predictability of jurisdiction in this context.

Even though standardisation is voluntary (standards only represent non-binding recommendations in order to harmonise economic transactions) **standards can develop an immediate impact on legal standards and result in legal insecurity and unpredictability:**

- Standards can become binding by contractual inclusion or by reference within national law or directives
- Moreover, standards can be used as tools to concretise legal terms. In terms of negligence, standards can interpret legal obligations within contractual duties.
- In general, standardisation at EU level replaces any national standardisation. It cannot be ruled out that this priority could also inflict on less binding medical guidelines, which map out medical recommendations within ranges.
- Consequently because of this influence on national legal criteria for negligence healthcare standards alarms liability insurers because of legal insecurity und unpredictability. As shown above EU standardisation could introduce an additional standard of obligation of duty besides the national one. This could lead to a simultaneous existence of standards and differing assessment of medical treatment. Differing standards can not only create insecurity on the part of the patients but confusion of liability standards. Moreover, they confuse distribution within joint liability especially for cross border treatments (an increase is expected with view to telemedicine).

Therefore, the **following impacts on insurance industry result in strong objections against standardisation of healthcare:**

- All legal uncertainties or irritations of the trustful relationship between patients and doctors can provoke additional conflicts and increase the number of claims.
- Legal uncertainty jeopardise a proper risk assessment and the whole assessment basis for insurance cover for doctors and hospitals.
- Since professional insurances and hospital insurances already represent to a category of heavy risks (represent high likelihood of large losses especially with regard to bodily injury), any additional burden could impede the market and the availability of insurance cover.

- The sensitive balance of these risks is at stake through standardisation of healthcare services.

### **3. General objections against standardisation of health services at EU level**

From the German insurers' point of view, the impact of the above detailed intentions to standardise healthcare services will strongly affect liability insurance as it creates new criteria to assess medical treatment based on inappropriate assumptions. Further concerns include:

#### **a. Medical treatment is not appropriately assessable by standardisation**

In the German insurers' view, medical treatment cannot be standardised since standards represent an economic tool to limit the action scope and take a rather technical approach. Healthcare instead has **individual character**. While the standardisation of processes and products is easily feasible, the standardisation of services, especially in the health sector, fails because of a lack of unified criteria. A patient's treatment is usually determined by individual factors (a patient's individual symptoms, individual characteristics and the specific circumstances). Accordingly, medical treatment usually only knows recommendations within ranges, which only apply if the single case does not require otherwise (in Germany these recommendations are represented by guidelines set up by associations of medical specialists).

Moreover, national healthcare systems differ too strongly among Member States to be standardised. On the one hand, there are no mutual standards upon which EU standardisation can be set up. On the other hand, medical practice and functions of certain healthcare practitioners differ among Member States, so that it lacks a common framework of healthcare (i.e. cooperation of midwives and gynecologists).

#### **b. Standardisation of healthcare services jeopardises the quality of healthcare**

In the German insurers' view, standardisation of healthcare services is very likely to lower quality of medical care: Standardisation in the healthcare sector would derive from a wide range of European national standards; the main goal therefore would be to find a common denominator. As harmonisation of healthcare standards inevitably represented the lowest standard in order to prevent standard conflicts, a levelling down of existing standards is to be feared. Existing national standards might be undermined by lower EU standards incorporated in contracts for medical treatments. A simplified and general standardisation would jeopardise proper treatment and patients' safety.

### **c. There is no EU competence for healthcare regulation**

The European Standardisation System should not expand its operations into fields that are not within the competence of the Union. The competence for regulation of healthcare systems remains with member states (see i.e. Art. 152 paragraph 5 EGV). Standardisation of healthcare services infringe upon the explicit exclusion of healthcare from EU competence as stipulated in Art. 168 paragraph 7 TFEU. This clause explicitly clarifies, that the EU has to respect the competence of member states for regulation of health services in the context of standardisation. Moreover, Regulation 1025/2012 on European standardisation (Consideration nr. 12) excludes health care from standardisation through top-down-procedure on the basis of a standardisation mandate by the Commission. Unfortunately, CEN acts outside these regulations through bottom-up-procedures.

### **d. There is no need for standardisation of healthcare**

All national systems have established fitting criteria and guidelines which evaluate quality of medical treatment – adjusted to their individual system. These national standards create legal predictability and legal security. Risk assessment of insurers strongly depends upon this predictability and continuity. Therefore, standardisation leads to simplification of medical treatment and creates misleading legal criteria.

### **e. There is no sufficient guaranty for quality of standards and competence in CEN project groups**

There are no standards for the composition of CEN project groups. Participation is organised through national standardisation institutions and participants are charged with fees.

## **4. Position of the German health sector**

The German health sector is united in its strong opposition to intentions to standardise healthcare service on a European level.

Consequently, the parties within the German Society for Insurance research and development (**GVG**)<sup>3</sup>, including the GDV but also physicians, private health insurers, etc. presented a **joint position paper**<sup>4</sup>, which details many of the GDV's points as raised above.

Berlin/Brussels, December 2014

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<sup>3</sup> For the website of the German Society for Insurance research and development (GVG) see <http://gvv.org/>

<sup>4</sup> For the GVG position paper on Standardisation of healthcare services please see <http://www.gdv.de/2014/10/gdv-bezieht-position-gegen-die-normierung-von-gesundheitsdienstleistungen-auf-eu-ebene/>