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DIGITIZATION IN THE HEALTH SECTOR IN THE TRADE-OFF BETWEEN TECHNICAL AND LEGISLATIVE POSSIBILITIES AND LEGAL LIMITS ACCORDING TO GERMAN LAW[1]

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ABSTRACT

In May 2018, the 121st German Medical Association in Erfurt decided to relax the prohibition of exclusive remote treatment which had previously been standardized in the Model Professional Code of Conduct for physicians working in Germany (MBO-Ä). With this, the German Medical Association has responded to the continuing call for progress and further development in terms of digitization. Nevertheless, many questions remain unanswered, such as the implementation and interpretation of the provisions of § 7 para. 4 MBO-Ä in its new wording and their embedding in existing regulations. Data protection, which defines the legal limits of remote treatment, also plays an important role here.

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I. INTRODUCTION

Digitization in the health sector has been a perennial issue in legal and medical expert discussions for several years now. The respective legislative progress can be considered rather sluggish, not least because of the controversial picture of opinions. Despite the high number of supporters in favor of digitization in health care, the amount of critics and skeptics is decreasing slowly.

The supporters of remote treatment see an advantage for improving health care, especially regarding the demographic changes and the shortage of physicians, not only in rural areas. Moreover, due to the possibility of offering short-term consultations, improvements in quality of medical services are predicted. Not only the fully employed patient appreciates remote treatment as a huge timesaver. Besides, the risk of infection in the physician's office can be reduced. Critics of (exclusive) remote treatment fear that the trustful relation between patient and physician might suffer from the lack of personal contact. An increase of diagnostic errors is predicted due to a restriction in the possibilities of perception and cognition. Last but not least, the "new" digital methods of data transfer imply a higher risk for the highly sensitive patient health data[2].

The physicians' professional code in Germany reflected these concerns and the requirements for patient safety in its former version, valid until the decision of the 121st German Medical Association in May 2018. In contrast, neighboring countries such as Switzerland have already permitted exclusive remote treatment – without being swamped with reproaches of medical malpractice. Foreign providers of remote treatment have already established themselves on the German market by requisitioning German physicians[3]. This shows that a "head-in-the-sand-policy" can have counterproductive effects on digitization. The decision of the German Medical Association in May 2018 on opening the ban of exclusive remote treatment is therefore to be welcomed.

Needless to say that despite all the euphoria about digital progress and digital freedoms, the patient health data concerned, which are particularly sensitive in relation to fundamental rights, should not be neglected. However – and this aspect is often overlooked – data protection requirements are applicable not only for remote treatment, but also in every "conventional" physician's office. Regarding the possibility of fast transfer of large datasets and the resulting increased risk potential[4], data protection becomes more virulent

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2 For advantages and disadvantages cf. Peter Kalb, *Rechtliche Aspekte der Telemedizin (Legal aspects of telemedicine)*, 8, GESR, 481, 483 (2018).

3 Cf. speech of the president of the German Medical Association and the German Physicians' Board, Prof. Dr. Frank Ulrich Montgomery, *Opening of the 121st German Physicians' Board in the Steigerwaldstadion Erfurt on the 8th of May 2018*, 9, https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/121.DAET/Eroeffnungsrede_Prof._Montgomery.pdf (last visited Sept. 28, 2018).

4 Already: Wilfried Berg, *Telemedizin und Datenschutz (Telemedicine and data protection)*, 8, MEDR, 411, 413 (2004) with further references.

in the context of telemedicine.

II. LEGAL POSSIBILITIES OF REMOTE TREATMENTS IN GERMANY

The revised version of § 7 para. 4 sentence 3 MBO-Ä now reads as follows: "Exclusive consultation or treatment via communication media is permitted in individual cases if this is medically justifiable and the necessary medical care is maintained, in particular through the way in which findings are made, consultation, treatment and documentation are provided, and the patient is also informed about the special features of exclusive consultation and treatment via communication media.". In the future, patients should be provided with medical care that corresponds to the recognized state of medical knowledge, which includes the further development of telemedicine, digital, diagnostic and other comparable possibilities, without establishing a model of primary telemedicinal treatment. The personal doctor-patient contact should thus continue to be regarded as the "gold standard" of medical treatment[5]. But what does the change of the MBO-Ä mean for physicians? How is the new regulation to be interpreted? And: How does it fit in with other legal systems in force?

A. Physicians' Professional Law

The reformulation of the MBO-Ä alone does not change anything for the attending physician. The MBO-Ä itself has no legal norm quality and therefore needs to be transposed into the professional regulations of the Federal States' Chambers of Physicians. Although the MBO-Ä is not legally binding, it nevertheless serves as a guidance for the Federal States' Chambers of Physicians, so that the earlier prohibition of exclusive remote treatment (old § 7 para. 4 MBO-Ä) has also been adopted analogously by all Federal States' Chambers of Physicians in their professional regulations. Today, however, this no longer applies without restrictions. In summer 2016, the State Chamber of Physicians in Baden-Württemberg has already changed its professional regulations and approved remote treatment of Baden-Württemberg patients by Baden-Württemberg physicians for model projects. This year, the Federal States' Chambers of Physicians of Schleswig-Holstein and Saxony have also legitimized the exclusive remote treatment in cases of medical justifiability by amending the respective Professional Code of Conduct.
Finally, the representatives' meeting of the Rhineland-Palatinate State Chamber of Physicians – very recently – decided on 20th September 2018 on a corresponding new regulation of the Professional Code of Conduct.

It can be assumed that other regional Chambers of Physicians will amend their professional regulations in accordance with the new provisions of § 7 para. 4 MBO-Ä. On the

5 *Synopsis of the changes in § 7 Abs. 4 MBO-Ä (remote treatment)*, https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MBO/Synopse_MBO-AE_zu_AEnderungen____7_Abs._4.pdf (last visited Sept. 28, 2018).

other hand, in May 2018 the Saarland Chamber of Physicians – following the resolution of the 121st German Medical Association – expressly spoke out against a relaxation of the prohibition of exclusive remote treatment[6], with the result that the professional law will probably be fragmented in this respect. In the context of remote treatment, the question of the applicable professional law will therefore soon arise.

The physician is a compulsory member of the regional Chamber of Physicians in whose district he practices his profession. He is therefore also subject to their professional code of conduct. In the case of a "normal" visit to the doctor, it is clear that the doctor exercises his profession at the office. But does this also apply if the doctor offers online video consultation hours from his practice, during which he treats patients from other chamber districts? There is much to be said in favor of continuing to determine the physician's place of business as the place where he exercises his profession[7]. A different understanding would lead, in particular, to considerable practical difficulties. Based on the patient's actual whereabouts during treatment – which could alternatively be taken as a basis – the attending physician would possibly become a compulsory member of a large number of regional chambers of physicians, which in turn could lead to an unreasonable burden on the exercise of the physician's profession. Ultimately, determining the patient's actual whereabouts could also mean unreasonable additional work for the doctor. All this would in any case make remote treatment extremely unattractive from a medical point of view, so that the desired progress would not be achieved.

B. New wording of § 7 para. 4 of the Model Professional Code of Conduct (MBO-Ä)

According to § 7 para. 4 sentence 3 MBO-Ä in its new wording it should definitely be decisive in the future whether the attending physician considers the exclusive remote treatment to be medically justifiable in the individual case. But when is remote treatment medically justifiable? And what defines an individual case? There is no legal definition for this.
It is safe to assume that the previously permitted options of remote treatment will also be permitted under the new regulation[8]. However, the new regulation is expressly intended

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6 Cf. Andeas Kindel, *Fernbehandlung, Saar-Ärzte fürchten Kontrollverlust (Remote treatment, Saar-physicians fear loss of control)*, ÄRZTEZEITUNG ONLINE (May 2 2018), https://www.aerztezeitung.de/politik_gesellschaft/berufspolitik/article/963095/fernbehandlung-saar-aerzte-fuerchten-kontrollverlust-telemedizin.html (last access Sept. 28, 2018).

7 The question of the professional law also arises in particular with regard to the cross-border telemedical activities of physicians who are established in another EU member state.

8 § 7 para. 4 MBO-Ä (old version) has not standardized a general prohibition of remote treatment measures, rather only diagnosis and therapy recommendation for unknown patients via print and communication media – i.e. in the context of the first contact – should be completely prohibited by this law, cf. in this regard: *Notes and explanations of the Federal Chamber of Physicians on § 7 para. 4 MBO-Ä (remote treatment)*, 11.12.2015 https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Recht/2015-12-11_Hinweise_und_Erlaeuterungen_zur_Fernbehandlung.pdf (last visited Sept. 28, 2018); Anna Kristina

to permit other forms of remote treatment, in particular the initial contact via means of communication.

In order to determine the regulatory content, the view taken here is that the principle of freedom of medical treatment recognized by the highest court[9] and the case-law on medical liability can be relied upon. Medical freedom of therapy means here that the physician can in principle choose the examination and treatment methods – among the permissible treatment methods – freely, he thus possesses a discretionary and judgmental scope in this respect[10]. This means that the proper course of medical action is determined exclusively by whether the physician has made justifiable decisions about diagnostic and therapeutic measures using "the medical knowledge and experience required from him in the specific case and has carefully implemented these measures"[11].

Correctly, the physician must therefore ask in relation to the intended purpose what "form of depth of the physicians' perception of the patient is necessary for the physician for standard treatment"[12]. The physician must therefore assess the risks of remote treatment on his own responsibility on a case-by-case basis, i.e. in relation to the treatment and the patient. As soon as the doctor considers a personal visit of the patient to be indicated, he has to point this out to the patient and interrupt the remote treatment. As with any other therapy recommendation, it is then up to the patient to actually follow this up.

If the physician decides to carry out remote treatment, even though this was not medically justifiable in the individual case, this violation of professional duties can lead to civil liability.
The choice of a medically unjustifiable form of therapy can quickly be regarded as a gross medical malpractice in a lawsuit.

The physician should also pay special attention to patient information, because in the context of remote treatment the physician must also inform about the special features of consultation and treatment exclusively via communication media. The obligatory content of this information is not defined, but can also be determined according to the traditional principles. However, it is recommended to expressly point out to the patient that not all diagnostic possibilities, such as palpating, can be used in the context of remote treatment – even if this is likely to be self-explanatory to the patient on a regular basis. This recommendation applies at least as long as there is no highest court jurisdiction on

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Kuhn, *Grenzen der Digitalisierung der Medizin de lege lata und de lege ferenda (Limits to digitization in health care de lege lata and de lege ferenda)*, 12, GESR, 748 (2016).

9 Cf. BGH (German Federal Supreme Court), decision dated Sept. 22, 1987 – VI ZR 238/86, NJW 1988, 763, 764.

10 LAUFS/KERN, HANDBUCH DES ARZTRECHTS (MANUAL OF MEDICAL LAW), § 97 Rn. 36, (4th ed. 2010).

11 BGH (German Federal Supreme Court), decision dated March 10, 1987 – VI ZR 88/86, NJW 1987, 2291, 2292.

12 Michael Hahn, *Telemedizin und Fernbehandlungsverbot – Eine Bestandsaufnahme zur aktuellen Entwicklung (Telemedicine and ban of remote treatment – an inventory of the latest developments)*, 36, MEDR, 384, 386 (2018).

this, because in a medical liability lawsuit the physician has to prove the correctness of the information. The special information and consent should also be included in the patient documentation.

C. Federal regulations

The amendment of the MBO-Ä or the professional law alone is not sufficient to reasonably integrate remote treatment into the system of medical care. Rather, an extensive action by the legislator is required here. Some statutory provisions currently stand in the way of an effective offer of remote treatment services – this is illustrated by the example of the provisions of § 9 of the German Act on Advertising of Medicinal Products (HWG) and § 48 of the German Medicinal Products Act (AMG).

1. § 9 German Act on Advertising of Medicinal Products (HWG)

According to § 9 HWG, advertising for the recognition or treatment of diseases, sufferings, bodily injuries or pathological complaints that are not based on the physician's own perception of the patient is not permitted. Although it is not the remote treatment itself that is prohibited, but only the advertising for the same, the provision under the law on therapeutic product advertising nevertheless stands in the way of an appropriate offer of remote treatment services. There is no distinction according to whether distance treatment is permissible or inadmissible under professional law, so that the wording of the provision is clear. It is well known that the wording represents the limit of any interpretation. Any interpretation to the effect that forms of remote treatment permitted under professional law are not covered by the advertising ban cannot be made for this and other reasons[13]. The medical professional codes of conduct are established as statutory law in the hierarchy of norms below formal statutory law. The result of an interpretation cannot be that the formal-legal prohibition norm of § 9 HWG is leveraged by sublegal statute right. In addition, this type of interpretation would (probably) lead to the fact that federal law would have to be interpreted inconsistently in the individual chamber districts, since - as previously described - not all regional medical associations have adopted or will adopt the opening clause adopted in the MBO-Ä in their professional regulations.

According to the opinion represented here, it is questionable whether the "mere" offering of remote treatment services on a doctor's homepage is already to be regarded as advertising in the sense of the provision[14]. However, this is possible in individual cases, depending

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13 Different view: Julia Braun, *Die Zulässigkeit von ärztlichen Fernbehandlungsleistungen nach der Änderung des § 7 Abs. 4 MBO-Ä (The admissibility of remote treatment services after the change of § 7 para. 4 MBO-Ä)*, 36, MEDR, 563, 566 (2018); Michael Hahn, *Telemedizin und Fernbehandlungsverbot – Eine Bestandsaufnahme zur aktuellen Entwicklung (Telemedicine and ban of remote treatment – an inventory of the latest developments)*, 36, MEDR, 384, 386 (2018).

14 According to the Ministry for Social Affairs and Integration of the State of Baden-Württemberg, remote treatment in the context of public services should not be subject to the advertising concept of § 9 HWG, cf. LT B-

on the form it takes, due to the broad advertising concept of the law on the advertising of therapeutic products[15]. Enabling the provision of exclusive remote treatment services without mentioning this on the homepage, on the other hand, would be a waste of time. Even if the legal literature rightly raises the question of whether "own perception" within the meaning of § 9 HWG requires an offline contact purely conceptually[16], this will not lead to a legally secure solution for the physician. In any case, it has already been decided in the case law of higher courts that remote treatment within the meaning of § 9 HWG is to be present if the treating person makes a diagnosis or submits treatment proposals solely on the basis of written information, information provided by telephone, other media or third parties at a distance[17]. Undoubtedly, the online video consultation should also be subsumed under this heading. Legislative action is therefore absolutely necessary, not least because a violation of § 9 HWG under § 15 para. 1 No. 6 HWG constitutes an administrative offence, which can be punished with a fine of up to € 50,000.00 (§ 15 para. 3 HWG).

2. § 48 German Medicines Act (AMG)

Pursuant to § 48 para. 1 sentence 1 AMG, medicinal products intended for human use may not be supplied if there has obviously been no direct contact between the doctor and the person to whom the medicinal product is prescribed prior to medical treatment[18]. According to § 48 para. 1 sentence 3 AMG, exceptions may be made in justified exceptional cases, in particular if the patient and doctor know each other from a previous direct contact or if the treatment is merely repeated or continued. This provision therefore at least opens up the possibility of interpretation to the effect that in the case of remote treatment permitted under professional law, there is a justified exception within the meaning of the provision. However, this conclusion is by no means mandatory, so that § 48 AMG also precludes a meaningful offer of distance treatment services.

W printed matter 16/3161 p. 3. This interpretation is, however, at least questionable, since such restriction is not included in the wording of § 9 HWG.

15 Cf. on this topic: Julia Braun, *Die Zulässigkeit von ärztlichen Fernbehandlungsleistungen nach der Änderung des § 7 Abs. 4 MBO-Ä (The admissibility of remote treatment services after the change of § 7 para. 4 MBO-Ä)*, 36, MEDR, 563, 566 (2018).

16 Cf. Michael Hahn, *Telemedizin und Fernbehandlungsverbot – Eine Bestandsaufnahme zur aktuellen Entwicklung (Telemedicine and ban of remote treatment – an inventory of the latest developments)*, 36, MEDR, 384, 386 (2018).

17 OLG (Higher Regional Court) Munich, decision dated Aug. 2, 2012 – 29 U 1471/12, MMR 2012, 824.

18 On the concerns about this provision under European law see Ulrich M. Gassner, *Verbot von Online-Verschreibungen von Medikamenten: Patientenautonomie unter Dauerfeuer (Ban of online-prescriptions of medicines: patient autonomy under constant fire)*, LEGAL TRIBUNE ONLINE, March 31, 2016, https://www.lto.de/recht/hintergruende/h/arzneimittel-recht-online-rezept-kontakt-arzt-patient-gesetz-entwurf-bevormundung/ (last visited Sept. 28, 2018).

III. LEGAL LIMITS TO DIGITIZATION: DATA PROTECTION IN THE HEALTH SECTOR

The new provisions of data protection law must also be taken into account when assessing permissible remote treatment and its limits. Due to the "new" technical possibilities of the rapid exchange of large amounts of data, measures must be taken in the interest of the persons concerned and the principle of data economy to take account of this change. In this respect, the new regulations at least contribute to raising awareness, despite all the displeasure. What, then, must doctors pay particular attention to when offering remote treatment services relating to data protection?

A. GDPR and BDSG-new

The regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and on the repeal of Directive 95/46/EC (General Data Protection Regulation, hereinafter referred to as "GDPR") entered into force on May24, 2016. In many places, however, it was only perceived shortly before or with its immediate commencement of application in all EU member states on May 25, 2018. It is intended to lead to a uniform application of the law and to give affected persons more control and transparency, especially in the digital age. The innovations go hand in hand with a tightening of the burden of proof on the part of those responsible for data processing. The GDPR addresses not only corporations such as Google, Facebook and Co., which were the primary target of the legislators in the reform, but also small companies, including physicians' offices, pharmacies and even privately run associations. The GDPR does not provide for the possibility of a general exemption for smaller units, but it does contain some exceptions, for example with regard to the requirement to appoint a data protection officer.

In addition to the introduction of the GDPR, which applies directly in all member states and does not require transposition into national law, the Federal Data Protection Act has also been amended in Germany and also entered into force on May 25, 2018 (BDSG-neu) by adapting some points to the European framework and filling in the reserved opening clauses. The criminal provisions are also reserved for the BDSG-new due to the lack of regulatory competence of the EU and can be found there in §§ 41 to 43 BDSG-new.

In terms of content, the principles of secure handling of personal data are not entirely new. Particularly with regard to sensitive data such as health data, the old BDSG, which implemented Directive 95/46/EC, already had high requirements. The increased requirements for information and proof obligations can therefore be implemented well by an appropriate internal data protection concept. Nevertheless, there are uncertainties in the interpretation of the Regulation with regard to individual special questions, which will be explained below and which will have to be answered in the near future by binding specifications of the European Data Protection Committee, the national data protection authorities and decisions of the courts.

B. Notions and definitions

First, the question arises as for which information the GDPR is applicable at all. According to Art. 4 No. 1 GDPR, personal data are "any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more specific characteristics which express the physical, physiological, genetic, psychological, economic, cultural or social identity of that natural person". This includes in particular information such as first name and surname, address, telephone number, e-mail address and date of birth, which are collected as standard in the medical practice. This is referred to as simple personal data.

1. Health data

Particularly sensitive data such as health data are subject to special protection under the GDPR. Health data are defined in Art. 4 No. 15 GDPR as such "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status". According to recital 35 of the GDPR[19], this includes in particular information on past, present or future physical and mental health. The information is already personally identifiable if numbers, symbols or identifiers assigned to a natural person are used to uniquely identify that natural person for health purposes.
Examples of health data can therefore already be the insurance number, pre-existing conditions, diagnoses (indications), as well as all laboratory results, blood and tissue samples, but also disease risks attributable to a natural person.

2. Anonymization and pseudonymization

It should therefore be noted that - in accordance with recital 26 of the GDPR - pseudonymized data also clearly fall within the scope of the GDPR. This also applies if the person who receives and processes the pseudonymized data cannot draw conclusions about the natural person without consulting further information. Pseudonymization is defined in Art. 4 No. 5 GDPR as "the processing of personal data in such manner that it can no longer be attributed to a specific person without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person". A classic example is the assignment of an identification number to a data set if the "allocation key" still exists.

19 The recitals are binding for the interpretation of the regulation.

Only for anonymous data the GDPR does not apply. However, the terms "anonymous" or "anonymization" are not defined. In general, anonymization is presumed when it is no longer possible to assign a person to a specific or identifiable natural person[20]. In this case, the allocation key for tracing the identification number back to the corresponding person must no longer exist.

The distinction between anonymization and pseudonymization plays an important role in the context of remote treatment, especially with regard to the transmission of data. In view of the new definition, the transfer of data to medical specialists can no longer be seen as anonymization, as it will always be possible to identify the person. In addition, the differentiation can become relevant when cooperating with pharmaceutical companies, e.g. when creating databases, registers or observational studies. Here, too, anonymization is only possible if neither the physician nor the pharmaceutical company can identify the individual patient.

It should also be emphasized that any operation relating to personal data constitutes processing within the meaning of Art. 4 No. 2 GDPR; even the collection, but also the mere deletion, is regarded as processing and no distinction is made between individual processing operations.

C. Legal bases for data processing

Furthermore, the fundamental prohibition of data processing without a legal basis, the so-called prohibition subject to permission, continues to apply. Corresponding legal bases can be found in Art. 6 para. 1 lit. a) to f) GDPR for "simple" personal data, in Art. 9 para. 2 lit. a) to j) GDPR for special categories of personal data, in particular health data, as well as in § 22 BDSG-new. Permission may be granted either by legal basis or by the express consent of the data subject.

Although consent is better suited as evidence, the use of a legal basis is likely to be more valuable overall - if a legal basis can be substantiated accordingly - as the consent can be revoked by the data subject at any time.

To determine the respective legal basis, each processing operation and the purpose of the data processing must be considered individually.

1. Medical treatment and health care as a legal basis

Generally, the collection of data by the physician should take place on the basis of the treatment contract and thus be permitted in accordance with Art. 9 para. 2 lit. h) GDPR in conjunction with § 22 para. 1 b) BDSG-new. A declaration of consent by the patient is

20 Cf. PAAL/PAULY/ERNST, DS-GVO KOMMENTAR (GDPR COMMENTARY), Art. 4 Rn. 49 (2nd ed. 2018).

therefore not usually necessary for "normal" treatment. However, due to the principle of purpose and data minimization (Art. 5 para. 1 lit. b) and c) GDPR), this only applies to the extent that data processing is necessary for the purpose, i.e. for carrying out the treatment, so that the scope of processing is limited to the extent necessary for this purpose[21].

But what is the necessary measure for a treatment via electronic communication media - e.g. the online video consultation? Is the assessment of necessity to be based on the performance of medical treatment in general, or on the specific form of treatment?

Referring to the treatment contract as a whole, it can be assumed that it is not necessary to use additional software to carry out the online video consultation, as the treatment contract can also be fulfilled in another way, namely by personal examination in the physician's office. The transmission of data by video goes beyond what is necessary, so that for the purposes of remote treatment a data protection consent would have to be obtained. Focusing, on the other hand, on the special form of treatment, i.e. remote treatment as such, one would come to the conclusion that no separate consent under data protection law has to be obtained, because the video consultation hour with the use of additional communication media is necessary to fulfil the treatment contract in its special form.

Also § 7 para. 4 MBO-Ä (new version) does not provide an answer to these questions, but only demands in medical regard that "the patient is also informed about the peculiarities of the exclusive consultation and treatment via communication media". An additional data protection clarification and informed consent is not expressly prescribed in any case - unlike, for example, § 40 para. 2a AMG for participation in the clinical trial.

In the direct contact between doctor and patient, the special type of data processing should be regarded as necessary according to the view held here. Finally the change of the MBO-Ä opens the clearance of the exclusive remote treatment for the physician in the context of its therapy choice and under consideration of the medical care to the physician. In the same way, within the framework of traditional treatment, he is free to decide on the manner and means of treatment in compliance with medical standards. Depending on which type of treatment he chooses, the appropriate implementation is necessary for the fulfilment of the specific treatment contract, so that no additional data protection consent is required in the context of remote treatment.

2. Informed consent for processing of patient health data

However, a direct transfer of personal health data, for example in order to obtain a (tele)consultation or in connection with a referral to a specialist - as in the context of conventional treatment - will only be possible with the consent of the patient, cf. also § 73

21 EHMANN/SELMAYR/HEBERLEIN, DSGVO KOMMENTAR (GDPR COMMENTARY), Art. 6 Rn. 5 (2nd ed. 2018).

para. 1b of the German Social Insurance Code (SGB V). It should be emphasized in this context that - as described above - pseudonymous data already fall within the scope of the GDPR. For this reason, the transmission of an X-ray image or ECG alone - without mentioning the patient's name - is already to be regarded as a processing operation[22]. The patient's consent must also be obtained for other purposes which go beyond the fulfilment of the treatment contract[23], e.g. the sending of appointment reminders. Since the transfer of data is often part of the treatment, the patient's general consent under data protection law will probably have to be obtained in these cases.

D. Further aspects of data protection

1. Rights of the data subject

It is important to note that, independent of the legal basis that permits the processing of personal data and health data, the data subject must always be informed in accordance with Art. 13 GDPR about the data collection in its concrete form - irrespective of whether the patient's consent under data protection law is obtained or not. Depending on the technical design, problems may arise with regard to the scope of the information obligations, for example if other players are involved in addition to the physician (e.g. platform operators). At a minimum, the physician must provide information on the identity of the person(s) responsible[24], the contact details of the data protection officer, the purposes of the processing, recipients or categories of recipients, the duration of the processing and the rights of the data subjects pursuant to Art. 15 et seq. GDPR to this effect. If the treatment is carried out exclusively via telephone/video telephony, the physician must also inform in this way. The reference to a notice in practice would therefore not be sufficient, but possibly data protection information on the doctor's website, if he actively refers to it during the online video consultation[25]. An exception to the duty to inform exists according to Art. 14 para. 5 lit. d) GDPR if the doctor has received the patient's data from a third party (permissibly) and they are subject to professional secrecy. This is the case, for example, if the primary care physician forwards the patient data to the specialist because it can then be assumed that the primary care doctor has already informed the patient comprehensively.

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22 Different according to the former legal status; cf. Wilfried Berg, *Telemedizin und Datenschutz (Telemedicine and data protection)*, 8, MEDR, 411, 414 (2004).

23 Cf. on this topic: Joachim Schütz/Bernd Halbe, *Wann die Patienteneinwilligung notwendig ist (When patient consent is necessary)*, ÄRZTEZEITUNG ONLINE (MEDICAL JOURNAL ONLINE), Aug. 24 2018, https://www.aerztezeitung.de/praxis_wirtschaft/w_specials/datenschutzverordnung/article/969712/daten-verarbeitung-wann-patienten-einwilligung-notwendig.html (last visited Sept. 28, 2018).

24 For joint controlling see below under 4.b.

25 Also: recommendation of the North Rhine Chamber of Physicians, *Die DSGVO in den Praxisalltag integrieren (Integrating GDPR into the physician's routine)*, RHEINISCHES ÄRZTEBLATT (RHENISH MEDICAL JOURNAL), 8, 12 et seq (2018).

In addition, the requirements of Art. 9 para. 3 GDPR must be fulfilled. Accordingly, processing is only permissible if it is carried out "by specialist personnel or under their responsibility" and if this specialist personnel or the person responsible for data processing is subject to a statutory professional secret or other confidentiality obligation[26]. This shall include appropriate measures to safeguard the interests of the data subject and data security in general[27].

Furthermore, it must be ensured that the data subject can exercise his or her right to information (Art. 15 GDPR) and, if applicable, data portability (Art. 20 GDPR) without any problems. The latter means that the patient can request a copy of his patient file. However, it only exists if the processing is based on consent or a contract and is carried out using automated procedures. In the case of remote treatment, this means that the patient has no right to data transferability if the data processing is based - as described above - on the treatment contract as legal basis, since the legal basis of the health care and the treatment contract from Art. 9 para. 2 lit. h) GDPR is not mentioned in the concluding enumeration[28] of Art. 20 para. 1 a) GDPR[29]. The right of the patient to inspect the patient file according to § 630g of the German Civil Code (BGB) remains unaffected by this. In contrast to the right under Art. 20 GDPR, the physician is not given a deadline to react and the patient must bear the costs incurred himself.

Even if a third party is involved as platform operator, this should not lead to a different result: A contract within the meaning of Art. 6 para. 1 lit. b) GDPR would – if at all – be concluded between platform operator and physician - but not between platform operator and patient[30]. Apart from hat, however, only the processing of "simple" personal data by the platform operator would be permitted, which would not be sufficient for the desired purposes.

2. Joint controlling/Commissioned data processing

Since the GDPR came into force, there have also been new responsibilities for the involvement of several actors in connection with data processing. Art. 4 No. 7 GDPR defines the

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26 Cf.EHMANN/SELMAYR/SCHIFF, DSGVO KOMMENTAR (GDPR COMMENTARY), Art. 9 Rn. 61 (2nd ed. 2018).

27 So called technical and organizational measures (TOMs) such as access restrictions, password protection, encryption and ensuring the integrity and availability of systems, etc., cf. Art. 24 para. 1 GDPR, § 22 para. 2 BDSG-new.

28 Cf. recital 68; PAAL/PAULY/PAAL, DS-GVO KOMMENTAR (GDPR COMMENTARY), Art. 20 Rn. 18 (2nd ed. 2018).

29 In the result also: Andreas Wolf, *Die Fernbehandlung nach dem 121. Deutschen Ärztetag im Lichte der DSGVO (Remote treatment after the 121st German Medical Association in the light of the GDPR),* 4, GUP, 129 et seq (2018).

30 Different view: Andreas Wolf, *Die Fernbehandlung nach dem 121. Deutschen Ärztetag im Lichte der DSGVO (Remote treatment after the 121st German Medical Association in the light of the GDPR),* 4, GUP, 129 et seq (2018).

person responsible as the person who alone or jointly with others differentiates between the purposes and means of data processing. Accordingly, anyone who collects, stores, transmits, etc. data for himself is responsible. Responsible person in the sense of the GDPR[31]. In contrast, the processor is, according to Art. 4 No. 8 GDPR, a person or body who processes personal data on behalf of the data controller. The delimitation is important because the responsible person and the processor have different obligations[32] and a corresponding agreement must be reached on the distribution of responsibilities in accordance with Art. 26 or Art. 28 GDPR.

Due to the contractual and professional duties of a physician to document patient data and to archive it beyond the treatment[33], the physician defines the processing purposes at least to this effect and is therefore generally to be regarded as the person responsible. The specialist to whom the referral is made by the family doctor also does not act as processor on behalf of the primary physician[34], since an independent legal relationship is established with the patient and he does not act on his behalf[35]. Cooperation between physicians and pharmaceutical companies - not only within the framework of clinical trials[36] - will also regularly be a joint responsibility, since in some areas decisions are made on data processing and corresponding internal regulations are required.

In the context of remote treatment, it is conceivable, depending on the technical implementation, that the physician may use one or more service providers who, in accordance with their dependence on the physician's mandate or their own influence on data processing, are to be classified as contract processors or joint responsible parties.

3. Data protection officer

In addition, the appointment of a data protection officer pursuant to Art. 37 GDPR will be necessary in practices offering remote treatment. Although the core activity of a medical practice mentioned in Art. 37 para. 1 lit. c) GDPR is not usually seen as an extensive

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31 PAAL/PAULY/ERNST, DS-GVO KOMMENTAR (GDPR COMMENTARY), Art. 4 Rn. 55 (2nd ed. 2018).

32 At the same time, the obligations of commissioned data processors have increased and an independent liability has been established.

33 Cf. § 630 f para. 3 BGB, § 28 RöV (X-Ray Regulation).

34 According to the statement of the Data Protection Officer of North-Rhine Westphalia, which is no longer available, cf. *the resolution of the Concerted Action of the Professional Associations at the German National Association of Statutory Health Insurance Physicians*, June 22, 2018, http://www.kbv.de/html/35530.php (last visited Sept. 28, 2018).

35 Already: BGH (Federal Supreme Court), decision dated Jan. 14, 2010 – III ZR 188/09, NJW 2010, 1200; BGH, decision dated Jan. 14, 2010 – III ZR 173/09, NJW 2010, 1203.

36 Cf. *Short paper of the Data Protection Conference on Joint controlling*, March 19, 2018, https://www.ldi.nrw.de/mainmenu_Aktuelles/submenu_EU-Datenschutzreform/Inhalt/EU-Datenschutzreform/KP_16_GemeinsameVerantwortliche.pdf (last visited Sept. 29, 2018).

processing of personal data[37], it is subject to the duty to assess the impact of data protection due to the "use of new technologies" pursuant to § 38 para. 1 sentence 2 BDSG-new in conjunction with Art. 37 para. 1 GDPR, so that even smaller practices with less than ten employees must appoint a data protection officer when offering remote treatment. In addition, a list of processing activities in accordance with Art. 30 GDPR must be maintained in which the steps to be taken in connection with remote treatment must be listed as individual processing steps.

Finally, what are the consequences of the GDPR for breaches of data protection provisions? On the one hand, the framework for the imposition of fines has been drastically increased and can now amount to up to EUR 20 million or 4% of the annual turnover in the case of serious infringements, for example of consent requirements or the rights of the data subject pursuant to Art. 83 para. 5 GDPR. On the other hand, pursuant to Art. 82 para. 1 GDPR, the data subject has a claim for damages against the data controller and the processor if he or she succeeds in proving material or immaterial damage resulting from a breach of data protection.

IV. CONCLUSION

The amendment to § 7 para. 4 MBO-Ä (new version) is a first important step towards enabling exclusive remote treatment, which is becoming increasingly important in the course of digitization. Fortunately, it has now been recognized that the current attempt to close off the German healthcare market from remote treatment cannot be the future. The restraint of the medical profession in this regard can only be countered, however, if more legal clarity is created regarding the interpretation of the new professional regulations and regarding the possible consequences of the impending fragmentation of professional law with regard to the prohibition of remote treatment. In addition, legislative action is absolutely necessary, as the currently applicable statutory provisions blatantly stand in the way of a meaningful offer of distance treatment services. In addition to the professional limits, the physician in charge must also take into account the new data protection regulations, which will entail a number of organizational hurdles. Against the background of stricter accountability obligations and monetary liability risks, compliance plays an increasingly important role in this context.

37 Different view: Chamber of Physicians of the State of Hesse, which advises to appoint a data protection officer in health care institutions with less than ten employees at least for a transitional period of two years, cf. *Handout on Appointment of DPO in the view of the Chamber of Physicians of the State of Hesse*, https://www.laekh.de/images/Aerzte/Neues_Datenschutzrecht/Bestellung_eines_Datenschutzbeauftragten.pdf (last visited Sept. 29, 2018).