Medical Law Aspects: Germany

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Stephan Krempel

Abstract

The specific German way of dealing with malpractice is highlighted.

The German Medical Liability Law had not been codified until the so-called Patient Rights Act came into effect in February 2013.

Up to that point, the treatment contract had followed the rules of service contract law (§§ 611 ff. BGB). A "new type of contract" was created with the introduction of the Patient Rights Act, the treatment contract according to § 630 a BGB, which provides for the exchange of medical services against payment. This is a "specific type of contract" that not only regulates physicians' activities but also the activities of other members of the medical profession (see Wagner, Kodifikation des Arzthaftungsrechts, VersR 2012, 790 ff). It incorporates midwives, perinatal nurses, masseurs, medical balneotherapists, psychologists, psychotherapists, ergotherapists, speech therapists, and dentists as well (see Wagner, loc. cit.).

The regulations of the Patient Rights Act are, however, no novelty; they just couch past and present court rulings summed up in legal articles (§§ 620 ff. BGB).

S. Krempel
Fachanwalt für Medizinrecht,
Futterstr. 3, Saarbrücken 66111, Germany
e-mail: kanzlei@anwaltskanzlei-krempel.de

German physician liability law/medical malpractice law is eventually governed by the burden of proof. The law initially defines the rights and duties of the parties involved (medical professional and patient) and finally regularizes – in § 630 b BGB – the prerequisites as effective consent being the requirement to justify bodily injury/damage to person related to any physical intervention. Details ensuing from the obligation to informing the patient are regulated by § 630 e BGB, meaning the patient must be informed in detail of all major circumstances needed for his/her consent as to the kind, extent, and execution of medical action, possible sequelae, and risks linked with the procedure, its necessity and urgency, agreements, and prospects regarding diagnosis and treatment. Alternatives to the suggested procedures must clearly be pointed out when there are several medically similarly and commonly indicated methods, which may lead to significantly less stress and risks or different prognosis for cure. This also encompasses the question of "conservative versus surgical procedure," outpatient versus inpatient treatment, especially when an intervention is being suggested that is not contained in the catalog of outpatient procedures, e.g., varied types of incision or surgical techniques.

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In any case, information will have to be provided in a face-to-face meeting by either the attending physician or by a knowledgeable third party with professional credentials, while documents are (merely) being referred supplementarily and which the patient needs to receive in print. This excludes simply handing over an information form – for instance, by Diomed™ or ProCompliance™ – with the verbal request to read it carefully and to sign it, even when the patient has been told that he/she is welcome to ask any questions he/she may have after reading the text.

It's, moreover, paramount that information is provided in due time so that the patient may base his informed consent on well-founded considerations. Early patient information – the more serious and hazardous the operation (diagnostic intervention) is expected to be – is the principle behind this stipulation. It's desirable to inform the patient prior to inpatient admission – and best even before an appointment for surgery has been made, leaving the patient enough time to get a second opinion if he/she so wishes. It goes without saying that patient information has to be tailored to the patient's capacity of understanding.

Lawmakers provided (§ 630 e section 3 BGB) that patient information/informed consent is exempted under particular exceptions, which would include unpostponable interventions and/or the patient's explicit refusal of information. The latter has to be approached with particular precaution: It will take scrutinized documentation and calling in of witnesses, who should sign that they had been informed thereof. This paper must be put into the patient's file and/or be added as a document in the electronic documentation.

The physician needs to furnish proof that he has informed the patient accordingly regarding the risks of intervention. He can do that by presenting his documentation supplemented by his own hearing if that documentation is sufficient. Of course, witnesses may come in in addition, when, for example, the hospital "alone" is being sued, and the informing physician is available as a witness. In nonhospital, office-based settings, nurse practitioners or doctor's receptionists may qualify to bear witness.

The development of standards is recommended in this respect since the hearing of evidence with regard to proper information often takes place years after the treatment at stake and witnesses' recollections are naturally vague; they are unable to remember patients who had come to the office 5 or even 12 years ago. In such cases, jurisdiction has clearly acknowledged that it will suffice if witnesses (can) describe a common procedure, moreover confirming that there had been no deviation from the standard.

Dispute arises over and again whether certain measures had been taken, examinations been carried out or been advised, or if the patient had been given behavioral instructions. Article (§) 630 f, section 2 BGB describes the attending physician's obligation to document in the patient file each and every medical approach and its results, which, by professional perspective, might be essential as to present and future therapy. This particularly applies to the patient's history, diagnoses, tests, examination results, findings, treatments and their effect, interventions and their outcome, informed consent, and previous information. Within this context, please mind § 630 a, section 3 BGB, which assumes that no measure had been taken if pertinent medically indicated treatment options and their results are not documented in the patient file – or if the patient file had been disposed of prior to the 10 years' safekeeping period (§ 630 f, section 3 BGB).

This assumption may, of course, be contradicted by testimonial proof; it would, however, seem quite unlikely that another physician working in that office or a nurse practitioner or other staff still has a precise recollection of what had been done a decade ago, an ultrasound examination, for instance, without a printout at hand or any other documentation in this regard.

The author is convinced that erroneous or negligent documentation really figures large in the processing of medical malpractice warrants of attorney. In fact, it often happens and not just rarely that experts will deny malpractice, whereas patients maintain that they had not been

duly informed of the risks of the intervention or not been alerted to alternative treatments, and at loss is the physician who fails to furnish satisfactory evidence for lack of a diligent documentation in terms of indisputable informed consent. If it is merely a question of therapeutic information or medical safety advisory (i.e., information on all circumstances which should be observed to ascertain a curative outcome, compliance to treatment, and the avoidance of possible self-endangerment), the onus of proof is cast upon patient; he/she has to produce evidence that the physician neglected his duties to the effect of injuriousness to the patient's health. Since medical safety advisory – in jurisdiction – may lead to petty, simple malpractice, the burden of proof rests with the patient.

In the event of so-called grave malpractice, however, the burden of proof is shifted to the physician; the assumption behind it is that injuriousness to health was caused by malpractice. The same holds true when the attending physician, by passive negligence or nonfeasance, failed to make or corroborate a medically indicated diagnosis early enough, inasmuch as this finding would have most probably been a result which, in turn, would have given reason for further action (now § 630 h, section 5, BGB).

The steadily rising number of reproaches heaped upon physicians for once reflects that patients are taking a more critical stand, which is basically not bad. The relative small number of physician condemnations in lawsuits for legal award on the other hand also speaks out for the eminent quality of medical services. It remains in the open though – or leaving something to argue about – whether the generation of the Patient Rights Act had truly been called for.

Explanation:
BGB = Bürgerliches Gesetzbuch: German Civil Code