



Systematic Second Opinion before Surgical Procedures in Germany - New directive -

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Oral session O4.4 „Health literate healthcare organizations“

AGENDA

- New legal framework in Germany
- The new directive „Second Opinion“
- Implications for hospitals, health services and patients



German healthcare system

Shared decision making powers between the National Level (federal government), the Federal State Level and legitimized civil society organizations

Financing healthcare: Statutory Health Insurance System: 90% of population (>70 Mio)

Traditional separation between **hospital and ambulatory care sector**: seen as a barrier for change

Current focus: **improving cooperation** between the stakeholders of the 2 sectors (Quality assurance, quality management, etc.)

„Second opinion“:

- Patient have free choice of physicians and hospitals
- Patients have the right to see their medical records – and get copies
- Insurance companies offer their patients second opinion options
- Private market for second opinions (paid by patients)



New legal framework

Act to strengthen the Supply in the Statutory Health Insurance

Came into force in July 2015

Aim of legislator: raise quality of care, improve care in rural areas, faster access to physicians, financial support of innovations, empower patients

Ensure that all patients get an independent medical second opinion for selected procedures

GKV-Versorgungsstärkungsgesetz:

https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl115s1211.pdf#_bgbl_%2F%2F*%5B%40attr_id%3D%27bgbl115s1211.pdf%27%5D1558602086789

Implication on Social Code Book V: §27b Abs. 2

= Legal basis for Federal Joint Committee (G-BA)

Highest decision making body in German hcs

4 umbrella organizations: providers + insurers

Under statutory supervision of Federal Ministry of Health

Tasks: development of directives, ensure that legal instructions are implemented in everyday work

https://www.gesetze-im-internet.de/sgb_5/_27b.html



Development of national directives



Gemeinsamer
Bundesausschuss

Über den G-BA Themen Richtlinien Beschlüsse Bewertungsverfahren Presse



Startseite // English

English Version

About the Federal Joint Committee

The Federal Joint Committee (G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany.

It issues directives for the benefit catalogue of the statutory health insurance funds (GKV) for more than 73 million insured persons and thus specifies which services in medical care are reimbursed by the GKV.

[read more](#)

Benefit Assessment of Pharmaceuticals

The G-BA must put every new active pharmaceutical ingredient through an early benefit assessment within six months after it is launched on the German market. During the early benefit assessment, the G-BA examines whether the drug is really something new: if it offers patients greater benefit than comparable treatments that are already available.

[read more](#)

The G-BA – explained in four minutes



<https://www.g-ba.de/english/>

- Federal Joint Committee (G-BA): New directive „Second opinion“
 - Select elective procedures for this purpose
 - Set up requirements for the formal second opinion process
 - Set up requirements for involved physicians (excl. dentists)



Scope of the new directive „Second Opinion“

Directive = part of the quality assurance system for healthcare providers according to SGB V

- All directives: sublegal norms, binding for all actors in the German hcs
- This directive: part of the ambulatory care sector regulations
- Requirements defined in the directive ensure that the second opinion is of high quality

Advantages for patients:

- Education about their right to seek an independent second opinion: strengthens patient sovereignty
- Free Choice of high profile specialists
- Easy access to structured independent medical second opinion
- Informed decision for or against an operation/alternative treatment options
- Financed by health insurance companies



Formal aspects of the directive

General Part

- §1 Legal basis and purpose
- § 2 Objectives
- § 3 Definition and scope of the structured second opinion
- § 4 Selection of interventions accessible to second opinion
- § 5 Origin of the property claim
- § 6 Duties of the physician making the first indication
- § 7 Duties of the physician performing the second opinion
- § 8 Qualification requirements of the physicians
- § 9 Information about recognized physicians for s.o.
- § 10 Reporting and evaluation of the directive
- § 11 Transitional regulations

Specific Part

Procedure 1: Tonsillectomy/tonsillotomy

- § 1 Definition of the planned intervention
- § 2 Intervention-specific requirements for physicians

Procedure 2: Hysterectomy

- § 1 Definition of the planned intervention
- § 2 Intervention-specific requirements for physicians

All procedures: Elective, not acute operations

No malignancies (Tumorboards!)



Duties of the physician at first indication

- He/she must inform the patient about
 - his right to seek an independent second medical opinion, at least 10 days before planned elective operation
 - where to find other physicians
 - specific patient information sheet, intervention-specific decision aid and further evidence-based information
 - his right to get copies of his medical records and assessment results
 - the fact that second opinion can not be given by physicians or a hospital through which the procedure is going to be performed
- Personal contact necessary, comprehensible explanations



Duties of the physician for second opinion

- Requirements:
 - No existing conflicts of interest or financial relations
 - Personal contact between him and the patient, exceptionally use of telemedicine if necessary
 - Patient history, physical examination, counsel about operation and other treatment options
 - Allow patients to make an informed decision with regard to the recommended procedure
- Share findings with first physician only with consent of patient
- Hand out patient-oriented report on request

“Second opinion process” completed when assessment and consultation ended

= indication for OP confirmed or not + all treatment options have been explained to the patient



Public information about physicians

- Coordination at Federal States level: Region. Ass.of Statutory Health Insurance Physicians
- Information accessible on Internet nationally
- Contact details defined



www.116117.de/zweitmeinung

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Who is entitled to give a second opinion?

- Law: “Physicians, hospitals and medical care centers that qualify”
- Requirements according to directive:
 - Specialist qualification
 - 5 years specialist experience with patient care in that specialty
 - knowledge of the current state of scientific research on the respective diagnostics and therapy including alternative therapies
or authorized for medical education/academic teaching
 - authorized by the Regional Associations of Statutory Health Insurance Physicians (Federal State level) to carry out billing for second opinions
- Further requirements: in Specific Part of the directive



Patient decision aids

Patient information sheet

Joint Federal Committee

- Explains procedure and identifies potential that may assist the patient in decision making process
- Indication by first physician and possibilities by second opinion
- Process voluntary, well-informed decision
- Sufficient time to weigh the advantages and disadvantages of both medical opinions
- Links to the list of physicians, further topics and other medical questions

https://www.g-ba.de/downloads/17-98-4765/2019-04-11_G-BA_Patientenmerkblatt_Zweitmeinungsverfahren_bf.pdf

Patient decision aid

IQWiG (independent scientific institute)

- Based on clinical problems and symptoms
- E.g. Hysterectomy:
 - Uterine fibroids
 - Endometriosis
 - Uterine prolaps
 - Menstrual disorders

<https://www.arbeitskreis-frauengesundheit.de/2018/12/31/iqwig-entscheidungshilfe-gebaermutter-entfernung/>



Reporting

- Data collection at Federal State level
 - by the Regional Associations of Statutory Health Insurance Physicians (Kassenärztliche Vereinigungen)
 - They document the results of the procedure by the Panel Medical Associations and publish them annually
- Data forwarded to the National level
 - National association (Kassenärztliche Bundesvereinigung)
 - They aggregate the data and direct a report to the Joint Federal Committee
 - Report: Information on the n^o of applications, n^o of licenses granted for settlement and rejection, also reasons for refusals
- Evaluation of the directive...
 - if requirements have exhausted all quality improvement potentials
 - if there is need for further development of the directive



Summary

Legislation: ensure that patients continue to receive high quality medical care and to provide them with a rapid and cross-sector-wide access

Directive “Second opinion”

- compulsory for all actors in the German healthcare system
- Voluntary for patients
- Regulates structured “second opinion process”
 - Start of process = Indication for selected procedure by a medical doctor
 - End of the process = Completed assessment and counselling
- Physicians: high demands on them to ensure high quality
- Operations: HE, TE, more under development

Acceptance? Improvement?

Thank
you!