BUNDESÄRZTEKAMMER

## Bekanntmachungen

**On the recommendation of the Scientific Advisory Board, the Executive Board of the German Medical Association adopted at its meeting on 25 September 2015:**

### Abridged Version of the Statement on the

# "Standardisation proposals regarding healthcare services from the physicians point of view"

Standards are ubiquitous in our healthcare sector. In the field of medical technology, in particular, they contribute to patient safety and quality of health services. However, the EU Commission is increasingly pursuing a strategy that would subject healthcare services – and therefore the practice of the medical profession itself – to standardisation. This is evident in the work programmes enacted by the European Committee for Standardisation, particularly those for the year 2014 (COM(2013) 561 final).

The German Medical Association's statement on the standardisation proposal regarding healthcare services calls attention to the problem from a scientific, medical point of view. It addresses the key questions

- what constitutes individualised state-of-the-art medical care,
- where might standardisation be reasonable from the point of view of physicians and patients, and
- in which areas do other methods grounded in evidence-based medicine have to be applied in order to ensure high-quality medical care that is targeted at individual case.

While the primary objective of standardisation is the methodical, collaborative achievement of uniformity of tangible and intangible goods, the task of physicians is to preserve life, protect and restore health, alleviate suffering, support the dying and to help preserve natural resources with regard for their importance to human health. Practicing medicine requires the necessary professional qualifications and compliance with the recognised state-of-the-art in medical knowledge.

Healthcare services must be regarded as fundamentally complex interventions. Accordingly, internationally as well as nationally, quality assurance relies on the principle of evidence-based medicine and on clinical practice guidelines. The recommendatory nature of guidelines takes into account, on the one hand, the physician's duty to treat patients according to the recognised state-of-the-art in medical knowledge as well as, on the other hand, the patients' right of self-determination when medical procedures are to be administered. In contrast, in the case of standardisation, requirements are formulated regarding the usual, technically proper course of action and the expediency of the services, respectively.

[1] DIN 820-Series of Standards by the German Institute for Standardisation (Deutsches Institut für Normung) and the regulations "Clinical Practice Guidelines" by the Association of the Scientific Medical Societies (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF)

Consulting the relevant regulations[1], it becomes clear that there are both considerably divergent objectives as well as conceptual differences in the development of clinical practice guidelines, on the one hand, and the development of standards on the other – despite some similarities in terms of relevant aspects and requirements:

| | | Standards | Clinical Practice Guidelines |
|---|---|---|---|
| 1. | Area of application | Preferably international | Preferably national – but also international – taking into account specific features of the system. |
| 2. | Objectives and purpose | Formulation of requirements on the usual, technically proper course of action and the expediency of the services, respectively. (conformity) | Formulation of recommendations and decision-making aids for physicians and patients regarding the diagnostic and therapeutic procedure in individual cases. (individuality) |
| 3. | Development prompted by | Requirements of the market; core criterion: economic benefit. | Room for improvement in patient care, information needs; core criteria: Optimisation of patient care, knowledge transfer, quality assurance. |
| 4. | Representativeness, involvement of stakeholders | Stakeholders, including industry, shall be represented in reasonable proportion to each other. | The involvement of all stakeholders shall be ensured; direct participation of industry is not permitted. |
| 5. | Contents are based on | Current state of the art of science and technology. | Evidence base: independent systematic research, selection and assessment of literature. |
| 6. | Decision-making process | Use of unspecified methods for achieving consensus. No provision for expressing dissent. | Use of methods for achieving consensus that are (demonstrably) suitable for avoiding bias. Declaration of the degree of consensus and of reasonable dissent, both in terms of individual details and as a whole. |
| 7. | Transparency | Poor The process of developing a standard is only transparent to the public to a limited extent (during each of the temporary opportunities to comment). | High The process of developing a guideline is made publicly available (e. g. by "Clinical Practice Guideline Reports"). |
| 8. | Editorial independence | No regulation of how conflicts of interest are handled. Third parties not precluded from exerting financial influence. | Regulated and transparent way of dealing with conflicts of interest. Influence by third parties via financial means ruled out. |
| 9. | Accessibility | Limited, because fee required – only accessible for free in a few places for display. | Unrestricted access on the Internet free of charge. |

**Conclusion**

The juxtaposition of the differences between clinical practice guidelines, on the one hand, and standards on the other demonstrates that in the field of healthcare services, particularly regarding a physician's genuine medical activity, standards are neither a necessary nor a suitable tool for ensuring or improving the quality of the service provision.

In reference to the unique physician-patient relationship as well as the therapeutic freedom of the physician based on evidence-based medicine, the European Committee for Standardisation (CEN) does, in fact, emphasise the recommendatory nature of standards. However, deliberately departing from or watering down abstract universal standards leads to the questionable outcome of lending standards in the healthcare services sector the character of clinical practice guidelines. There is no evidence base for such an amalgamation of methods. Therefore, this is not applicable for patient care. Standardisation in this sensitive field leads instead to legal uncertainty and considerable friction with national regulations governing the profession and with liability law, among other things. At the European level, standardisation of healthcare services infringes upon the principle of preserving the autonomy of the member states in charting their healthcare policy as well as in organising public health service and medical care.

In summary, it should be noted that standardisation should be applied in areas where abstract, universal and more technical provisions are to be developed. In those cases, however, where information or specifications have to be interpreted and evaluated on an individual basis, standardisation is not a suitable regulatory instrument. This is one more reason to strongly object to standardisation in the healthcare services sector.

In contrast, there are promising efforts underway for developing supranational clinical practice guidelines in addition to national clinical practice guideline processes. These efforts should be further strengthened and supported by policy.

The present statement complements other statements that have already been published (see selection of references in the long version of the statement) and is intended to provide stakeholders at the national and European level with additional supporting arguments with regards to the evaluation of attempts at standardisation.

The long version of the present statement – including a list of authors and a selection of references – can be accessed on the website of the German Medical Association **http://www.baek.de/wissenschaftlicher-beirat-normung**.