

German Act on Fighting Corruption in the Healthcare Sector – Strengthening criminal anti-corruption law with regard to healthcare professionals

On 4 June 2016 the German Act on Fighting Corruption in the Healthcare Sector (Gesetz zur Bekämpfung der Korruption im Gesundheitswesen) ("Act") entered into effect under which the criminal offences of taking and giving bribes in the healthcare sector were incorporated into the German Criminal Code ("StGB") as sections 299a and 299b. The Act aims to close the legal loopholes identified by the German Federal Supreme Court (Bundesgerichtshof) in its decision dated 29 March 2012, whereby the German Federal Supreme Court declared that private practitioners could not be held criminally liable as perpetrators of the corruption offences in force at that time since they are neither public officials nor employees or agents of a business.

The new offences of taking and giving bribes in the Healthcare Sector

Due to the deletion of the so-called professional ethics model (Berufsrechtsmodell) as well as the deletion of the dispensing alternative (Abgabewarante) in the so-called competition model (Wettbewerbsmodell) and the inclusion of a modified procurement alternative (Bezugsvariante) resulting in the exclusion of pharmacists as potential offenders, the scope of application of the new offences is significantly narrower than originally intended in the government draft.

Pursuant to section 299b StGB, criminal liability is applicable to anyone who offers, promises or grants a benefit to someone in connection with the exercise of his/her profession, if he/she belongs to a medical profession that requires

government-regulated training in order to practice the profession or to carry the professional title for himself/herself or for a third person so that he/she prefers the grantor or another person in an unfair manner in the domestic or foreign competition in the context of:

1. prescribing pharmaceuticals, remedies, adjuvants or medical devices,
2. obtaining pharmaceuticals, adjuvants or medical devices, which are intended for direct application on the patient by the healthcare professional or his/her assistant, or
3. referral of patients or examination material

as a consideration for being offered, promised or granted the benefit.

Conversely, section 299a StGB governs criminal liability for taking bribes in the Healthcare Sector and provides the offence for actions of healthcare professionals. In general, the new statutory provisions set forth a range of penalties

starting with a fine up to imprisonment of a maximum of three years; whereas in more serious cases, the penalty will be imprisonment from three months up to five years.

Beneficiaries (of a bribe) can only be members of academic healthcare professions, such as physicians, as well as healthcare professionals whose education is regulated by law, such as state qualified nurses (Krankenpfleger) in each case regardless of whether the healthcare professional is self-employed or employed. However, it has to be noted that the benefit can be provided either to a healthcare professional for himself/herself or also for a third party (third-party-benefit).

The term benefit is construed in accordance with the definition of the term in case law regarding section 299 StGB (taking and giving bribes in business transactions). A benefit is a grant to which the recipient is not legally entitled and which improves his/her economic, legal or personal situation. Also, the unlawful agreement (Unrechtsvereinbarung) (benefit as consideration for an unfair preference in competition) is similar to the corresponding term inherent to section 299 StGB. In particular, benefits which are granted in order to achieve general goodwill are – unlike in the case of taking and giving (illegal) benefits by or to public officials (sections 331, 333 StGB) – not encompassed by section 299b StGB. The same applies to benefits granted in order to reward past preferences, contrary to sections 332 and 334 StGB (taking and giving bribes by or to public officials).

The term prescription (Verordnung) means the provision of pharmaceuticals, remedies, adjuvants or medical devices regardless of their prescription-only status. Obtaining (Bezug) means any form of procurement regardless if on one's own account or for the account of others. The term referral (Zuführung) is identical to the respective term in social law and the physicians' professional rules, and encompasses all impact on patients with the intention of influencing their choice of a physician or any other healthcare service provider, such as formal assignments but also mere recommendations.

The revised procurement alternative only encompasses pharmaceuticals, adjuvants or medical devices that are intended for direct application on the patient by the healthcare professional or their assistants, for example implants or pharmaceuticals administered by injections. However, it remains unclear whether medical devices such as an x-ray apparatus or a dentist's drill are covered by the new procurement alternative. These medical devices would be encompassed if their use was considered a direct application to the patient. The initial government draft of the pro-

urement alternative excluded such devices, since the alternative required that pharmaceuticals and medical products are intended to be handed over to the patient. Equipment for medical practices was not supposed to be covered under the provision in the government draft.

As it is the case for the provision of taking and giving bribes in business transactions (section 299 StGB), an employer's consent does not protect against criminal liability pursuant to sections 299a, b StGB. However, in the course of the free consideration of evidence (freie Beweiswürdigung) by the court, its existence can be considered as an indication for the lack of an unlawful agreement. Therefore, obtaining an employer's consent is still of great importance with regard to the new statutory provisions.

Investigations must be initiated ex officio as soon as an initial suspicion (Anfangsverdacht) has been identified. Unlike in the government draft, a request to investigate is no longer necessary. This modification, of course, does not prevent any individual from making the authorities aware of circumstances by reporting an offence or from expressing one's interest by filing requests to investigate.

The new provisions in a nutshell

- Giving bribes to self-employed healthcare professionals (as private practitioners) is punishable for the first time under a criminal anti-corruption provision
- Sections 299a, b StGB are applicable in cases of giving bribes to employed and self-employed healthcare professionals
- New offences have a similar structure as section 299 StGB
- Employer's consent does not preclude criminal liability but helps mitigating risks of investigations

Deviations from the initially planned provisions

Due to constitutional concerns, the new provisions in the German Criminal Code only include the competition model (benefit in return for an intended unfair preference in competition). The controversial professional ethics model (benefit in return for an intended breach of professional ethics, in particular an infringement of the healthcare pro-

professional's independence) has been deleted without substitution.

Furthermore, the dispensing alternative was removed and – as mentioned above – a modified procurement alternative was included in the competition model. According to the Committee on Legal Affairs of the German Bundestag, the dispensing alternative would have been of limited relevance since in practice, benefits would be granted for the prescription or procurement rather than for dispensing of pharmaceuticals, adjuvants and medical devices. Pursuant to the modified procurement alternative, the benefit for an unfair preference when obtaining pharmaceuticals, adjuvants or medical devices, which are intended for direct application by healthcare professionals or their assistants has to be offered, promised or granted (as "donor") or requested, allowed to be promised or accepted (as "receiver"). In contrast, the government draft merely referred to pharmaceuticals,

remedies, adjuvants or medical devices which are intended to be handed over to patients.

The deletion of the dispensing alternative and the inclusion of the modified procurement alternative effectively resulted in pharmacists not being recognised as receivers of a benefit by the new provisions. In any case, neither pharmacists nor their assistants apply obtained

Deviations from the government draft

- Deletion of the professional duty model
- Deletion of the dispensing alternative in the competition model
- Inclusion of a modified procurement alternative into the competition model
- Prosecution ex officio

products on patients but rather dispense products to patients. However, pharmacists – as every other person – are still subject to criminal liability under section 299b StGB (giving bribes in the Healthcare Sector) as "grantor" of the benefits.

Implications for Companies

The enactment of the new statutory provisions is likely to have a substantial impact on companies since giving bribes to self-employed healthcare professionals is for the first time punishable as a criminal corruption offence. Moreover, the (intended) preferential treatment in competition as consideration for a benefit is covered not only regarding obtaining products but also regarding the prescription thereof.

Risk of prosecution and conviction

There might be a higher risk of criminal investigations and convictions (compared to sections 331 et seqq. StGB and section 299 StGB) since, for example, certain possibilities of transparency, which could be seen as indicators against an unlawful agreement in the course of the free consideration of evidence, are not existent for self-employed healthcare professionals (which lack the ability to obtain an approval of the superior or the option to provide financial resources to the medical facility as contractual partner for the physician's participation in advanced training).

Risk mitigating measures

In order to minimize the risk of criminal investigations and convictions, we recommend in particular that companies implement the following risk mitigating measures:

- ensure that employees of companies in the pharmaceutical and medical device industry (i) do not induce physicians or other healthcare professionals to breach their professional duties and (ii) meet the requirements of the German Law on the Advertising in the Healthcare Sector (HWG) (especially those of section 7 HWG). A violation of professional ethics (if their purpose is to also regulate a fair market) and section 7 HWG could qualify as an unfair commercial practice under section 3a of the German Act Against Unfair Competition (UWG), which might be seen as an indication of an unfair preference in competition;
- comply with the regulations of the FSA-Code of Conduct for Healthcare Professionals (FSA-Kodex Fachkreise), the FSA-Transparency Code (FSA-Transparenzkodex), the BVMed-Code on Medical Devices (Kodex-Medizinprodukte des BVMed) as well as other relevant industrial codes and the separation principle stipulated therein, in order to avoid any appearance of an unlawful agreement from the outset. In particular, the enactment of the FSA-Code of Conduct for Healthcare Professionals more than ten years ago was based on the idea of creating coherent compliance guidelines for private practitioners and clinic-employed physicians;
- replace missing transparency measures for self-employed healthcare professionals due to missing employers (as the approval of the superior) with other transparency measures (e.g. diligent documentation or measures under the FSA-Transparency Code);
- existing agreements which have been concluded before the enactment of the new provisions and which

are still valid in order to reassess their conformity with the new provisions;

- adapt all relevant internal guidelines to the new provisions, for example, due to the inclusion of criteria for the determination of fair market value or

selection criteria for participants invited to conferences or congresses; and

- provide all relevant employees with appropriate training.

Contact



Dr. Peter Dieners

Partner, Düsseldorf

E: peter.dieners@cliffordchance.com



Dr. Ulrich Reese

Partner, Düsseldorf

E: ulrich.reese@cliffordchance.com



Ann-Kristin Cahnbley, LL.M. (Wellington)

Senior Associate, Düsseldorf

E: ann-kristin.cahnbley@cliffordchance.com



Jan Szemjonneck

Associate, Düsseldorf

E: jan.szemjonneck@cliffordchance.com

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www.cliffordchance.com

Clifford Chance, Königsallee 59, 40215 Düsseldorf, Germany

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