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Date of this translation: 15 September 2015

Draft Law to Combat Corruption in Health Care

A. Problem and Objective

Corruption in health care interferes with competition, increases the costs of medical care and undermines patients' confidence in the integrity of decisions made by health care professionals. Because of the significant social and economic impact of health care, it is also necessary to move against corrupt practices in this area by means of criminal law. The legal framework in place at this time does not adequately allow for this.

According to a decision handed down by the Grand Senate of the German Federal Supreme Court of Justice, practicing physicians providing medical care through the statutory health insurance system act neither as public officials (as per § 11 subsection 1 number 2 c of the German Criminal Code - StGB) nor as official agents of the statutory health insurance companies (§ 299 StGB), so that the corruption offences set forth in the German Criminal Code do not apply to physicians practicing under the statutory health insurance system (court decision dated 19 March 2012 – GSSt 2/11). Furthermore, the offences relating to embezzlement (§ 266 StGB) and fraud (§ 263 StGB), which are concerned with asset protection, can only partially reflect the giving and receiving of bribes and do not adequately cover the unlawful substance of corruption.

As a result, there are gaps in the criminal code where fighting corruption is concerned, which this draft legislation seeks to address.

B. Solution

This draft law proposes introducing the criminal offences of corruptibility in health care and bribery in health care. All health care professions whose training or licensure is regulated by the state are included within the scope of this proposal, which encompasses circumstances both within and outside the statutory health insurance system. The proposed criminal offences are to be added to subpart 26 of the German Criminal code (offences against competition) as a new § 299a StGB (corruptibility in health care) and a new § 299b StGB (bribery in health care) to reflect the structure of § 299 StGB (corruptibility and bribery in the commercial practice). Furthermore, this proposal provides for an extension of the rule in § 300 StGB, which in turn allows a higher penalty in cases with aggravating circumstances, to the newly proposed offences. The proposal also includes a relative duty to petition as a prerequisite for the prosecution of these offences (§ 301 StGB). The previous regulation on confiscatory expropriation and on extended confiscation in § 302 StGB

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are to be adapted to prevailing legal norms by striking the reference to confiscatory expropriation by extending its scope to the new rules set forth in §§ 299a, 299b StGB. The draft legislation also contains proposed changes to the Book V of the German Social Code, which serve to establish a regular exchange of information between the agencies involved in fighting misconduct in health care in consultation with public prosecutors.

C. [Not translated. Content considered irrelevant for comment.]

D. [Not translated. Content considered irrelevant for comment.]

E. [Not translated. Content considered irrelevant for comment.]

F. [Not translated. Content considered irrelevant for comment.]

Legislative Proposal of the German Federal Government

**Draft Law to Combat Corruption in Health Care
Dated**

The Bundestag has passed the following law:

Article 1

Amendment of the Criminal Code

The Criminal Code in the version published on 13 November 1998 (Federal Gazette [BGBl.] I p. 3322), most recently amended by ..., is amended as follows:

1. The table of contents is amended as follows:
 - a) The following statements are inserted after § 299:

“§ 299a Corruptibility in health care
§ 299b Bribery in health care”.
 - b) The words “and in health care” are added to the statement in § 300.
2. The §§ 300 to 302 are replaced by the following §§ 299a to 302:

“§ 299a

Corruptibility in health care

(1) Any member of a health care profession requiring state-regulated training in order to practice or to hold a professional title who, in connection with the practice of their profession, demands, accepts the promise of or directly accepts a benefit for themselves or a third person as compensation in return for the prescription or dispensing of medicinal products or other health care services and products or of medical devices or for the referral of patients or test materials in such a way as to

1. give unfair preference to another in domestic or foreign competition or to
2. violate their obligation to maintain professional independence

shall be punished by up to three years' imprisonment or a fine.

(2) Similar punishment will be imposed on any member of a health care profession in terms of subsection 1 who demands, accepts the promise of or directly accepts a benefit as compensation for violating their obligation to maintain professional independence in procuring medicinal products or other health care services and products or medical devices intended to be dispensed to patients.

§ 299b

Bribery in health care

(1) Whoever offers, promises or grants a member of a health profession in terms of § 299a subsection 1 or a third person a benefit as compensation for their prescription or dispensing of medicinal products, other health care services and products or medical devices or for the referral of patients or test materials in such a way that the health care professional

1. gives unfair preference to another in domestic or foreign competition or
2. violates their obligation to maintain professional independence

shall be punished by up to three years' imprisonment or a fine.

(2) Similar punishment will be imposed on anyone who, in connection with a health professional's practice of their profession, offers, promises or grants a member of a health profession in terms of subsection 1 or a third person a benefit as compensation for said health professional violating their obligation to maintain professional independence in procuring medicinal products or other health care services and products or medical devices intended to be dispensed to patients.

§ 300

Particularly serious cases of corruptibility and bribery in commercial practice and in health care

In particularly serious cases, the offences in § 299, 299a or § 299b shall be punishable by imprisonment of three months to up to five years. A case is usually considered particularly serious when

1. the offence is connected with a benefit of large dimensions or
2. the perpetrator acts on a commercial basis or as a member of a gang formed for the recurrent commission of such offences.

§ 301

Charges

(1) Corruptibility and bribery in commercial practices as per § 299, as well as corruptibility in health care and bribery in health care as per §§ 299a, 299b will only be prosecuted if formal charges are brought, unless the prosecuting agency deems intervention *ex officio* necessary because of particular public interest in the prosecution of the offence.

(2) Aside from the injured party, the charge in terms of subsection 1 may be brought forward by,

1. in cases referring to § 299 subsection 1 number 1 and subsection 2 number 1, business persons, associations and chambers described in § 8 subsection 3 numbers 2 and 4 of the Law against unfair competition, and
2. in cases referring to §§ 299a, 299b
 - a) the professional chamber and the association of statutory health insurance physicians or dentists of which the perpetrator was a member at the time the offence was committed,
 - b) any professional association with legal capacity representing the interests of the injured parties in matters of competition, and
 - c) the statutory health insurance companies of the patient or the private health insurance company of the patient.

§ 302

Extended confiscation

In the cases referring to §§ 299, 299a and 299b, § 73d is applicable if the perpetrator acts on a commercial basis or as a member of a gang formed for the recurrent commission of such offences.”

Article 2

Amendment of the Judicature Act

In § 74c subsection 1 sentence 1 number 5a of the Judicature Act as published by ordinance on 9 May 1975 (Federal Gazette [BGBl.] I p. 1077), most recently amended by ..., the words “as well as” are replaced by a comma, while the words “as well as corruptibility in health care and bribery in health care” are inserted after the words “commercial practice”.

Article 3

Amendment of Book V of the Civil Code

Book V of the Civil Code – statutory health insurance – (Article 1 of the law published 20 December 1988, Federal Gazette [BGBl.] I p. 2477, 2482), most recently amended by ... is further amended as follows:

1. § 81a is amended as follows:

a) The following sentences are added to subsection 3:

“Within their respective area of influence, the National Associations of Statutory Health Insurance Physicians coordinate a regular exchange of information with institutions referred to in subsection 1 sentence 1, in appropriate consultation with the representatives of the institutions referred to in § 197a subsection 1 sentence 1, the professional chambers and the public prosecutors. The regulatory authorities are to be informed of the results of this exchange of information.”

b) Subsection 5 sentence 2 is replaced by the following sentences:

“The reports shall also contain the number of members of Associations of Statutory Health Insurance Physicians for whom there was suspicion of a violation of duty, the number of proven violations, the nature and severity of the violation of duty and the measures taken against these, including the measures per § 81 subsection 5, as well as the prevented or incurred damages. Recurrent cases and other suitable cases are to be presented as anonymized sample cases. These reports are to be forwarded to the competent regulatory authority. The reports of the Associations of Statutory Health Insurance Physicians are also to be forwarded to the National Associations of Statutory Health Insurance Physicians.”

c) The following subsection 6 is added:

“(6) By no later than ..., the National Associations of Statutory Health Insurance Physicians shall issue more detailed rules concerning

1. the harmonized organization of the institutions referred to in subsection 1 sentence 1 among their membership,
2. the exercise of the controls described in subsection 1 sentence 2,
3. the process for following-up on reports of suspected misconduct per subsection 2

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4. the cooperation per subsection 3,
5. the briefings described in subsection 4 and
6. the reports described in subsection 5.

The rules set down per sentence 1 are to be submitted to the Federal Ministry of Health. The Associations of Statutory Health Insurance Physicians shall collate the reports submitted by their members as per subsection 5 and, after reconciling them with the results of the Central Federal Association of Health Insurance Funds, shall publish their own reports on the internet.”

2. § 197a is amended as follows:

a) The following sentences are added to subsection 3:

“The Central Federal Association of Health Insurance Funds coordinates a regular exchange of information with institutions referred to in subsection 1 sentence 1, in appropriate consultation with the representatives of the institutions referred to in § 197a subsection 1 sentence 1, the professional chambers and the public prosecutors. The regulatory authorities are to be informed of the results of this exchange of information.”

b) Subsection 5 is amended as follows:

aa) the words “and the Central Federal Association of Health Insurance Funds” are inserted in sentence 2 after the word “regulatory authority”.

bb) the following sentence is added:

“The report shall also summarize the number of health care providers and insured persons for whom violation of duty or abuse of benefits was suspected, the number of proven cases of such, the nature and severity of the violations and the measures taken against these as well as the prevented or incurred damages. Recurrent cases and other suitable cases are to be presented as anonymized sample cases.”

c) The following subsection 6 is added:

“(6) By no later than, the Central Federal Association of Health Insurance Funds shall issue more detailed rules concerning

1. the harmonized organization of the institutions referred to in subsection 1 sentence 1 among their membership,
2. the exercise of the controls described in subsection 1 sentence 2,

3. the process for following-up on reports of suspected misconduct per subsection 2
4. the cooperation per subsection 3,
5. the briefings described in subsection 4 and
6. the reports described in subsection 5.

The rules set down per sentence 1 are to be submitted to the Federal Ministry of Health. The Central Federal Association of Health Insurance Fund shall collate the reports submitted by their members as per subsection 5 and, after reconciling them with the results of the National Associations of Statutory Health Insurance Physicians, shall publish its own report on the internet.”

3. The phrase “subsection 1” is inserted after the integer “202” in § 307 subsection 2 number 1 c.

Article 4

Entry into force

This law shall enter into force on the day after its promulgation.

Rationale / Justification *[Translation note: the following section was translated to present the most important content as a summary.]*

A. General

I. Objective and need for the new rules

Corruption in the health care negatively affects competition, causes significant cost increases and undermines the confidence of patients in a health care system free of the influence of unethical benefits. Because of the substantial economic and social importance of health care it is necessary to also counter corruptive practices in this area by means of criminal law. In doing so, the particular responsibility of health professionals in the health care system needs to be considered, while at the same time ensuring that health care decisions are made independently without undue external influences.

Cases of such corruptive practices have repeatedly been the subject of legal decisions in various courts, including cases involving the payment of bonuses by pharmaceutical companies to physicians in order to influence the physicians' prescription behavior in favor of a particular medicinal product. It was in such a case that the Grand Senate of the German Federal Supreme Court of Justice decided that the anti-corruption regulations in their current form did not apply to statutory health insurance physicians (BGH decision dated 29 March 2012, docket GSSt 2/11). Other cases have been brought to light in which a clinic, a health care supply store or a laboratory made payments in return for referrals of patient or test materials. Similarly, there have been cases where the procurement and dispensing decisions of pharmacists were influenced by circumventing the pricing regulations in order to achieve dishonest competitive advantages.

Such corrupt behavior of individuals can lead to an entire profession becoming suspect and result in patient confidence in the health care system being eroded.

The risk for corruption in health care stems most particularly from the enormous decision-making power concentrated in the hands of certain health professions, which can in turn have substantive effects on other market participants. This can incentivize attempts to exert undue influence on medical or pharmaceutical decisions taken by these professions. The key role of physicians and pharmacists in the health care system is based on the requirements for dispensing prescription-only and pharmacy-only medications, but also on the right to prescribe medicines. The pharmaceutical industry in particular is dependent on the prescription and dispensing behavior of these professions, but other health care professions and manufacturers of medical devices are also dependent on physicians' willingness to prescribe their services and products.

Therefore, physicians have a steering function of significant economic impact.

Current criminal law does not adequately address all forms of corruption in health care because the corruption offences currently described in §§ 331 ff. of the German

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Criminal Code only apply when the receiving party is a public official. According to the ruling of the Grand Senate of the Federal Supreme Court of Justice of 29 May 2012, practicing physicians working in out patient care in the statutory health insurance system are not public officials. Instead, the relationship of the insured patient with the physician is based primarily on trust and is free of intervention by the statutory health insurance. Even when a physician works in a public hospital in an official capacity, bribes paid to such a physician to influence his or her therapeutic decisions would still go unpunished because therapeutic decisions do not fall within the scope of public administration and therefore are not per se part of the physician's public function (see §§ 331 ff German Criminal Code).

According to the court ruling cited above, a statutory health insurance physician does not function as an agent of the statutory health insurance companies, so the offences of corruptibility and bribery apply neither to said practicing physicians nor to pharmacists or other similarly self-employed members of health care professions. When a physician employed by a hospital accepts benefits in return for preferring certain goods or services in procuring them for the hospital, an offence per § 299 StGB may be applicable; however, when the goods and services are procured by the patient, then § 299 StGB does not apply as this does not constitute commercial procurement.

The offences relating to embezzlement (§ 266 StGB) and fraud (§ 263 StGB), which are concerned with asset protection, are not always applicable. For example, the prescription of medicinal products or other health care services and products whose prices are inflated to allow for kickback payments to the physician can be punishable as an instance of fraud and breach of trust. However, other cases, such as those involving referral bonuses are not covered by these laws and do not constitute a violation of fiduciary duties with respect to the statutory health insurance system. Regardless, the current Criminal Codes does not adequately reflect the substance of corruptive offences that undermine competition and trust in the integrity of the health care system.

Corruption in health care disrupts fair competition and penalizes honest market participants. It can also lead to lower quality health care because competitive advantages are not gained fairly through pricing and quality, but through dishonest incentives. Aside from the economic consequences of corruption in health care, with increased costs for medical services and increases in overall health care costs, another equally serious impact is the loss of trust in the integrity of decisions made in medical practice. Individual cases of corruption can tarnish the reputation of an entire group of health care providers and lead to patients not making use of medical services when they feel these are not driven by medical need but by dishonest incentives.

In its decision of 29 March 2012, the Grand Senate of the Federal Supreme Court of Justice conceded that the wish to combat corruption in health care, which otherwise leads to higher health care costs, is legitimate.

The new offences to be introduced into the Criminal Code serve to protect both fair competition in health care and the general reputation of the vast majority of honest physicians, pharmacists and other health care practitioners. They also are intended

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to protect patients' trust in the integrity of the medical decisions made in their care. In the mid-term, the introduction of these offences into the Criminal Code will also protect the financial interests of stakeholders in the health care market as well as those of patients and the statutory health insurance system.

The need for introducing these more adequate means of fighting corruption in health care are not affected by the already existing anti-corruption rules found in professional and social codes. The physicians' chambers have adopted anti-corruption rules against corrupt practices and bribery in their respective professional codes, which are overseen and enforced by the state physicians chambers. Similar rules are also found in the professional codes of conduct for dentists and pharmacists. In the § 73 subsection 7 Social Code (Book V), it is forbidden to accept payment (or the promise of such a payment) in exchange for referrals of patients, while § 128 SGB V regulates other illicit forms of cooperation between statutory health insurance physicians and medical service providers concerning the provision of medical supplies. With his licensure, a statutory health insurance physician has the right and the duty to participate in patient care subject to the statutory health insurance system, and in doing so, is obligated to follow the abovementioned rules.

Despite various initiatives to self-regulate corruptive behavior among their constituents, the codes of social law and professional law do not adequately reflect the degradation of norms that corruptive behavior in health care represents. The sanctions set down in social and professional codes are milder than criminal penalties and therefore cannot adequately reflect and compensate for the socially and ethically reprehensible nature of such acts. This is particularly true for infringements upon the abovementioned professional codes of conduct.

Furthermore, sanctions based on professional law are only valid for the members of a particular profession, so that professional associations are not able to sanction corruptive behavior originating outside the profession.

Social codes, on the other hand, only apply to activities that fall within the scope of the statutory health insurance system, so consistent prosecution of corruptive behavior is not always possible, especially since the protection of fair competition and the public's trust in the integrity of medical decisions should be dependent on the patient's membership in the statutory health insurance system.

Finally, professional and social codes lack the necessary intervention powers to enforce the rules they set down. As many cases of corruption involve a certain degree of concealment, investigation of such cases requires more than just hearings and expert opinions. The statutory health insurance funds lack the investigative powers to pursue many of the less obvious cases of corruption.

[Sections A.II – A. VII are not translated. They contain information on administrative impact, the costs of the proposal for the proposal and brief statements concerning aspects such as sustainability, competencies, conformity with European Law and international agreements]

B. Specific Part

On Article 1 (Amendment of the Criminal Code)

On Number 1 (Table of contents)

This amendment is an editorial change that follows directly from the insertion of § 299a and § 299b StGB and from the changes made to §§ 300, 301 and 302 StGB.

On Number 2 (Insertion of §§ 299a and 299b and amendments of §§ 300 to 302 StGB)

On § 299a StGB (Corruptibility in health care)

This provision introduces the offence of corruptibility in health care. This offence includes all professional health care groups requiring state-regulated training in order to practice or to hold a professional title and extends in scope to both issues within and outside of the statutory health insurance system. The draft proposal follows the draft proposal of the Bundesrat for a ... Law Amending the Criminal Code to Fight Corruption in Health Care from the 17th legislative period (Bundestagdrucksache 17/14575).

The offence to be introduced responds to the higher risk for corruption in health care and to the particular vulnerability of fair competition in health care and trust in the integrity of medical decision-making. The anti-corruption laws can only partially capture corruptive practices in health care that are worthy of punishment. This proposal is intended to close these regulatory gaps.

The new offence is to be placed in the subpart 26 of the Specific Part of the Criminal Code (Offences against competition). The offences contained in this subpart primarily aim to protect the mechanisms of discipline structuring fair competitive practices. This is the particular intent of the offences described in subsection 1 number 1, which render benefits received as compensation for unfair preference or advantages in domestic or foreign competition punishable under criminal law. The placement of the new offence in this section is also appropriate because the proposed offence reflects the substance of § 299 StGB. That the new rule also aims to protect other interests in protecting patients' trust in the integrity of medical decisions does not stand in the way of its placement in the subpart dealing with offences against competition. On the other hand, its placement in subpart 30 of the Criminal Code (offences in public office) is not appropriate, as the members of the professions the new rule is aimed at are usually not holders of public office.

If a benefit accepted in compensation for a breach of duty also fulfills the criteria for other offences, such as embezzlement, fraud or personal injury, the principles developed for §§ 299, 331 ff. StGB may be applied to evaluate the competing

interested between the new offence according to § 299a StGB and the other offences committed.

Where the relationship between the corruption offences in §§ 331 ff. StGB and the new offence described in § 299a StGB is concerned, the principles laid down in the case-law relating to § 299 StGB and §§ 331 ff. StGB may be applied (see decision of the Federal Supreme Court of Justice dated 10 February 1994, 1 StR 792/93). Because of the partly diverging protective functions of § 299 StGB and § 299a StGB, if a perpetrator fulfills the criteria for offences under both these subsections, the offences should usually be considered one and the same act.

On Subsection 1

The offence of corruptibility in health care is intended to ensure that medical prescription, dispensing and referral behavior is free of illicit influence. Therefore, the offence of corruptibility in health care in § 299a applies not only to physicians, but to all health care practitioners whose training or licensure is regulated by the state. The definition of the scope of potential perpetrators follows the rule set down in § 203 subsection 1 number 1 StGB (Violation of personal privacy). The usual addressees are academic health care professions, which may only be practiced after completion of training regulated by law and a licensure regulation (physicians, dentists, veterinarians, psychotherapists, child and youth psychotherapists and pharmacists), or those health care practitioners (such as nurses, occupational therapists, speech therapists and physiotherapists), whose training is also regulated by law.

However, the group of potential perpetrators is not limited to academic health professions. While non-academic health professions are not as directly involved in the allocation of costs in the health care sector as physicians and pharmacists, and while they do not have the same economic impact on other service providers within the health care system, so that the general risk of undue influence on their decisions is likely smaller, this should not lead to the conclusion that corruptive influence on these other health care practitioners and their behavior in patient care is less criminal. On the contrary, the decisions made and the services provided by these non-academic health professions are equally important and necessary to the individual patient and overall health care. These health care professions are also susceptible to corruptive, anti-competitive arrangements concerning the referral of patients to other health service providers, with the result that honest health care providers suffer competitive disadvantages, while patients cannot trust that the decisions made are based solely on medical considerations and the welfare of the patient. Therefore, the means of prosecuting under criminal law must extend also to such health care services, ensuring that they are provided in conformity with the principles of fair competition and are free of undue influence. This is all the more relevant because there is an increasing trend of transferring activities formerly restricted to physicians to other health professions, particularly within the statutory health insurance system (see § 63 subsection 3c SGB V). To not include these other health professions in the group of potential perpetrators would therefore lead to gaps in legal protection.

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The offence of corruptibility in subsection 1 comprises the demanding of, accepting the promise of and the acceptance of benefits and correlates with the variants of this offence in § 299 subsection 1 StGB. It is legitimate to consult the corresponding case-law and jurisprudence. The aspects of accepting the promise of or the outright acceptance of benefits requires the agreement of both the giver and the receiver, while the aspect of demanding such benefits only requires an intended agreement from one party (Fischer, StGB, 62th Edition, § 299 recital 17). The criteria for this offence are fulfilled even when the demand is not successful.

The “benefits” associated with this offence include all benefits, regardless of whether or not they are material or immaterial or who stands to profit from them, the perpetrator or a third person. The principles applicable to § 299 StGB and §§ 331 ff. StGB may be applied in interpreting the concept of “benefit” in this context. The term “benefit” includes any grant or service to which the receiver has no rightful claim and which objectively improves the receiver’s economic, legal or personal situation (Federal Supreme Court of Justice, decision dated 11 April 2001, 3 StR 503/00).

This characteristic of the offence correlates broadly with the concept of “benefit” in §§ 31, 32 MBO (model professional code of conduct), which also includes any grant or service of the giver to which the receiver has no claim based on a reciprocal grant or service rendered, and which materially or immaterially objectively improves the receiver’s economic position (Scholz, in Spickhoff, Medizinrecht, 2nd Edition, § 31 MBO, recital 5, § 32 MBO recital 2). The offence described in the new § 299a StGB expands the scope of the concept of “benefit” only in that it also includes immaterial benefits, such as honors and honorary positions (see Fischer, StGB, 62nd Edition, § 331 recital 11 e). The definitions are identical with respect to material benefits.

No lower limit is defined for the value of such benefits, either in § 299 StGB or in §§ 331 ff. StGB. However, when there is no objective agreement to influence medical decisions in place, such as in the case of insignificant and generally acceptable promotional gifts or small gifts from patients, a socially acceptable grant may be assumed, as it would be for § 299 StGB, which does not fulfill the criteria for the offence in question (see Krick, in Münchner Kommentar, 2nd Edition, § 299 StGB, recital 29). Benefits, however, which give rise to the impression that the independence of the medical decision maker is being influenced and which are therefore forbidden in professional codes are not considered acceptable. Gifts from patients expressing thanks for successful treatment are retrospective benefits and therefore are not within the scope of the offence of concern.

Benefits may also include – as also stipulated in § 31 MBO – invitations to conferences, assumption of costs for continuing education (for example, see Federal Supreme Court of Justice decision dated 23 October 2002, 1 StR 541/01) or a participation in profits or assets (Scholz, in Spickhoff, Medizinrecht, 2nd Edition, § 31 MBO recital 6). A benefit may also consist of the conclusion of a contractual agreement that results in payments or services rendered to the perpetrator, even if these represent appropriate compensation for the service the perpetrator himself is contractually required to provide (see Federal Supreme Court of Justice decision dated 10 March 1983, 4 StR 375/82). This means that making available opportunities for financial gain, such as the participation in a observational study with

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compensation or in entering into a therapeutic contract, are within the scope of the concept of “benefit” in terms of the offence of concern.

The sole acceptance of a benefit, however, is not sufficient to establish the offence. The perpetrator must accept the benefit, or the promise thereof, as compensation for an at least intended, dishonest preference in competition or for an at least intended violation of his or her professional duty to maintain professional independence. This combination of benefit and reciprocal service, the illegal agreement, is the prerequisite for establishing the offence and is intrinsic to all corruption offences of the Criminal Code in justifying their specific criminal nature.

The aforementioned illegal agreement as per § 299a StGB must fulfill particular requirements. Benefits given with the intent of securing the general approbation of the receiver or to reward the receiver for an action already taken is insufficient to establish an offence. The liberalization of the illegal agreement applied to offences of accepting advantages and granting advantages for persons in public office (§§ 331, 333 StGB) is not applicable to the new offence. Instead, the principles developed in connection with illegal agreements in the context of venality and bribes in business practice (§ 299 StGB) should be applied (see Krick, in Münchener Kommentar, 2nd Edition, § 299 StGB recital 24 f.; Rönnau, in Achenbach/ Ransiek, Handbuch Wirtschaftsstrafrecht, 4th Edition, p. 307 f.).

The granting of benefits that are justified solely by the treatment of patients or by other health care services do not fulfill the requirements for the new offence. However, making available an opportunity for financial gain, for example by referring a patient as compensation for the previously agreed referral of a patient by the beneficiary, is a different situation. Such a situation is a violation of the professional interdict against referrals in return for financial gain, which may not be circumvented by professional collaborations (§ 18 MBO).

As far as opportunities for financial gain result from professional cooperation, it must be considered that such current health policy sees professional cooperation as generally desirable and as being in the interest of the patient (see Halbe, *Moderne Versorgungsstrukturen: Kooperation oder Korruption?*, MedR 2015, 168). This includes cooperation agreements on pre-hospitalization and post-hospitalization treatment (§ 115a SGB V), on outpatient treatment (§ 115b SGB V) and on outpatient specialist care (§ 116b SGB V), as well as the form of health care regulated in §§ 140a SGB V ff. (integrated care), which involves the cooperation of various health care providers from various fields (e.g. practicing physician and a hospital) in the care of patients. The payment of acceptable fees for the health care services provided in this context and the resulting opportunities for financial gain are legal. For example, this would apply to the acceptable fee charged for an outpatient operation performed in a hospital by a physician normally practicing within the statutory health insurance system (as per § 115b subsection 1 sentence 4 SGB V) after that physician had previously referred said patient to the hospital for admission (on the conformity of this practice with the indict in social law concerning referral bonuses, see Nebendahl, in Spickhoff, *Medizinrecht*, 2nd Edition 2014, § 73 SGB V, recital 20). Without other conditions being met, the simple remuneration of health care services in the context of professional cooperation cannot serve as grounds for the suspicion that the opportunity for financial gain was facilitated in compensation for the referral

of the patient and therefore constitutes an illegal agreement. However, if the fees paid were not fixed in an objective manner at an economically appropriate value that corresponds to the value of the health care services rendered and includes a hidden “referral bonus”, the situation is different (see Nebendahl, in Spickhoff, *Medizinrecht*, 2. Edition 2014, § 73 SGB V, recital 20).

Similarly, without other conditions being met, the mere existence of reciprocal referrals cannot be assumed to be based on a collusive compensatory relationship between the referrals and therefore on an illegal agreement.

Mere participation in an observational (non-interventional) study with compensation also does not fulfill the criteria for the offence in § 299a StGB. Observational (non-interventional) studies are intended to collect information on the use of authorized medicinal products (§ 67 subsection 6 German Medicinal Products Act; Wigge/Wille in Schnapp/Wigge, *Handbuch des Vertragsarztrechts*, 2nd Edition, § 19 recital 72). From the perspective of health and research policies, such studies are desirable, insofar as they do not serve the sole purpose of marketing and their results are made available to the public. Physicians are allowed to accept compensation for the additional effort they incur in participating in such studies. Such compensation must be of such a scale and nature so as not to provide an incentive for prescribing or recommending a particular medicinal product (§ 67 subsection 6 sentence 3 German Medicinal Products Act). Naturally, there is not impunity if the particular observational (non-interventional) study is part of an illegal agreement and the compensation granted is not intended to compensate the physician for additional effort, but serves as a bribe for the preferred prescription of certain medicinal products, giving undue preference to the payer. When the compensation paid does not appear to be related to a particular medical service rendered or when the compensation appears to be disproportionately higher than the service rendered, this can be suggestive of a punishable illegal agreement. In the past, precisely such contractual agreements concerning participation in observations (non-interventional) studies have been shown to be opportunities for exerting undue influence over the prescription practices of physicians.

Participation in a commercial enterprise in health care may also lead to benefits as described in § 299a StGB. When a physician refers a patient to a company in which said physician has an interest and the physician then receives economic benefits (e.g. shares, profit participation) in payment for the referral, this may constitute a illegal and punishable combination of participation in a commercial enterprise and medical decision-making (see Scholz, in Spickhoff, *Medizinrecht*, 2nd Edition 2014, § 31 MBO, recital 6). Such arrangements unfairly disadvantage companies that do not offer such forms of profit participation. Also, in such circumstances, patients cannot be sure that the medical advice they receive was offered solely on medical considerations. The principles set down by the Federal Supreme Court of Justice in its jurisprudence on fair competition (see court’s decision dated 13 January 2011, I ZR 111/08) can also be applied to § 299a StGB. Any contract in which the physician’s participation in profits or any other benefit is directly dependent on the number of referrals or the turnover generated by such referrals is therefore inherently illegal. When the physician is only indirectly involved in a commercial enterprise, especially a general profit participation scheme, then the legality of the physician’s

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commercial interest depends on whether or not the physician is able to objectively influence the profits of his interest in the company through patient referrals.

These same considerations are applicable where the referral of biological (patient) samples and test materials to laboratories for the purposes of testing is concerned. Physicians and dentists are required by professional codes of conduct choose the laboratory for the testing of materials based solely on medical considerations in the interest of the patient (Federal Supreme Court of Justice, decision dated 21 April 2005, I ZR 201/02 and decision dated 23 February 2012, I ZR 231/10). This principle is also not contradicted by the model professional code (MBO) of the Federal Chamber of Dentists, where § 11 MBO explicitly allows dentists to have their own laboratory or to participate in group laboratories (Federal Supreme Court of Justice, decision dated 23 February 2012, I ZR 231/10). To grant or give the promise of benefits to a physician or dentist in order to incentivize the health care professional in question to violate their duty to protect these interests. Agreements that grant benefits (e.g. as participation in profits) as compensation for a physician's or dentist's commitment to referring patients or test materials to a particular laboratory are therefore illegal and henceforth also punishable.

When physicians run their own laboratories and provide laboratory services, this is a different situation. In such cases, it must be clarified, on a case-by-case basis, if there truly is a referral of patients or test materials taking place. In any case, offering laboratory services at particularly competitive prices can only lead to dishonest preferential referrals when the offer of these service is legally and factually linked to another referral decision (Federal Supreme Court of Justice, decision dated 21 April 2005, I ZR 201/02).

Bonus payments on the basis of social law (see e.g. § 84 subsection 4 SGB V) also constitute benefits. However, agreements that are intended to incentivize economical prescription behavior in conformity with legal requirements in such a way as to encourage the physician to prescribe the cheapest medicinal product among the group of product suitable for a particular patient (see Federal Chamber of Physicians, *Wahrung der ärztlichen Unabhängigkeit – Umgang mit der Ökonomisierung des Gesundheitswesens – Hinweise und Erläuterungen*, Deutsches Ärzteblatt 2007, p. 1607, 1608) serve both the interests of fair competition and the interests of patients and the statutory health insurance system, and such agreements do not fulfill the criteria for an offence. These agreements are legal according to professional law, when the physician retains the right to take a decision, for medical reasons, that goes against the choice incentivized by the agreement (§ 32 subsection 1 sentence 2 MBO). Such agreements are not instituted to provide a competitive advantage to any party or to violate the duty to maintain professional independence, but to encourage economical prescription behavior and an efficient allocation of resources (Scholz, in Spickhoff, *Medizinrecht*, 2nd Edition, § 32 MBO, recital 7; on the conformity of this practice with the indict in social law concerning referral bonuses see Bundestagsdrucksache 17/6906, p. 56). In such cases, the required substantial link between the benefit and the prescription decision is missing.

Benefits conferred for preferential treatment in the past do not fulfill the criteria of the offence unless the benefit conferred is subject to an illegal agreement and the

perpetrator had allowed the promise of the benefit to be given in advance (see Fischer, StGB, 62nd Edition, § 299 recital 13).

The preferential treatment must be associated with the dispensing or prescription of medicinal products, other health care services and products or medical devices or in the referral of patients or test materials. The terminology derives largely from the professional codes of conduct of the affected professions (see e.g. § 31 MBO), as well as the Social Code and medical law. Medicinal products are defined in the German Medicinal Products Act (AMG) while medical devices are defined in the Law on Medical Devices (Medizinproduktegesetz, MPG), more specifically in § 2 AMG and § 3 MPG). The term “other health care services and products” (Heil- und Hilfsmittel) is derived from §§ 32 and 33 SGB V. The definitions developed in the context of jurisprudence is applicable. The term *Heilmittel* denotes a service prescribed by a physician that service a curative function or is intended to ensure successful treatment and may only be provided by specifically trained personnel. Such health care services include physical therapy, podological therapy, speech therapy and occupational therapy (see Wabnitz, in Spickhoff, Medizinrecht, 2nd Edition, § 32 SGB V, recital 4). The term *Hilfsmittel* refers to physical products which have a supportive, supplementary or mitigating function in ensuring the success of a particular treatment or in compensating for or preventing some sort of impairment (Wabnitz, in Spickhoff, Medizinrecht, 2nd Edition, § 33 SGB V, recital 2). The aspect of the new offence concerning the dispensing and prescription of medicinal products, other health care services and products and medical devices is intended to include all behaviors and actions by which the professional groups named in subsection 1 procure these products and services or by which such products and services are made available to patients.

The term “prescription” means the prescription of medicinal products, other health care services and products and medicinal devices in the interest of patients, independent of whether or not particular product or service is classified as “prescription-only”. Also included in this term are activities that have an inherent relationship with prescribing, such as the transmission of prescriptions to a service provider.

“Dispensing” includes any delivery of a good or service to a patient, including the administration of a good or service.

The term “referral” is equivalent to the term used in the Social Code and the professional codes (§ 73 subsection 7 SGB V, § 31 MBO). The term refers to any action taken to exert an influence on a patient’s choice of physician or another service provider. The term includes referrals, references, allocation and recommendations of every kind (Scholz, in Spickhoff, Medizinrecht, 2nd Edition, § 31 MBO, recital 3; Federal Supreme Court of Justice decision dated 13 January 2011, I ZR 111/08). The use of the terms allocation (Zuführung) and referral (Zuweisung) is intended to make clear that the type of influence exerted on the patient is irrelevant. Verbal and non-binding recommendations are also included in this definition. The term also includes the referrals that take place in the context of contractual cooperations such as group practices. The referral of test materials refers to the transmittal of biological samples for the purposes of laboratory testing.

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The offence only addresses such activities as are executed in the context of the practice of the specific profession. Private activities that take place outside the professional realm are not punishable.

Unlike the offences of corruptibility and bribery in commercial practice (§ 299 StGB), the beneficiary in this new offence does not need to be acting in the context of an employment contract or as an agent. However, the dishonest preferential treatment in the dispensing, prescription or referral practice referred to in an illegal agreement will normally take place in the context of a contractual relationship with the patient.

Subsection 1 number 1 includes benefits that are granted in payment for dishonest preferential treatment given in domestic or foreign competition. Just as in § 299 StGB, the new offence constitutes an abstract strict liability tort. Therefore, it is not required that the preferential treatment actually occurs. Instead, it is sufficient that this preferential treatment is subject of an (at least intended) illegal agreement (see Rönna, in Achenbach/Ransiek, Handbuch Wirtschaftsstrafrecht, 4th Edition, p. 312).

The aspect of the offence referring to the dishonest preference given to an entity is equivalent to the rule set down in § 299 subsections 1 and 3 StGB, so that the interpretations developed for that rule can be applied. As such, “preference” refers to a choice of one competitor over another based on extraneous factors, which therefore requires both competition and the disadvantage of one of the two competitors (Federal Supreme Court of Justice, decision of 18 June 2003, 5 StR 489/02). The context of competition may be absent when a particular commercial enterprise holds a monopoly (Schönke/Schröder/Heine/Eisele, StGB, 29th Edition, § 299 recital 23).

Such preferential treatment is dishonest when the preference harms co-competitors by circumventing the regulations concerning competition and by neutralizing competitors (see Fischer, StGB, 62nd Edition, § 299, recital 16). The interpretive principles for § 299 StGB apply. The dishonest element is missing when the preference given is permitted by professional codes of conduct, assuming the required link between benefit and the medical activity is not already absent in such cases, so that no illegal agreement exists.

The variant of the offence described in § 299a subsection 1 number 2 StGB includes benefits granted in compensation for the health care professional violating their duty to maintain professional (medical) independence. The rule shall also apply when the existence of a monopoly precludes a state of competition and when the benefit is granted in payment, not for a preferential choice between competitors, but in exchange for medically unnecessary prescriptions, which constitutes illegal activity outside the realm of competition (see Schönke/ Schröder/Heine/Eisele, StGB, 29th Edition, § 299 recital 6).

As in subsection 1 number 1, this variant of the offence is restricted to benefits received in exchange for the prescription or dispensing of medicinal products, other health care services and products or medical devices or for the referral of patients or test materials. The benefit must be given in compensation for the violation of the beneficiary’s duty to maintain professional independence.

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Professional duties concerning maintenance of professional independence follow particularly from the binding professional codes of conduct of the professional chambers.

Physicians are required by professional law to take decisions concerning prescriptions, dispensing and referrals based solely on the interests of the patient. They are not to take into consideration whether or not a particular medicinal product or a particular referral might lead to a personal advantage for themselves. This duty is explicitly regulated in § 31 subsection 1 MBO, where physicians are forbidden to require benefits in return taking certain prescribing or referral decisions. For example, when a physician commits him- or herself (to a payer), contractually or otherwise, to prescribe certain medicinal products or to make certain referrals, then said physician is in violation of § 31 subsection 1 MBO. The medical consideration rendered in this case consists of an illegal restriction of the medical autonomy in decision-making; the effectiveness of such agreements in civil law is irrelevant in such cases (see Federal Supreme Court of Justice MedR 2012, 388, 392). It is also irrelevant whether or not a real and actual disadvantage to patient interests resulted from such arrangements and whether or not the agreement was disclosed to the patient (Scholz, in Spickhoff, 2nd Edition, § 31 MBO, recital 1).

Similar rules are set down for dentists in § 2 subsections 7 and 8 of the model professional code of the Federal Chamber of Dentists.

Pharmacists are also obligated to maintain their professional independence in respect to the patient where the dispensing of medicinal products and the referral of patients is concerned, irrespective of the competitive context. Such an obligation is expressed in the requirement to advise the patient without consideration for the manufacturer (see e.g. § 7 subsection 1 of the code of conduct of the state chamber of pharmacists of Berlin and § 7 subsection 2 of the code of conduct of the state chamber of pharmacists of Bavaria). A violation of this duty can result, for example, when a pharmacist accepts benefits in return for the dispensing of certain medicinal products and therefore aligns the advice given to patients and his or her dispensing behavior accordingly.

Since the professional independence of health care professionals serves to protect the patient (see Scholz in Spickhoff, Medizinrecht, 2nd Edition, § 30 MBO, recital 1), benefits granted by the patient with the intent of influencing a health care practitioner's decision-making, for example to procure an unnecessary medical treatment desired by the patient or to seek help in assisted suicide, are not included in the new offence.

Beyond this, simple violations of the professional indict against accepting benefits, such as described in § 32 subsection 1 MBO, are not punishable according to § 299a StGB. To fulfill the criteria for the new offence, the benefit must be given in the context of the illegal agreement required also for cases referenced in number 2, and must be given in the interest of the giver as a compensation for the violation of professional duties. This reciprocal relationship between benefit and violation of duties is absent when the violation is restricted to the acceptance of the benefit itself. A benefit the acceptance of which is a violation of professional obligations is not necessarily also a compensation for that violation. For example, the acceptance of

benefit based on the participation in a scientific continuing education event which exceeds the required travel costs and educational fees, while constituting a violation of professional duties and obligations (§32 subsection 2 MBO), is only punishable under criminal law if the benefit accepted is in compensation for a dishonest preferential treatment or any other violation of professional independence in the interest of the giver.

As with number 1, benefits accepted for past violations of professional duties do not fulfill the criteria for the new offence, unless the benefit conferred is subject to an illegal agreement and the perpetrator had allowed the promise of the benefit to be given in advance (see Fischer, StGB, 62nd Edition, § 299 recital 13). The actual violation of duties as per number 2 and the actual occurrence of preferential treatment as per number 1 are not required for the fulfillment of the criteria of the offence.

On subsection 2

§ 299a subsection 2 StGB regulated the criminality of corruptibility in procurement activities in health care. In this context, “procurement” refers to any form of gaining access to something, for oneself or for a third person. It is essential to include the aspect of procurement because procurement decisions influenced by benefits granted or promised can continue to have significant impact, in particular in the dispensing of the procured object or service.

The procurement of medicinal products, other health care services and products and medical devices not intended for delivery to a patient are not the subject of this offence. In procuring an examination chair or any other medical device (see § 3 MPG) to furnish the treatment rooms, the concerned person may pursue their own economic interests in making these decisions (on the acceptance of benefits for the owner of a commercial enterprise under § 299 StGB see Rönnau, in Achenbach/Ransiek, Handbuch Wirtschaftsrecht, 4th Edition, p. 302 f.; Fischer, StGB, 62nd Edition, § 299 recital 11a). Patient interests are also not affected when the procurement of object for one’s own use (as an exception) results in dishonest preferential treatment.

In procurement of medicinal products, other health care services and products and medical devices intended for delivery to patients, a criminal offence is only present when the benefit is accepted in compensation for a violation of the duty to maintain professional independence on the part of the beneficiary. Contrary to the actions described in number 1, the criminality of the offence is not dependent on dishonest preference given in competition, since dishonesty in procurement decisions may also result from infringements on pricing and rebate regulations, where the criminal elements specific to corruption and the undermining of trust in the integrity of medical decision-making are absent.

The criminality of the offence requires that the procurement decision is normally subject to a professional duty to maintain professional independence. This is the case for physicians, as § 31 subsection 1 MBO forbids accepting benefits in return for procuring medicinal products, other health care services and products or medical

devices. Similar regulations are set down in the model professional code of the Federal Chamber of Dentists in § 2 subsection 7 and 8. Such a violation of duties is present when the procurement decision is dependent on the receipt of benefits and the interests of the giver take precedence over the interests of patients.

The prerequisites for the criminality of the offence in § 299a subsection 1 sentence 2 StGB correlate with the prerequisites for § 299a subsection 1 sentence 1 StGB. Benefits for third persons are included in the offences. As the duty to maintain professional independence serves to protect patients (see Spickhoff/Scholz, § 30 MBO, recital 1), benefits that actually benefit the patient, such as rebates that are passed on to the patient, do not fulfill the criteria for this offence. However, hidden rebates that are obscured in order to prevent the patient from benefiting from them certainly fulfill the criteria for the offence, as they are given as compensation for the violation of the duty to maintain professional independence.

When conventional and customary rebates and discounts are granted in conformity with usual commercial practice, an illegal agreement may be absent because these rebates and discounts are not granted for a specific procurement decision, but are made available to everyone (see Scholz, in Spickhoff, Medizinrecht, § 33 MBO, recital 7; Rönnau, in Achenbach/Ransiek, Handbuch Wirtschaftsstrafrecht, 4th Edition, p. 317).

On § 299b StGB (Bribery in health care)

§ 299b mirrors § 299a StGB in that it makes punishable the offence of active bribery. The group of possible perpetrators on the side of the givers of the bribes is not restricted to the health care professions named in § 299a subsection 1 StGB, but includes any person who gives a benefit to those named there with the criminal intent described.

The explanations given on the characteristics and features of § 299a StGB otherwise apply.

On § 300 StGB (Particularly serious cases of corruptibility and bribery in commercial practice and in health care)

The allowance for higher penalties in cases with aggravating circumstances regulated in § 300 StGB is also applicable to the offences of corruptibility and bribery in health care. The principles developed for the interpretation of §§ 299, 300 StGB are applicable. The not otherwise specific serious cases as mentioned in sentence 1 may be assumed when injury or serious endangerment of the health of patients results from malpractice that results from corruptive influences.

On § 301 StGB (Charges)

The proposed law contains an extension in the scope of the relative duty of petition defined for corruptibility and bribery in commercial practice as described in

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§ 301 StGB to include the offence of corruptibility and bribery in health care. The bringing of charges is a prerequisite for the prosecution of corruptibility and bribery in health care, unless the prosecuting agency deems intervention ex officio necessary because of particular public interest in the prosecution of the offence.

The charges may be brought forward by those harmed by the corrupt practices (§ 77 StGB). In cases concerning § 299a subsection 1 number 1 and § 299b subsection 1 number 1 StGB, these are the co-competitors (see Federal Supreme Court of Justice decision dated 18 January 1983, 1 StR 490/82; Fischer, StGB, 62nd Edition, § 301, recital 4).

Furthermore, corrupt agreements do not just violate competitive obligations. Such agreements also violate the right of patients to receive treatment guided solely by the welfare of the patient when they lead to treatment decisions influenced by benefits received. In such cases, patients may also bring charges.

Professional associations with legal capacity that represent co-competitors as well as the statutory health insurance companies and private health insurance companies are also able to bring charges. Professional associations with legal capacity include professional associations organized according to private law, which are concerned with the representation and promotion of the interests of particular professions. These include professional chambers of which the disadvantaged competitor is a member. The professional chambers of which the perpetrator is a member may also bring charges. The segregation of the persons able to bring charges for the offence per § 299 StGB (number 1) and the new offences in §§ 299a and 299b StGB (number 2) was done in the interest of clarity.

When a particular public interest in the prosecution of a particular offence may exist, the determination of this public interest should also take into account the possible consequences of the act in respect to the community of solidarity formed by the insured persons.

The proposed law forgoes classifying the new offences as an offence subject to private prosecution (§ 374 of the Code of Criminal Procedure). When charges are brought forward, the prosecuting agencies are then required to open investigations without first determining if there is a public interest in the prosecution of the offence.

On § 302 StGB (Extended confiscation)

The reference to § 43a StGB that was stricken in the proposed law reflects the decision by the Federal Constitutional Court dated 20 March 2002 (BVerfGE 105, 135), which declared the rule unconstitutional. As a differentiation is no longer necessary, the proposed law now consolidates the two subsections. At the same time, the scope for application of § 302 StGB is extended to the new §§ 299a and 299b StGB, which makes extended confiscation (§ 73d StGB) applicable when the perpetrator acts on a commercial basis or as a member of a gang formed for the recurrent commission of such offences.

On Article 2 (Amendment of the Judicature Act)

§ 74c subsection 1 sentence 1 number 5a of the Judicature Act is amended to include the offence of corruptibility and bribery in health care. As in cases of corruptibility and bribery in commercial practice per § 299 StGB, this means the competent courts for these new offences are the court divisions for business offences at the regional courts. As with the offences regulated by § 299 StGB, the evaluation of the new offences in §§ 299a and 299b StGB will normally include circumstances requiring specialized knowledge of commercial practices,

[Explanations concerning Article 3 not translated. Content considered irrelevant for comment.]

On Article 4 (Entry into force)

This article regulates the entry into force of the proposed law.