

Focus "New Regulations on Corruption in the Healthcare Sector"

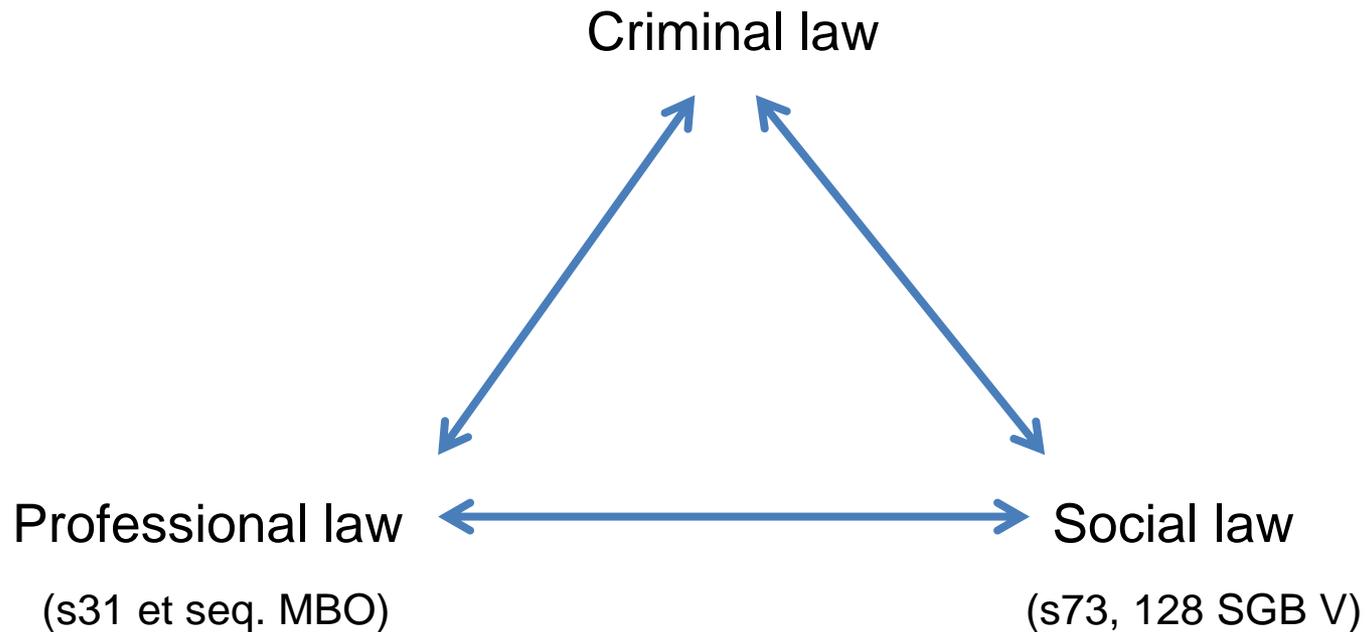
Professional Law Aspects

Matthias Wrana, LL.M.

Lawyer

Licensed Specialist for Medical Law

Berlin, 19 May 2016



Provisions of the Professional Law of Medical Practitioners

Purpose of Section 31 et seq. MBO

As a rule, prescriptions and recommendations by medical practitioners should be based solely on medical aspects.

Section 299a StGB vs Section 31 MBO

| Section 299a No 3 StGB | Section 31(1), 1st case MBO |
|--|--|
| <p>Whoever as a member of a health profession, (...) demands, allows himself to be promised or accepts a benefit for himself or a third party as consideration for according an unfair competitive preference to another in</p> <p>the referral of patients or the provision of examination material</p> <p>shall be liable to imprisonment not exceeding three years or a fine.</p> | <p>Medical practitioners are not allowed to demand, to have promised or granted to themselves or third parties or to promise or grant a fee or other benefits for the referral of patients (...).</p> |

| Section 299a No 1 StGB | Section 31(1) 2nd case MBO |
|---|--|
| <p>Whoever as a member of a health profession, (...) demands, allows themselves to be promised or accepts a benefit for themselves or a third party as consideration for according an unfair competitive preference to another</p> <p>in prescribing pharmaceuticals, aids and appliances or medical products</p> <p>shall be liable to imprisonment not exceeding three years or a fine.</p> | <p>Medical practitioners are not allowed to demand, to have promised granted to themselves or third parties or to promise or grant a fee or other benefits for the prescription or acquisition of pharmaceuticals, aids and appliances or medical products (...).</p> |

...not without valid reason...

Recommendations and referrals are normally not permitted. There must be "a valid reason" for a **permitted exception**.

- Request of the patient (BGH GesR 2011, 246)
- Medical considerations, such as ensuring a therapy success (OLG Schleswig NJW 1995, 3064)
- Quality of medical care
- Avoiding long distances for walking-impaired patients
- Negative experience with other suppliers

...not without a valid reason...

BUT...

Quality medical care requires that, from the view of the medical practitioner, a referral to a specific aid supplier offers **special advantages due to specific needs of the individual patient.**

Positive experience gained during long years of trustful cooperation or a general high technical competence of the supplier alone will not suffice.

Corresponding Medical Contract Law Provisions

Section 299a StGB vs Section 31 MBO vs Section 73 (7) SGB V

| Section 299a No 3 StGB | Section 31 (1), 1st case MBO | Section 73 (7) SGB V |
|---|--|---|
| <p>Whoever as a member of a health profession, (...) demands, allows himself to be promised or accepts a benefit for himself or a third party ... as consideration for according an unfair competitive preference to another in</p> <p>the referral of patients or examination material</p> <p>shall be liable to imprisonment not exceeding three years or a fine.</p> | <p>Medical practitioners are not allowed to demand, to have promised or granted to themselves or third parties or to promise or grant a fee or other benefits for the referral of patients (...).</p> | <p>Contracted medical practitioners are not allowed to demand, to have promised or granted or to promise or grant a fee or other financial benefits for the referral of insured individuals.</p> |

"Tried and Tested Models"

A total of eight medical practitioners and five pharmacists set up a pharmaceutical company to manufacture and market pharmaceuticals. All medical practitioners concerned are oncologists and prescribed the cytostatic medicines of the pharmaceutical company in which they held an interest.

The profits made by the company, which had increased as a result of the prescriptions, were skimmed off as part of their share in the profits of the company.

Higher Regional Professional Court for Healthcare Professionals at the Higher Administrative Court of North Rhine-Westphalia, decision of 6 July 2011

A benefit as referred to in s31, s34 MBO includes any paid-for material or immaterial benefits that objectively improve the recipient's financial, legal or personal circumstances. This may also include profits or other income from a shareholding in a company.

The prescribing doctor could be certain that their intensive prescribing may not reflected 1:1, but would definitely lead to an increase in the profits distributed to them. They would not gain anything from prescribing products of another company; only prescribing products of this very company led to any financial advantage.

The defendant, a university hospital, had sent a letter to all referring doctors in private practice within the region, informing them that the hospital could pay, under a quality assurance programme and after fulfilment of formal requirements described in detail, a pre- and post-surgery referral fee of EUR 52 to all recipients of this letter for each patient who was insured under the statutory health scheme and underwent cataract surgery in their eye clinic.

Higher Regional Court Koblenz, judgment of 20 May 2003

With the announcement of granting the referral fee, the defendant disregarded the patients' right to free choice of their doctor (section 7(2) 1st sentence MBO). The payment promise made to the practising doctor limits the doctor's decision-making scope as to which surgeon to suggest to their patient for further treatment in an impermissible manner and in contravention of the ban in s31 MBO.

- Doctors working with the statutory health organisations sign a cooperation agreement with a hospital carrier on "cross-sector care".
- The medical practitioner advises the patient, for whom they have set the indication for inpatient hospital treatment, to contact the hospital. The hospital then asks such medical practitioner to do the pre-ward work in respect of the specific patient.
- Following treatment in the hospital, the hospital then asks, where necessary, the medical practitioner to carry out the post-ward care work after discharge from the hospital.
- The hospital bills pre- and post-ward care to the statutory health insurance organisation. The medical practitioner in private practice then receives from the hospital the remuneration stipulated for these services in the German Fee Schedule for Medical Practitioners (GOÄ).

Higher Regional Court Dusseldorf, judgment of 1 September 2009

A doctor's recommendation of a specific hospital which is also based on the fact that the doctor will gain a benefit is incompatible with the principle that a decision must be based solely on medical aspects.

The chance of a lucrative business (here: billing of pre-/post-ward treatment at GOÄ rates) is enough to be deemed a benefit granted.

Consequences of Non-Compliance

- S31 MBO is a prohibitive provision!
- Agreements violating s31 MBO are null and void.
- Fees paid and benefits granted are reversed under the German law on unjust enrichment. Yet, a claim for return is excluded under s817 2nd sentence BGB!

- Under s4 No 1, s3 UWG, warnings may be issued against contracts violating s31 MBO.
- As a rule, kick-back payments are subject to VAT and trade tax. Booking them as income from medical activities may be treated as tax evasion (s370 German Fiscal Code, AO).
- Danger of withdrawal of the licence to practice medicine for the reason of unsuitability to practice medicine (s5(2) 1st sentence in conjunction with s3(1) 1st sentence of the German Federal Medical Practitioners Act, BÄO)

Speaker

Matthias Wrana, LL.M.



Associate | Lawyer | Licensed Specialist for Medical Law
BEITEN BURKHARDT | Kurfürstenstraße 72-74 | 10787 Berlin

Practice group Corporate / M&A
Telephone: +49 30 26471-245
Email: Matthias.Wrana@bblaw.com

Specialisations Pharmaceutical Industry, Medical Technology
Non-Profit Organisations
Corporate and Transformation Law, Law Governing Groups
Healthcare, Medical Law
Mergers & Acquisitions
Litigation & Arbitration

Languages German, English, French

WWW.BEITENBURKHARDT.COM

Beijing • Berlin • Brussels • Dusseldorf • Frankfurt am Main • Moscow • Munich • Nuremberg • Shanghai • St. Petersburg