

# SMART 2007/0059

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Study on Legal Framework of  
Interoperable eHealth in Europe

## **NATIONAL PROFILE GERMANY**

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European Commission  
Directorate General Information Society

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**1 Documents**

**1. Applicable Documents**

[AD1]	Services Contract 30-CE-0162056/00-04

**2. Reference Documents**

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 <a href="http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf">http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf</a>
[RD2]	eHealth Action Plan, Progress Report <a href="http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf">http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf</a>
[RD3]	Recommendation of the Commission on eHealth interoperability, <a href="http://ec.europa.eu/information_society/activities/health/docs/policy/200807_02-interop_recom.pdf">http://ec.europa.eu/information_society/activities/health/docs/policy/200807_02-interop_recom.pdf</a>
[RD4]	Database of European eHealth priorities and strategies (Empirica), <a href="http://www.ehealth-era.org/database/database.html">http://www.ehealth-era.org/database/database.html</a> (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, <a href="http://www.euro.who.int/observatory/Hits/TopPage">http://www.euro.who.int/observatory/Hits/TopPage</a>
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, <a href="http://www.euro.who.int/observatory/Publications/20060522_4">http://www.euro.who.int/observatory/Publications/20060522_4</a>
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, <a href="http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf">http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf</a>
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: <a href="http://ec.europa.eu/information_society/europe/i2010/docs/benchmarking/">http://ec.europa.eu/information_society/europe/i2010/docs/benchmarking/</a>

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	<p><a href="#">gp_survey_final_report.pdf</a>, Country profiles: <a href="http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm">http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm</a></p>
[RD9]	<p>Communication from the European Commission, “A Community framework on the application of patients' rights in cross-border healthcare”, 2 July, 2008, <a href="http://ec.europa.eu/health-eu/doc/com2008415_en.pdf">http://ec.europa.eu/health-eu/doc/com2008415_en.pdf</a></p>
[RD10]	<p>Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, <a href="http://ec.europa.eu/health-eu/doc/com2008414_en.pdf">http://ec.europa.eu/health-eu/doc/com2008414_en.pdf</a></p>
[RD11]	<p>European Commission, IDABC, eID interoperability for public government services (with country profiles): <a href="http://ec.europa.eu/idabc/en/document/6484/5938">http://ec.europa.eu/idabc/en/document/6484/5938</a></p>
[RD12]	<p>European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): <a href="http://ec.europa.eu/idabc/en/chapter/6000">http://ec.europa.eu/idabc/en/chapter/6000</a></p>
[RD13]	<p>Legally eHealth, Study on Legal and Regulatory Aspects of eHealth, <a href="http://www.ehma.org/projects/default.asp?NCID=140">http://www.ehma.org/projects/default.asp?NCID=140</a></p>
[RD14]	<p>Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML</a></p>
[RD15]	<p>Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, <a href="http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf">http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf</a></p>
[RD16]	<p>International Encyclopedia of Medical Law (editor: Herman Nys), <a href="http://www.ielaws.com/medical.htm">http://www.ielaws.com/medical.htm</a>, (with country monographs)</p>

## 2 Glossary

### 3. Definitions

In the course of this Study, a number of key notions are frequently referred to. To avoid any ambiguity, the following definitions apply to these notions and should also be used by the correspondents.

- **Authorization:** refers to:
  - the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
  - or: the process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
- **Data authentication:** information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
- **eHealth:** a very broad term that encompasses many different activities related to the use of the information and communication technology (ICT) for healthcare. Many of these activities focus on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care.
- **Electronic health record:** a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;
- **Electronic signature:** data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
- **ePrescription:** a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC47, issued and transmitted electronically
- **Healthcare:** the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions. Health care embraces all the goods and services designed for people's health, including preventive, curative and palliative infections, whether directed to individuals or to populations.
- **Health professional:** a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on

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the recognition of professional qualifications or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.

- **Identification:** using claimed or observed attributes of an entity (e.g. a person) to distinguish the entity in a given context from other entities it interacts with (= entity authentication).
- **Identifier:** attribute or set of attributes of an entity (e.g. a person) which uniquely identifies the entity in a given context.
- **Identity management:** Identity management (ID management) is a broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
- **Patient:** any natural person who receives or wishes to receive health care in a Member State;
- **Patient summary:** subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;
- **Registration:** process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
- **Telemedicine:** exchange of medical information from one site to another via electronic communications with the purpose to improve patients' health status.

**2.1 Acronyms**

<b>CBSS</b> .....	Crossroads Bank for Social Security
<b>EHR</b> .....	Electronic Health Record
.	
<b>eGK</b> .....(	electronic health card, Elektronische Gesundheitskarte
<b>GE)</b>	
<b>eID</b> .....	Electronic Identity
<b>eIDM</b>	Electronic Identity Management
.....	
<b>GP</b> .....	General Practitioner
<b>HiT</b> .....	Health in Transition

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<b>OCSP</b> .....	Online Certificate Status Protocol
<b>PKI</b> .....	Public Key Infrastructure
<b>NRN</b> .....	National Register Number
<b>SIS</b> .....	Social (security) Information System
<b>SSCD</b> .....	Secure Signature Creation Device
<b>SSIN</b> .....	Social Security Identification Number
<b>TTP</b> .....	Trusted Third Party

### 3 Introduction

#### 3.1 General overview of the German healthcare system

The German healthcare system is rooted in the so-called “Bismarckian System”, an invention of the late 19<sup>th</sup> century. Since then, it has been being renewed and reformed for uncollectible times. Today it can be characterized by the following principles: Organization on different levels, decentralization and self-government. These principles are closely connected. Further characteristics are the two kinds of health insurance bodies, compulsory membership on principle, co-financing system.

A recent (2004/2006) evaluation on the German healthcare system, the delivery of healthcare, financing and healthcare reforms has been drafted in the framework of “Health Care Systems in Transition” the World Health Organization on behalf of the European Observatory on Health Systems and Policies. <http://www.euro.who.int/Document/E85472.pdf>

From the German country brief, we take over the following key findings

The German health system is organized on three levels, i.e. federal, regional meaning *Länder* level or state level and corporatist level.

On the federal level the Ministry of Health is responsible for administration, international health, health policy planning, pharmaceuticals, health protection, health care, statutory health insurance, securing long-term care prevention, combating disease and biomedicine.<sup>1</sup>

On the Länder level, the *Länder's* Ministries are responsible for public health services, prevention and AIDS care, state-owned hospitals and hospital planning, supervision of health professions and their professional institutions, supervision of pharmacists and their professional institutions and supervision of the sickness funds operating in the Land., psychiatry, pharmaceuticals and illegal drugs. Additionally, they organize undergraduate medical education, health education and promotion and clinical examination of school children.<sup>2</sup>

But there are also responsibilities and legislation on corporatist level: All SHI-authorized physicians are organized in regional physicians' associations (Kassenärztliche Vereinigungen).<sup>3</sup> Autonomous sickness funds, statutory health insurance bodies, which are organized on a regional and/or federal basis, pay for the health care.<sup>4</sup> These statutory health insurance bodies, “their associations and associations of SHI-affiliated physicians have assumed the status of quasi-public corporations. These corporatist bodies constitute the self regulated structures that operate the financing and delivery of benefits covered by statutory health insurance within the legal framework.”<sup>5</sup>

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<sup>1</sup> See Busse R., Riesberg A. Health care systems in transition: Germany. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004 [RD 5], p. 29.

<sup>2</sup> See [RD 5], p. 33, 42.

<sup>3</sup> See [RD 5], p. 34.

<sup>4</sup> See [RD 5], p. 35.

<sup>5</sup> See [RD 5], p. 29.

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Furthermore on corporatist level professional ‘chambers’ (Ärzttekammern) exist for physicians, dentists, pharmacists, veterinarians, and psychologists providing psychotherapy. The membership for health care professionals in their respective chambers is obligatory.<sup>6</sup>

Since April 2007, membership in health insurance body is compulsory for everybody. Up to then, some self-employed and persons who had failed to pay contributions to the insurance were uninsured.<sup>7</sup> The new act also obliges the private health insurance bodies to offer a standard scale of charges with a minimum catalogue of benefits to a certain amount, and they are obliged to re-insure their former members.<sup>8</sup> About 120.000 people could be re-insured.<sup>9</sup> The two kinds of health insurance bodies are the non-profit statutory health insurance<sup>10</sup> bodies and the profit-orientated private health insurance bodies. Contributions for SHI are dependent on income, and not risk. Insured citizens can jointly insure non-earning spouses and children without any surcharges.<sup>11</sup> For artists and students, retired and unemployed people and employees get co-contributions.<sup>12</sup>

Citizens have a free choice between all state insurance bodies. Furthermore, those citizens whose income exceeds the threshold of 4012,50 EUR can choose if they become SHI-insured or private patients. About 90% of the population in 2007 were SHI-insured, 10% took out private health insurance.<sup>13</sup>

The non-SHI insured patient pays the set fee for the consultation directly to the physician, and patients are then directly reimbursed by their sickness funds. SHI-insured patients do not pay this fee to the physician, they only pay their 10-EUR-consulting fee and “individual health services” (IGeL), when they demand such deliveries and co-payments to certain deliveries which are not completely financed by the SHI.<sup>14</sup> SHI-accredited physicians get their fees from the Regional Association of SHI-Accredited Physicians<sup>15</sup>. The Association gets the contracted amount of money from the SHI-bodies.<sup>16</sup>

Only the SHI-authorized physicians offer ambulatory medical care. Hospitals, communities, sickness funds and others are not allowed to do so except for some purposes.<sup>17</sup> The *Länder* governments are responsible for maintaining hospital infrastructure, which they do through

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<sup>6</sup> See [RD 5], p. 37.

<sup>7</sup> See [RD 5], p. 57.

<sup>8</sup> See German Federal Ministry of Health, press release, February 7, 2008, available at [http://www.bmg.bund.de/cln\\_117/nn\\_1168294/SharedDocs/Pressemitteilungen/DE/2008/pm-07-02-08.html?\\_\\_nnn=true](http://www.bmg.bund.de/cln_117/nn_1168294/SharedDocs/Pressemitteilungen/DE/2008/pm-07-02-08.html?__nnn=true) (last visited Spet. 1, 2008).

<sup>9</sup> Data provided by the Federal ministry of health, July 2008.

<sup>10</sup> Abbrev. SHI.

<sup>11</sup> See [RD 5], p. 58.

<sup>12</sup> See [RD 5], p. 59.

<sup>13</sup> Data provided by the Federal ministry of health, July 2008.

<sup>14</sup> See [RD 5], p. 199, 183.

<sup>15</sup> Kassenärztliche Vereinigung *in German*.

<sup>16</sup> See [RD 5], p. 177.

<sup>17</sup> See [RD 5], p. 43 f.

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“hospital plans” and their funding.<sup>18</sup> The reimbursement-system is a DRG- (diagnosis-related groups-) system.<sup>19</sup> A DRG takes into account the diagnosis and its clinical severity.<sup>20</sup> Pharmaceuticals are exclusively distributed through hospital, institutional and public pharmacies and those ones which are not labelled “pharmacy-only”, by drug stores and supermarkets. Within the last years, the market was started to be “liberalized”: Permission of e-commerce under strictly regulated conditions, end of uniform prices for over-the-counter drugs, permission of more than one pharmacy per pharmacist.<sup>21</sup> There is no positive list, however not all drugs are partly reimbursable (patients have to bear a certain amount of co-payments to all drugs<sup>22</sup>). Restrictions result e.g. from the pharmaceutical directives of the Federal Committee. Those restrictions are legally binding and limit the prescription of some drugs to certain indications.<sup>23</sup>

**3.2 Use of ICT in the German healthcare sector**

A recent (2007) status of the use of ICT by *general practitioners* in Germany has been drafted in the framework of the European Pilot Study on ehealth indicators: 'Benchmarking ICT use among General Practitioners in Europe' (Empirica):

[http://ec.europa.eu/information\\_society/eeurope/i2010/benchmarking/index\\_en.htm](http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm) (last visited 2008-05-24).

From the German country brief, we take over the following key findings (p. 1):

“Germany is among the average eHealth performers in the EU27. This concerns both the availability of ICT infrastructure (computer, Internet) and the use of ICT for different eHealth related purposes. In terms of infrastructure, 99% of the German GP practices use a computer. This puts Germany on a par with 13 other EU countries where a computer availability rate of nearly 100% is reached. However, only 59% of the German GP practices are connected to the Internet. This result stays behind the EU average of 69%. Broadband connections can be found in only 40% of the GP practices, as compared to about 50% on average in the EU 27. The storage of electronic medical patient data is also quite common in Germany. At least one type of individual data is stored in 96% of GP practices. In regard to the different types of stored medical data German GP practices however score slightly below the European averages. A computer is available in the consultation room in 85% of the German GP practices. It is actually used for consultation purposes with the patients (e.g. to display a patient's file to the practitioner, to explain medical issues to the patient by means of a photo or animation or to run a Decision Support System) by 72% of the German GP practices. 77% of the German GP practices use a Decision Support System either for diagnosis or prescribing (50% on average in the EU27). In Germany the transfer of electronic patient data via networks or the Internet is not very common. Only 3% of the German GPs exchange

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<sup>18</sup> See [RD 5], p. 41.

<sup>19</sup> See [RD 5], p. 165.

<sup>20</sup> See [RD 5], p. 172.

<sup>21</sup> See [RD 5], p. 140.

<sup>22</sup> See [RD 5], p. 199.

<sup>23</sup> See [RD 5], p. 143.

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administrative data with other care providers. With only 4% of the GP practices that exchange administrative data with reimbursers, Germany also scores below the EU average of 15%. 4% of the GP practices in Germany exchange medical data with other health care providers compared to an average rate of 10%. On the other hand, already 63% of the GP practices receive results from laboratories, a result that exceeds the EU27 average of 40%. In Germany, not even 1% of the GP practices reported making use of ePrescribing. However, apart from the three frontrunners Denmark, Sweden and the Netherlands adoption levels of ePrescribing are never higher than 5%.”

Over 114000 physicians use special software in order to manage their billing procedure.<sup>24</sup> Nevertheless, this figure has to be separated from the question, if data which are relevant for the billing procedure are transmitted electronically, on data media or printed on paper.

Electronic communication among the health care service providers exchanging health related data is not naturally used by all health care service providers all over the country.<sup>25</sup>

Nevertheless, model projects have been started local communication networks in regions all over Germany, promoting the exchange of information between surgeries, hospitals and statutory health insurance funds. Main issue of this model is the communication among the health care service providers. One example is the *Gesundheitsnetzwerk* in the region of Flensburg.<sup>26</sup>

Electronic communication between the health care service providers and their patients is mainly realised by individual communication via e-mail and internet presentations of surgeries and other institutions offering health care service.

### 3.3 National eHealth strategy

The German Federal Ministry of Health regards the use of ICT as an essential means to promote the efficiency of the health system. ICT should fulfil two essential functions: First, it could improve the quality of medical care. Second, it opened up possibilities to rationalize the medical care system as 20 to 40 % of the current medical care service is made up of data collection and communication activities. In this regard, the implementation of ICT shall help to improve the efficiency of the German health system in comparison with other countries' health systems.<sup>27</sup>

The central element of Germany's current national ehealth strategy is the implementation of the electronic health card<sup>28</sup>.

The project started in 2001 when the Federal German health minister and the colleagues on *Länder*-level recognized the importance of eHealth and telemedicine and supported to set up a

<sup>24</sup> See <http://daris.kbv.de/daris/link.ASP?ID=1003737294> (last visited Sept. 6, 2008).

<sup>25</sup> See Federal Health Ministry, Gesundheitspolitische Informationen 2007, iss. 4, page 2, available at [http://www.bmg.bund.de/cln\\_110/nn\\_1168300/SharedDocs/Publikationen/DE/GPI/gpi-04-07,templateId=raw,property=publicationFile.pdf/gpi-04-07.pdf](http://www.bmg.bund.de/cln_110/nn_1168300/SharedDocs/Publikationen/DE/GPI/gpi-04-07,templateId=raw,property=publicationFile.pdf/gpi-04-07.pdf) (last visited Sept. 6, 2008).

<sup>26</sup> See Zillich, Deutsches Ärzteblatt/PraxisComputer 2004, iss. 3, p. 12, available at <http://www.aerzteblatt.de/V4/archiv/pdf.asp?id=43258> (last visited Sept. 6., 2008) for further information.

<sup>27</sup> See [http://www.bmg.bund.de/nn\\_604258/DE/Themenschwerpunkte/Gesundheit/gesundheitsnode,param=.html\\_\\_nnn=true](http://www.bmg.bund.de/nn_604258/DE/Themenschwerpunkte/Gesundheit/gesundheitsnode,param=.html__nnn=true) (last visited June 26, 2008).

<sup>28</sup> Electronic health card, *Elektronische Gesundheitskarte* in German, abbrev. eGK).

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German telematic platform to be realised by the GEMATIK-Group.<sup>29</sup> At the moment, it is planned to issue the electronic health card to all insureds in the region of North-Rhine early in 2009 and go on issuing the cards in neighbouring regions after a successful launch in the region of North-Rhine.<sup>30</sup>

The German Federal Minister of Health outlined the following points on the issue of the electronic health card:<sup>31</sup>

“This IT-System will link 82 million insured, more than 100,000 office-based physicians, round about 60,000 dentists 22,000 pharmacies, 2,200 hospitals and roughly 300 private and statutory health insurers.

The electronic health card will hold all of the life-saving data that are needed in case of emergency. It will allow health professionals to store a medication history and keep a patient record. Thanks to this card, every physician - anywhere in Germany - will have easy access to the health details of their patients and be able to avoid treatment errors. It goes without saying that the storage of these data will have to satisfy the most stringent security precautions.

The e-health card project currently is the biggest of its kind in the world. By providing better information while reducing paperwork, it will help avoid errors, improve quality and care coordination and generate major savings.”

The electronic health card project shall provide several functions and therefore several eHealth measures shall be implemented at the same time:

- enabling administration and accounting. In this regard, the electronic health card partly simply replaces the conventional health insurance card. Those functions are planned to be non-voluntary.
  - Especially Insurance details, including information on patients’ contributions shall be stored.<sup>32</sup>
  - Furthermore, the Entitlement to treatment in other EU member states (replacing forms such as the E111) shall be stored.<sup>33</sup>
- eGK shall also replace prescriptions on paper and store paperless prescriptions.<sup>34</sup> In so far, eGK goes beyond what it’s possible with the conventional insurance card today. Paperless prescriptions shall be non-voluntary.

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<sup>29</sup> For further description see 3.7 Overview of relevant legislation, p. 18.

<sup>30</sup> See <http://www.gesundheitskarte-rlp.de/component/content/article/124-pressespiegel/82-nordrhein-wird-durchstichregion.html> (last visited Sept. 1, 2008); <http://www.dlz-agrarmagazin.de/?redid=220097> (last visited Aug. 31, 2008); [http://www.bmg.bund.de/cln\\_117/nn\\_1168248/SharedDocs/Standardartikel/DE/AZ/E/Glossar-Elektronische-Gesundheitskarte/Testphase.html](http://www.bmg.bund.de/cln_117/nn_1168248/SharedDocs/Standardartikel/DE/AZ/E/Glossar-Elektronische-Gesundheitskarte/Testphase.html) (last visited Aug. 31, 2008).

<sup>31</sup> Quoted from the German federal health minister’s speech in June 2006, available at [http://www.germany.info/relaunch/info/press/releases/pr\\_01\\_27\\_06.htm](http://www.germany.info/relaunch/info/press/releases/pr_01_27_06.htm) (last visited Aug. 31, 2008).

<sup>32</sup> See [http://www.bmg.bund.de/cln\\_117/nn\\_1168300/sid\\_9FC0BBDF415B18906F95B67106F12597/SharedDocs/Publikationen/EN/Broschueren/G-430-en.html?\\_\\_nnn=true](http://www.bmg.bund.de/cln_117/nn_1168300/sid_9FC0BBDF415B18906F95B67106F12597/SharedDocs/Publikationen/EN/Broschueren/G-430-en.html?__nnn=true), p. 7 (last visited Sept. 6, 2008).

<sup>33</sup> See [http://www.bmg.bund.de/cln\\_117/nn\\_1194096/SharedDocs/Standardartikel/DE/AZ/E/Glossar-Elektronische-Gesundheitskarte/Administrative-Funktionen.html](http://www.bmg.bund.de/cln_117/nn_1194096/SharedDocs/Standardartikel/DE/AZ/E/Glossar-Elektronische-Gesundheitskarte/Administrative-Funktionen.html) (last visited Aug. 31, 2008).

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- storing of medical reports. In this regard, the features of the e-health card will be voluntary.
  - Record of medicines taken
  - Information for emergencies (blood group, chronic organ dysfunction, allergies, heart disease, dialysis, asthma, etc.)
  - Electronic patient's records (recent diagnoses, operations, inoculations, scans, etc.)
  - Capability for storing electronic memos (notices to physicians, etc.)
  - Information for patients about medical treatment they have received and the estimated cost
  - Storage of data provided by patients themselves (diabetes diaries, reference to any advance directives, instructions on organ donation, etc.)<sup>35</sup>

In order to be able to read the stored data, chemists and practitioners need special identity cards.<sup>36</sup> They and the patients get PINS and the patient shall determine who should be able to read which part of her data. That's why the Ministry hopes the card will give patients greater responsibility and a greater role in the health system.<sup>37</sup>

Two different phenomena are characterizing the German eHealth market: Private Service Providers, offering medical advisory services via telephone and some offering telemonitoring and/or electronic patient files.<sup>38</sup>

The other phenomenon of telemedical applications are private and public hospitals offering telemedical services.<sup>39</sup> Patients have the possibility to take their vital signs and to transfer these information to their hospital where the information are evaluated and interpreted by medical Experts and – if necessary – advise the patients which measures of therapy to take or start coordinating measurements of therapy of several health care service providers.

Subsequently, the data is transmitted to the patient's practitioner. Application fields are cardiac arrhythmia, electrocardiogram monitoring in order to prevent or detect cardiac infarction and apoplectic stroke. Other patients transmit their blood sugar level so that the medical staff can assist them finding the right entrainment of their insulin unit. Most of these services are provided within model projects and are limited to certain regions.

These ICT-applications are restricted to certain areas and institutions respectively. The central aim of the GEMATIK is setting technical standards, so that an infrastructure be established, which can serve as a central basis to link up all acteurs of health care for similar applications.

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[http://www.bmg.bund.de/cln\\_117/nn\\_1168300/sid\\_9FC0BBDF415B18906F95B67106F12597/SharedDocs/Publikationen/EN/Broschueren/G-430-en.html?\\_\\_nnn=true](http://www.bmg.bund.de/cln_117/nn_1168300/sid_9FC0BBDF415B18906F95B67106F12597/SharedDocs/Publikationen/EN/Broschueren/G-430-en.html?__nnn=true), p. 7 (last visited Sept. 6, 2008)

<sup>35</sup>

[http://www.bmg.bund.de/cln\\_117/nn\\_1168300/sid\\_9FC0BBDF415B18906F95B67106F12597/SharedDocs/Publikationen/EN/Broschueren/G-430-en.html?\\_\\_nnn=true](http://www.bmg.bund.de/cln_117/nn_1168300/sid_9FC0BBDF415B18906F95B67106F12597/SharedDocs/Publikationen/EN/Broschueren/G-430-en.html?__nnn=true), p. 8 f. (last visited Sept. 6, 2008).

<sup>36</sup> See ch. 7.3 on Authentication of healthcare professionals - elektronischer Heilberufsausweis (eHBA)/electronic Health Professional Card (eHPC) on p. 39 for further information on these cards.

<sup>37</sup> <http://www.bundesgesundheitsministerium.de/> (chose the Union Jack button and follow the link *health* on the left, and then *The electronic health card* within the text).

<sup>38</sup> See Häcker/Reichwein/Turad, *Telemedizin*, 2008, p. 91 f. for a table on current supplies.

<sup>39</sup> See Häcker/Reichwein/Turad, *Telemedizin*, 2008, p. 93 ff. for a survey on the different programmes.

**Study on Legal Framework of Interoperable eHealth in Europe****3.4 Regulatory framework for patients' summaries**

Electronic patients' summaries shall be established through the electronic health card. In so far, the eGK is to be used for access to two different kinds of data collections: data that are necessary and useful in case of emergency according to art. 291a paragraph 3 sentence 1 n° 1 Social Code Book V (SGB V)<sup>40</sup> and data within an electronic patient record (*or file*, elektronische Patientenakte, EPA) according to article 291a par. 3 sentence 1 n° 4 SGB V. At the end of the test phase, the electronic health card-system must provide these applications. Nevertheless, at the moment, only the emergency data storage is tested.<sup>41</sup> Medical data to be used in cases of emergency must be accessible without using networks, meaning that key medical data will be stored directly on the electronic health card (art. 291a n° 1 SGB V). It is up to the patient's decision to get his doctor store the relevant data or store those data himself, but nobody is forced to doing so and the consent is revocable, art. 291a par. 3 sentence 3, 4 SGB V. Medical data, that are not that important for medical assistance in emergency cases, can also be stored, e. g. in central or in non-central electronic data processing units or also directly on the electronic health cards (n° 4). Those data make up the electronic patient file<sup>42</sup> shall inform about the facts, that and when which diagnostics, lab results have been made and which therapy is administered. The patient has to consent in the electronic-health-card-based data storage, regardless whether the data is stored central or non-central on external servers or directly on the card, article 291a par. 5, sentence 1 SGB V.

Furthermore, article 10 of the medical professional code rules the doctor's duties concerning the documentation of diagnosis and taken measures. Doctors have to make "necessary" documentations. There are several possibilities: paper based documentation and digital documentation. If the data are stored on electronic processing units within the institution that collects the data, e. g. the doctor in his surgery or the hospital, special rules in art. 10 par. 5 of the medical professional code and recommendations of the German medical assembly have to be observed.

Pursuant to general data storage rulings in article 9 of the Federal Data Protection Act<sup>43</sup> and article 10 par. 5 of the medical professional code the digital external storage of data requires actions to protect the data against unauthorised modification, destruction or utilization. The German Medical Assembly has published recommendations concerning digital data storing operations<sup>44</sup> and suggests use of digital signatures, vpn-clients, qualified digital time stamps.

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<sup>40</sup> Sozialgesetzbuch V *in German*, *abbrev.* SGB V, Act on Statutory Health Insurance, Act from Dec. 20,1988, Federal Law Gazette (Bundesgesetzblatt) BGBl. I 1988, p. 2477, as last amended by Act from May 28, 2008, BGBl. I 2008, p. 874..

<sup>41</sup> See [http://www.gesundheitskarte-wolfsburg.de/index.php?option=com\\_content&task=blogcategory&id=19&Itemid=79](http://www.gesundheitskarte-wolfsburg.de/index.php?option=com_content&task=blogcategory&id=19&Itemid=79) (last visited Sept. 1, 2008); <http://www.gesundheitskarte-rlp.de/> (last visited Sept. 1, 2008).

<sup>42</sup> Elektronische Patientenakte *in German*, *abbrev.* ePA.

<sup>43</sup> Bundesdatenschutzgesetz, BDSG, renewed Jan. 14, 2003, BGBl. I 2003, p. 66, as last amended by Act from Aug. 22, 2006, BGBl. I 2006, p. 1970

<sup>44</sup> Empfehlungen zur ärztlichen Schweigepflicht, Datenschutz und Datenverarbeitung in der Arztpraxis, *published in* 105 Deutsches Ärzteblatt (DtÄBl.) 19, p. A1026 of May, 9<sup>th</sup> 2008, *available at* [http://www.bundesaerztekammer.de/downloads/Empfehlung\\_Schweigepflicht\\_Datenschutz.pdf](http://www.bundesaerztekammer.de/downloads/Empfehlung_Schweigepflicht_Datenschutz.pdf) (last visited Sept. 1, 2008) *and technical attachment* Technische Anlage, *available at* <http://www.aerzteblatt.de/v4/plus/down.asp?typ=PDF&id=2316> (last visited Sept. 1, 2008).

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Beside this documentation under direct supervision of doctors and other health care service providers, it will be possible to file data concerning treatment, diagnoses, etc. by means of the electronic health card and the Health Professional Card<sup>45</sup>. Relevant data protection is ruled in art. 291a SGB V. The data within the electronic patient file are in charge of the patients in so far as they decide by themselves, if data are stored at all, which data to be stored and whom to grant access. The access to these data is restricted by a two-key-principle: In general, access is only possible, if the reader uses an electronic health professional card or an equivalent and the patient admits access by entering his PIN. An exemption from this is made for the so called *Patientenfach*, the patient's storage area: art. 291a SGB V guarantees that the patients get access to this storage area. They will be able to store their blood sugar levels or keep a diary on their dizzy spells in this storage area for instance.<sup>46</sup> Up to now, there are plans that the patients will be able to store the data on the eGK or by means of their eGK by themselves via the so called *eKiosk*, *EKiosks* are special card reading and internet connected terminals which enable the patients to access their data out of a physician's control.<sup>47</sup>

This fact sets ePA's apart from so called personal eGA's (persönliche elektronische Gesundheitsakte, personal electronic health records), a service offered by a third party, (private) service providers. Those data are in charge of the patients, too. . Those records are not ruled by the strict rules in art. 291a SGB V, but only by article 68 of SGB V – regulating the financial support of electronic storage of patients' data in general – and the statutes of the health insurance companies. The insurance health companies may grant the insured party financial support, when patients use third party services to store and transmit their health related data. Each insurance company decides by itself in its statutes if such contributions towards the costs for the third party services are granted. Up to now, not very many statutory health insurance companies have introduced such services.<sup>48</sup> The health insurance companies have developed different models: Some companies make contracts with particular third party service providers. Only if the patients and insured parties use services of these third party service providers, they can claim the contributions.<sup>49</sup> Others refrain from service contracts, but limit the contributions to a certain percentage and amount, e.g. 80 % or 150 EUR, and demand the use of the stored data by the patient's physicians to a great extend.<sup>50</sup>

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<sup>45</sup> See 7.3 - Authentication of healthcare professionals - elektronischer Heilberufsausweis (eHBA)/electronic Health Professional Card (eHPC), p. 39 for further details.

<sup>46</sup> See <http://www.heise.de/newsticker/Elektronische-Gesundheitskarte-Befreites-Dokument-wirft-Fragen-auf-/meldung/81575> (last visited Sept. 5, 2008).

<sup>47</sup> See <http://www.heise.de/newsticker/Elektronische-Gesundheitskarte-Befreites-Dokument-wirft-Fragen-auf-/meldung/81575> (last visited Sept. 5, 2008).

<sup>48</sup> See for some examples BKK Bertelsmann, statutes art. 12, n° 13, available at <http://default.kunden.ogvit.de/tmp/pdftohtml549626305.html> (last visited Sept. 1, 2008); KKH, statutes article 29i, available at <http://www.kkh.de/fileserver/kkh2006/BROCHURES/Broschuere584.pdf> (last visited Sept. 1, 2008). .

<sup>49</sup> So does BKK Bertelsmann.

<sup>50</sup> So does KKH.

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**3.5 Regulatory framework for telemedicine**

The regulatory framework for telemedicine is not summarized within one code but is made up of regulations within several codes. One important part of telemedicine dominating current media reporting is the issue of the electronic health card which is regulated in art. 291a SGB V. According to art. 291a SGB V, infrastructure for telemedical applications is to be set up by help of the GEMATIK. The GEMATIK defines standards and certifies products of third party technique providers. This infrastructure will be open to be used by telemedical applications which are not bound to the eGK. But up to now, such concrete application scenarios do not exist. This telemedical infrastructure supports fulfilling the regulation of art. 67 SGB V which states that paper based information and communication is to be transformed into computer based forms and electronic transmission. The national confederations of regional associations of health care providers and SHI-funds shall bear all the costs. Although the main part of the costs will emerge from infrastructure which will be necessary in surgeries, pharmacies, hospitals etc., the SHI-funds will save the money. A special rule on the distribution of the costs in art. 291a art. 7-7e SGB V regulates this imbalance. In art. 87 SGB V, the introduction of the electronic forms for prescriptions of medicine and other medical prescriptions is laid down.

There is only few other regulatory framework especially made for telemedicine. Mostly, the general provisions have been adapted to telemedical applications. The provisions that have to be observed when telecommunication and teledocumentation are used are data protection laws (Data protection acts of the Federation and the German *Länder*) and rules on informational self-determination within the Basic Law. Telemedical applications concerning telecooperation and expertise via telemedia are covered by the law of medical profession and professional liability.

One major legal obstacle to practice (a certain manner of) telemedicine derives from the professional code of conduct. The code requires that physicians do not diagnose and start therapy if they have not examined the patients personally. A physician who practises offending the code of conduct does not practise in line with the professional standard. Therefore, liability for damages may arise. Of course, this is no obstacle for telemedical-applications which solely support the treatment. For further details, please see ch. 6.3 on Ban on Tele-treatment, p. 34.

Another obstacle is the observance of personal data protection law. The general provisions within the Federal and the state data protection acts have to be observed. Furthermore, specific provisions for the data protection within the Social Code Books are applicable. Those rules expressly refer to access and process of health related data as they are supposed to be accessible by means of the electronic health card. The problems of data protection law are closely connected to the health personnel's observance of medical secrecy. This issue is supposed to be solved by issuing the Health Professional Cards. Only the patient himself has access to his data, without needing a second person or card. All other persons who want to have access must be authorized by the patient (either in general – if technically registered within the IT-system, e.g. by means of an electronically recorded ticket which documents permissions for access – or case by case by using his PIN) and must authenticate themselves

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by their Health Professional Cards. For further details, please see chapter 7 on Identity management in the health sector on p. 38 of this report.

Application of product liability rules may be relevant but the use of sophisticated technical devices is not necessarily more frequent in telemedicine than in the traditional hospital environment.

### 3.6 Regulatory framework for electronic prescriptions

Up to now, the electronic prescription has not already been introduced all over the country. But in connection with the model project of the introduction of the electronic health card, the electronic prescription is planned to be started. Therefore, rules have been stated in several laws. Article 291a SGB V determines that the electronic health card system shall be able to support electronic prescriptions. Nevertheless, electronic prescriptions could also be realized by means of other techniques, the technique using eGK is not obligatory. Several acts previously only ruling paper based prescriptions have already been adapted to the new possibilities to use electronic prescriptions. In art. 87 SGB V, the introduction of the electronic forms for prescriptions of medicine and other medical prescriptions is laid down. For more details, please see Chapter 8 on Electronic prescription on p. 43 of this report.

### 3.7 Overview of relevant legislation

The most relevant legislation concerning telemedicine and ehealth applications is art. 291a SGB V<sup>51</sup>. This article is the basis for all telemedical applications which require the electronic health card. Other telemedical applications which do not use the electronic health card, are possible, but they are not ruled by art. 291a SGB V. The Social Code Book regulates all SHI-related issues: Statutory health insurance is dealt with in Social Code Book V (SGB V), amended and supplemented by numerous reform laws. Books IV and X define responsibilities and administrative procedures common to all social insurance agencies<sup>52</sup> and thereby contain special provisions on data protection rules which have to be observed by the insurance bodies and administrative actors. Furthermore, the laws relating to social security (in particular the provisions related to the insurance card and the use of the insurance identification number in art. 290 and 291 SGB V) are applicable to the electronic health card, which shall take over all functions of the present insurance card. Art. 291a par. 7 and art. 291b SGB V establish the Society for Health Telematics (GEMATIK – Gesellschaft für Telematik mbH). The GEMATIK is a centre for planning, implementing and managing the infrastructure for applications by means of the electronic health card. The GEMATIK is founded by the head associations of the actors in the German healthcare system. According to art. 291b SGB V, the GEMATIK is responsible for setting standards on telematic infrastructure as far as the electronic health card, health professional card and appropriate terminals are concerned. The

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<sup>51</sup> Sozialgesetzbuch, abbr. SGB. Social Code Book V on Statutory Health Insurance, Act from Dec. 20, 1988, BGBl. I 1988, p. 2477, as last amended by Act from May 28, 2008, BGBl. I 2008, p. 874.

<sup>52</sup> See [RD 5], p. 40.

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GEMATIK is obliged to observe data protection rules. The GEMATIK is responsible for certification and licensing components and services within the telematic infrastructure. Further relevant legislative texts related to the practice of health care, in particular the Federal Medical Regulation Act<sup>53</sup>. Rules on civil and criminal liability are noted in Civil Code<sup>54</sup> and in Criminal Code<sup>55</sup> respectively. The laws on the protection of privacy in the context of personal data protection on state level and federal level<sup>56</sup> are of particular interest to eHealth. See ch. 5 on Processing of personal health data on p. 27 for further details. Legislation with regard to electronic documents and electronic signatures within art. 126a of the German Civil Code and the Act on signatures<sup>57</sup> is relevant as well.

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<sup>53</sup> Bundesärzteordnung, renewed by April 16. 1987, BGBl. I 1987, p. 1218, as last amended on Dec. 2, 2007, BGBl. I 2007, 2686.

<sup>54</sup> Bürgerliches Gesetzbuch, BGB, renewed by Jan. 2. 2002, BGBl. I 2007, p. 42, as last amended on March 26. 2008, BGBl. I 2008, p. 441.

<sup>55</sup> Strafgesetzbuch, StGB, renewed by Nov. 13.1998, BGBl. I 1998, p. 3322, as last amended on March 11. 2008, BGBl. I 2008, p. 306.

<sup>56</sup> Bundesdatenschutzgesetz, BDSG, renewed Jan. 14, 2003, BGBl. I 2003, p. 66, as last amended on Aug. 22, 2006, BGBl. I 2006, p. 1970.

<sup>57</sup> Signaturgesetz, SignaturG, Act of May 16, 2001, BGBl. I 2001, p. 876.

## 4 Regulatory framework for the healthcare profession

### 4.1 Legal conditions for the practice of healthcare

The regulation of the admission to the professions of physicians, dentists, pharmacists and veterinary surgeons in the healthcare sector in Germany is a competence of the Federation, art. 74 par. 1 n° 19 *Basic Law*. The Federal Medical Practitioners' Act<sup>58</sup> rules the admission to the profession of physicians. Physicians need to be licensed to practise as doctors, art. 2 par. 1 BÄO, so called *Approbation*. It is also possible to practise on the basis of a temporary licence or a licence that is restricted to specific activities, art. 2 par. 2 BÄO. In order to implement Council Directive 2005/36/EG, exemptions from the need of a licence are made for nationals of European Member States or nationals of a Signatory State which has granted a reciprocal treaty right to Germany and the European Community or to Germany and the European Union and who offer their medical service temporarily and occasionally. They only have to notify their service, art. 2, par. 3 BÄO. Another exception is made for physicians in areas close to the borders, if special intergovernmental contracts have been made, art. 2, par. 4 BÄO.

The licence has to be granted if the demands in art. 3 are fulfilled. These are: German nationality according to art. 116 of the Basic Law or an equivalent (especially EU-Member state nationality), no behaviour in blameworthy manner rendering the aspirant unreliable or unworthy to practise medicine, fitness to practise medicine, medical examination after 6 years of university studies of medicine including eight to ten months of practical training (or equivalent, e.g. medical training completed in EU-Member-States of equal value), and knowledge of German as deep as necessary to practice medicine.

This licence or temporary licence resp. ensures that exclusively physicians offer medical care services under the title “Arzt” (physician). The medical profession under the title “Arzt” is left to licensed, (“approbierte”) or temporary licensed persons. But unlike according to the French, Austrian or Swiss law, non-licensed persons may offer therapeutical service, too, but are not allowed to practice as “doctors” or “physicians” (“Art”). They may practise as “Heilpraktiker” (non-medical practitioners). But they also need a licence according to art. 2 par. 1 lit. i of the First Executive Decree of non-medical practice act<sup>59</sup>.

The medical care services that are left to licensed physicians comprise diagnosis and therapy. According to art. 3 par. 6 BÄO, in order to get the licence to practise medicine, the applicant has to submit: a certificate to proof nationality, an officially certified copy of competence or education, official documents presenting information about non blameworthy behaviour, certificate concerning the applicants health, an official document confirming the accordance of the certificate of competence with the regulations of the BÄO, and – if relevant – information or official documents on the contents of education outside Germany.

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<sup>58</sup> Bundesärzteordnung, *abbrev.* BÄO, *available* at [http://www.bmg.bund.de/cln\\_117/nn\\_1200414/SharedDocs/Downloads/DE/GV/GT/Gesundheitsberufe/7-Bundesaerzteordnung-.templateId=raw.property=publicationFile.pdf/7-Bundesaerzteordnung-.pdf](http://www.bmg.bund.de/cln_117/nn_1200414/SharedDocs/Downloads/DE/GV/GT/Gesundheitsberufe/7-Bundesaerzteordnung-.templateId=raw.property=publicationFile.pdf/7-Bundesaerzteordnung-.pdf) (last visited Sept. 2, 2008).

<sup>59</sup> 1. Durchführungsverordnung zum Gesetz über die berufsmäßige Ausübung der Heilkunde ohne Bestallung, as last amended BGBl. I 2002, p. 4456, 4458.

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According to art. 10 BÄO, the licence to practise medicine only temporary may be issued on application to persons who prove that they have completed training for medical profession. This license may only be issued on a revocable basis and for a total period of medical activity and may only be renewed to enable the applicants to finish their training as specialist doctors or if they fulfill certain alien law-connected characteristics.

Similar regulations to BÄO exist for dentists and veterinary surgeons.

The regulation of the education leading to the profession of a physician in Germany is a competence of the Federation. It is ruled within a statutory instrument by the German Ministry of Health on the basis of article 4 BÄO. The Ministry has enacted the statutory instrument *Approbationsordnung für Ärzte* (abbrev. ÄAppO, latest update in 2002<sup>60</sup>).

According to art. 1 par. 2 ÄAppO, medical education consists of six years of studies of medicine including 48 weeks of practical training.

The pursuance of the vocation as a physician is regulated by the laws of the *Länder*. Each physician has to be member of the Medical Association<sup>61</sup> in his region. Because of that, he is subject to the professional law of his Medical Association, the professional code of conduct<sup>62</sup> which codifies the physicians' professional duties by setting rules of the physicians' standard of treatment and codifying their rules of conduct.

### 4.2 Control over the practice of medicine

The practice of the physicians, dentists, veterinary surgeons, and psychological psychotherapists in Germany regarding the law of profession is supervised by the Medical Associations. Each medical branch has its own medical association, and generally, each one of them exists in all German *Länder*<sup>63</sup>. According to the Medical Associations Acts<sup>64</sup>, each physician etc. has to be member of the medical association in his area and branch. Nationals of other EU Member States who are established as physicians in a Member State are entitled to provide medical services in Germany. They also have to be members of the Medical Association if they are not only practising temporarily in Germany. If German physicians practise in Germany and start practising in another EU Member State at the same time, they have to announce that to their German Medical Association.

As its member, the physician is subject to the Medical Association's professional code of conduct. Furthermore, the members have to obey the Medical Associations Acts. These acts are ruling how to handle professional offences. Therefore, each member carrying out his profession has to notify this to the Medical Association in order to enable the Association to supervise the compliance with the professional code of conduct. Offences against the code of

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<sup>60</sup> Available at [http://www.bmg.bund.de/cln\\_117/nn\\_1200414/SharedDocs/Downloads/DE/GV/GT/Gesundheitsberufe/3-Approbationsordnung-fuer-aerz-,templateId=raw,property=publicationFile.pdf/3-Approbationsordnung-fuer-aerz-.pdf](http://www.bmg.bund.de/cln_117/nn_1200414/SharedDocs/Downloads/DE/GV/GT/Gesundheitsberufe/3-Approbationsordnung-fuer-aerz-,templateId=raw,property=publicationFile.pdf/3-Approbationsordnung-fuer-aerz-.pdf) (last visited Sept. 2, 2008).

<sup>61</sup> Ärztekammer in German.

<sup>62</sup> Berufsordnung in German.

<sup>63</sup> In North-Rhine/Westphalia, there are two associations for one branch; some associations have only one for all the 5 eastern New Länder, e.g. the Psychotherapeutenkammer Ostdeutschland.

<sup>64</sup> Kammergesetz für die Heilberufe (HKG) in German. This is federal state law, which results again in 16 of these Acts, one for each German Land.

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conduct may cause the following consequences: The Medical Association can rebuke physicians for a non-serious offence against the code of conduct, e.g. art. 64 of the Medical Associations Act of Lower Saxony<sup>65</sup>.

In case of serious offences, the infringement comes before the Professional Court of Conduct, e.g. art. 63 of the Medical Associations Act of Lower Saxony. In most of the German *Länder*, these Courts are part of the jurisdictions of the divisions of the state courts for administrative or ordinary jurisdiction. Only three *Länder* have introduced independent Courts of conduct.<sup>66</sup> The trial starts before the Professional Court of Conduct. Afterwards, the court of appeal, the *Landesberufsgericht*, makes the final decision. There is no third instance on federal level, which could ensure uniform jurisdiction all over the country. This results in jurisdiction that differs from *Land to Land*.<sup>67</sup> The physician could be reprimanded or be fined up to an amount of 50.000 EUR or could forfeit his eligibility for membership of the Medical Association's Assembly.

The Court may also judge that the physician has behaved in a blameworthy manner which renders him unworthy or unreliable for the practice of medicine and which has to result in the most severe sanctioning: the revocation of the license to practice medicine. It's within the competence of the German *Länder* to determine the authority that is competent to revoke the license. This competence is situated either at the Medical Association or at specially founded vehicles, like administration unions<sup>68</sup>, or at other administrative authorities<sup>69</sup>.

The Professional Code of Conduct shall ensure the upholding of the reputation, standards of discretion, probity and dignity of the members of the Order.

It contains the rules concerning the further vocational training, quality assurance, duty to inform the patient, medical secrecy and handing over of medical data to colleagues, duty to document diagnosis and therapy, conduct within physician-patient relationship, application of new measurements of therapy, dealing with ethical questions concerning abortion and medical research and death, shared praxis and corporation with other branches of health care providers, physicians as salaried employees, standby duty, advertising.

The rules of the Professional Code of Conduct differ from the rules within the disciplinary law of the Regional Association of SHI-Accredited Physicians which bind the physicians to the economically influenced rules on the SHI-accredited physician services. The utilization review committee of the Regional Association of SHI-Accredited Physicians, which are made up of an equal number of physicians and sickness fund representatives as well as an impartial chairman, is responsible for controls over the service provision and prescriptions *per capita*.

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<sup>65</sup> Act of Dec. 8, 2000, Official Journal of Lower Saxony (Nds. GVBl.) 2000, p. 301, last updated by act from May 18, 2006, Nds. GVBl. 2006, p. 209, available at [http://www.aekn.de/web\\_aekn/bibliothek.nsf/WebDocumentView/F44B714D87E6B941C1257180002FF124/\\$FILE/kamm\\_ergesetz.pdf](http://www.aekn.de/web_aekn/bibliothek.nsf/WebDocumentView/F44B714D87E6B941C1257180002FF124/$FILE/kamm_ergesetz.pdf) (last visited Sept. 2, 2008).

<sup>66</sup> So did e.g. Lower Saxony by founding Gerichtshof für die Heilberufe – court of justice for the health care professions.

<sup>67</sup> Hoppe/Schirmer, in: Wenzel, Handbuch des Fachanwaltes Medizinrecht, 2007, ch. 9, recital 35, p. 824.

<sup>68</sup> In Lower Saxony, e. g. the competent authority is the Niedersächsische Zweckverband zur Approbationserteilung (NiZZA), art. 12 par. 4 BÄO, art. 1 n° 1 lit. a and Verordnung zur Übertragung von staatlichen Aufgaben auf die Kammern für die Heilberufe, act from Nov. 25, 2004, Nds. GVBl. 2004, p. 516,

<sup>69</sup> For parts of Bavaria, the District Government of Upper Bavaria is competent.

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To escape financial penalties, the physician has to justify the higher rates of utilization.<sup>70</sup> The decision of the utilization review committee is appealable.

**4.3 Professional liability**

Professional liability of physicians is not regulated within special acts. Consequently, the professional liability of a physician is, with the exception of disciplinary liability, currently not governed by special laws in Germany, but derives from general laws of compensation of damage. The leading rules for liability of torts are articles 823 par. 1, 823 par. 2, 831 and 839 of the German Civil Code. In addition to these general rules on compensation of damage, the courts have developed special rules on medical professional liability. Liability of contract and liability of torts do coexist. Non-contractual or tortious liability is especially relevant when services are rendered to a patient who is not in a position to give consent to treatment, e.g. because of his medical problem or his minority. Nevertheless, in these cases, the parents or other representatives may have completed a contract for the benefit of a third party which builds up the foundation for contractual liability. In the case of damage to a third party, contractual liability is applicable if a contract with protective consequences for third parties has been made. One example is the protection of the unborn child on the basis of the contract on the delivery with the pregnant woman.

Characteristic of medicine in all its forms is that a patient is confronted with more than one physician working as a medical team. This often complicates the determination of responsibilities when an accident happens. Matters are still complicated because the physician may employ assisting staff (then liability of torts of the employed staff according to art. 823 par. 1 and 2 of the German Civil Code and the physicians' liability according to art. 831 is applicable). Also the physician him- or herself may act under differing statutes: as an employee (then liability according to art. 823 and employer's liability according to art. 831), a civil servant (physicians liability: art. 823, liability of the employing body), or as a private service provider on his own account (only physician's liability according to art. 823). The difference between these situations is directly relevant for the nature and the parties to the contract with the patient and consequently also for the discussion about liability for damages. Civil liability of a physician arises when an obligation is not fulfilled. Obligations originate either from a contract or from tort. The contract for medical services exists between a physician and his patient or between the employer of a physician (a hospital) and a patient. If the physician has referred the patient to another physician, e. g. a specialist, a second contractual relationship is build up between the latter physician and the patient.

Both the civil liability and the criminal liability of the physician for damage or injury caused by improper performance are possible. There are two sources of improper performance: medical malpractice on the one hand and a lack of patient information and education on the other hand.

The demand of sufficient patient information is rooted in the patient's fundamental rights. The importance of the patient information derives from its function as informational basis of the

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<sup>70</sup> See [RD 5], p. 182.

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patient's consent to the treatment. In Germany, the patient's consent is part of his self-determination. The self-determination is constitutionally enshrined in the guarantee of human dignity (sentence 1 of Article 1 par. 1 of the Basic Law), in the general right of personality (Article 2 par. 1 in conjunction with sentence 1 of Article 1 par. 1 of the Basic Law) and, most concretely of all, in the right to physical integrity (sentence 1 of Article 2 par. 2 of the Basic Law)<sup>71</sup>.

One problem of current interest is the advance health care directive. Such a directive may be stored as part of the data the ehealth card providing access according to art. 291a sec. 3 n° 5 SGB V. Approximately eight million Germans already have written such a directive. But up to now, the legal status for physicians treating a patient at the potential end of the patient's life is not clear. At the moment the German Parliament is debating a bill concerning the binding force of advance health care directives. The question which shall be answered is whether a physician is freed from civil and criminal liability for the death of a patient if the physician has acted in compliance with the patient's advanced directive. The bill tends to answer this question in the affirmative. Treatment of healthy people like cosmetic surgery or participation in clinical trials requires more intensive information.

The lack of patient information<sup>72</sup> can derive from insufficient information on the physician's diagnosis and on the course of the measurements of therapy and its risks. Both build up the foundation for the patient's consent. This consent can only be valid, if an *informed* patient consents to the treatment. And therefore, he/she must know what is in store for him or her without any treatment and under measures of treatment according to the physician's proposal. The physician's information must enable the patient to anticipate the effect of the treatment on his personal situation of life. The information on the measurements of therapy include that the physician explains how medical *apparatus* work and how it is affecting the patients health.

In order avoid liability caused by flawed diagnosis, the physician has to diagnose at all and has to do this as conscientious as required by the professional standard.

In particular wrong measurements of therapy are qualified as medical malpractice. Taken measurements are not proper if the methods are antiquated or are not the most saving ones or if the physician does not know the measurement. The physician also has to supervise the patient taking the prescribed medicine. Following the concrete treatment, the physician has to ensure the proper aftercare.

Furthermore the physician must care for a proper organizational system which ensures that the physician and his team treat the patient conscientiously.

During the whole process of the treatment, the physician must document his diagnosis and the taken measurements of therapy and the course of therapy, his instructions to the patient and all irregular incidents.

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<sup>71</sup> See the opinion of the Nationaler Ethikrat on the advance health care directive from 2005, available in English at [http://www.ethikrat.org/\\_english/publications/Opinion\\_advance-directive.pdf](http://www.ethikrat.org/_english/publications/Opinion_advance-directive.pdf).

<sup>72</sup> See Hoppe/Schirmer, in: Wenzel, Handbuch des Fachanwaltes Medizinrecht, 2007, ch. 4, recital 255 ff., p. 292 ff.

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As to the burden of producing evidence and to the burden of proof, the jurisdiction has developed several special rules.<sup>73</sup> The whole purpose is to shift of the burden of proof and make it easier for the patient to be awarded damages. This shifting derives from typical course of the things or from several kinds of mistakes of the professional health care provider: prima facie evidence that a certain violation of a legally protected right regularly results from a certain mistake; reversal of the burden of proof if the physician has made a grave error in treatment, presumption of incomplete therapy and diagnosis and surveillance if the documentation is incomplete.

One of the central questions within both civil law suits and trials is the question if there was an error of treatment, if the physician (or anybody in his team) has performed improperly. In order to answer this question, the courts make use of experts' opinions. The medical associations offer a procedure of peer review. Neither physician nor patient is obliged to appeal to this peer review committees. If both parties agree to appeal to a peer review committee, its peers (several physicians and at least one jurist) furnish an experts' opinion. This committee consists of physicians as well as of jurists. This committee is not subject to any directives and works on the basis of statutes of the Medical Health Associations<sup>74</sup>. The committee's opinion may become piece of evidence in a lawsuit between the parties, however it will not get this function, if at least of the parties does not accept the peer review. The procedure of peer review has to be stopped when a lawsuit or a trial between the physician and the patient takes place.

Criminal liability is ruled by general rules on bodily harm in art. 223 ff. of the Criminal Code. Each harmful treatment is an offence if the patient has not consented to the treatment and one cannot presume the patients consent.

**4.4 Professional secrecy**

One of the most important legal obligations owed by a physician to a patient is the protection of confidences revealed by the patient to the physician.

Article 203 par. 1 n° 1 and 2 of the Criminal Code lays upon a physician a legal obligation not to disclose confidential information concerning a patient which he learns in the course of his professional practice. Information on the patients' health as well as on the patient's difficulties and fears form such confidential information.

The obligation of non-disclosure applies not only to information acquired directly from the patient, but also to information concerning the patient which the doctor learns from other sources.

The duty of medical secrecy is not limited to physicians who are providing healthcare to the patient. According to art. 203 par. 3, sentence 2 of the Criminal Code, the physician's medical and further, e. g. technical and paramedical, assistants and staff have to observe this rule, too. Furthermore, a physician who medically investigates a person at the request of an employer or

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<sup>73</sup> For a survey see Spindler, in: Bamberger/Roth, BGB, 2008, commentary on art. 823, recitals 784 ff.

<sup>74</sup> See e.g. Northrhine-Westfalian statute, available at <http://www.aekno.de/htmljava/c/gutachterkommission2.htm> (last visited Sept. 2, 2008) or the statute of the northern Germany arbitration board <http://www.norddeutsche-schlichtungsstelle.de/verfahrensordnung.html> (last visited Sept. 2, 2008).

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an insurance company is also bound by the duty in relation to the employer or the insurance company, unless the patient has released the physician from the medical secrecy.<sup>75</sup>

The observance of the professional secrecy is also part of the Professional Code of Conduct, so that the violation possibly not only has consequences under criminal law, but also under law of profession, and therefore, may lead to the revocation of the licence to practise medicine.

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<sup>75</sup> See *Wenzel*, in: *Wenzel, Handbuch des Fachanwalts Medizinrecht*, 2007, ch. 4, recital 323, p. 307.

## 5 Processing of personal health data

### 5.1 Short overview of personal data protection legal framework

Since 1977 Germany has general legislation protecting the individual with regard to automatic processing of personal data. The *Bundesdatenschutzgesetz* (BDSG) of February 1, 1977<sup>76</sup> has been amended several times.<sup>77</sup> In 2001 it has been amended in order to implement the European Directive 95/46/EC into German data protection laws. Additionally, there are state data protection law as well as data protection rules within numerous federal and state laws on health-connected issues. Those rules supersede general federal and state data protection law as far as they contain special data protection rules. State and Federal acts have in common how they define personal data, processing, controller, processor, third party, recipient and consent. In general, both automatically collected data and data collected by hand without using electronic data processing are subject to data protection law.

If according to this order of precedence the BDSG is applicable at all, the personal data are protected by the following system:

According to art. 1 par. 2 n° 1 to 3 BDSG, the Federal personal data protection law is applicable to medical health data, if federal public authorities, state public authorities or non-public authorities are generating and processing the data. According to art. 1 par. 2 n° 2 BDSG state public authorities only have to obey BDSG if state law does not contain data protection rules.

The data processing rules applicable to public authorities in art. 12 ff. BDSG and those applicable to non-public authorities in art. 27 ff. BDSG differ.

The collection of data by public authorities shall be admissible under the condition that it is necessary for the public authority to perform its duties. Additionally, collecting special types of personal data requires the necessity for further purposes, see ch. 5.2. According to art. 14 par. 1 BDSG, data storage, modification and use shall only be admissible for the same purpose as the data were collected. If the purposes differ, according to art. 14 par. 2 BDSG, storage, modification and use shall only be admissible if it is stipulated by the law, the subject of data has given its consent, its interest in data storage etc. is evident or the data are already generally accessible or could be permittedly published. Other reasons may be the check of correctness of data, the aversion of threats to the public order or the infringement of other people's rights and the prosecution of criminal or administrative offences and for purposes of scientific research. If data had been stored exclusively in order to safeguard data, the purposes must not be changed when using the data, art. 14 par. 4 BDSG. Varying from the general principle in art. 4a par. 3 BDSG that the data subject has to consent expressly in storage, modification and use, according to art. 14 par. 6 BDSG, as far as special types of human data are stored, modified or used for health related purposes, data protection shall be ensured by the medical professional secrecy. Those special types of data are defined in art. 3 par. 9

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<sup>76</sup> See BGBl. I 1977, p. 201. A non-official English version is available at [http://www.bitkom.org/files/documents/BDSG\\_Synopse\\_englisch-deutsch.pdf](http://www.bitkom.org/files/documents/BDSG_Synopse_englisch-deutsch.pdf).

<sup>77</sup> Last update BGBl. I 2003, p. 66.

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BDSG and contain information on a person's racial and ethnic origin, political opinions, religious or philosophical convictions, union membership, health or sex life.

Art. 4d BDSG names an obligation to register if an entity puts automated data processing units into operation. An exception is made if a data protection official is appointed within the entity. In case of an offence against this obligation to register and against other data protection rules, the authorities may impose fines according to art. 43 BDSG. Art. 44 contains criminal offences.

According to art. 23 of directive 95/46/EC, art. 7 BDSG names a liability for damages. This can be claimed of state authorities as well as of a private body.

Other rules are applicable to the data collection by non-public authorities as well as to Federal and state public bodies in so far as they participate in competition as public-law enterprises. The conditions for collecting, storing, modifying and usage of data depend on if own purposes are pursued or if the data shall be used for transfer within the business course either non-anonymised or as anonymised version.

According to art. 28 par. 1 BDSG for own business purposes data processing requires accordance with the purpose of the contract or that data processing is necessary to safeguard justified interests of the controller of the data filing system or that the data are generally accessible or could be permittedly published. If purposes of data processing change after collection, according to art. 28 par. 3 BDSG, data transfer or use shall be admissible for reasons of safeguarding third parties justified interests or of the aversion of threats of the state's security, prosecution of offences or of marketing using lists containing only name, postal address, year of birth and one feature of group membership, or of scientific research in clearly defined exceptions. The data subject is protected by the possibility to oppose to the use for marketing purposes, art. 28 par. 4.

For special types of data e.g. health related, data processing shall be admissible under stricter conditions, namely the necessity for the protection of the data subject's or third party's vital interests, or evidently data subject-published data, the necessity to asserting legal claims or the necessity for scientific research, art. 28 sec. 6. Data collecting for health related purposes, namely preventive medicine, medical diagnosis, health care, or administration of health services, shall be admissible if medical personal obliged to professional secrecy is collecting the data. Data processing and use must be fulfilled in accordance to the rules of doctor's professional secrecy, even if the personnel apart from that has not to obey the rules of medical secrecy.

If the data shall be used non-anonymised for transfer within the business course, data collection shall only be admissible, if the data subject's interests do not go against or the data derive from generally accessible sources. The data transfer afterwards requires that the data subject's interests do not go against and that either the transferee has a justified interest in knowledge or only listed data like name and address and year of birth are transferred for purposes of marketing.

If the data shall be used anonymised for transfer, the data shall be stored separately from those ones allowing the re-identification.

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### 5.2 Transposition of article 8 of Directive 95/46/EC

As far as the processing of special categories of personal data is concerned (transposition of art. 8 of Directive 95/46/EC) the German law contains separate provisions for special categories of data. The exceptions from the general ban of collecting special categories of data do not distinguish between different types among these special categories.

Article 13 par. 2 BDSG states that the collection of special categories of data as they are defined in art. 3 par. 9, is only permitted under the afterwards named conditions. At least one of the named conditions must be applicable.

The following exceptions are made<sup>78</sup>:

Art. 13 par. 2 n° 1 1<sup>st</sup> alternative (alt.): if such collection is stipulated in a legal provision;  
*With regard to the collection and process of health data, the Social Code Books refer to data protection. Art. 284 SGB V entitles the health insurance companies to collect and process and store data on the data subject's social conditions (as defined in art. 67 par. 1 SGB X) if it is necessary for the administration of their management of health-care services. According to art. 285 par. 2 SGB V, the Medical Associations may do this, too, for the purpose of managing of health-care services.*

n° 1 2<sup>nd</sup> alt.: if such collection is essential on account of an important public interest;  
*Thereby, the German legislator has referenced recitals 34, 35 and made use of art. 8 par. 4 of directive 95/46/EC.*

n° 2 if the data subject has consented in a manner that the consent refers expressly to the special categories of data;  
*The consent has to be given in a written way, art. 4 a par. 1 3<sup>rd</sup> sentence BDSG. This rule shall ensure that the consent is given in line with art. 7 a of directive 95/46/EC. According to the general rule in art. 126 par. 3 Civil Code and for lack of a conflicting ruling, "writing" includes also electronic means used by the data subject to express his/her will.*

n° 3 if such collection is necessary in order to protect vital interests of the data subject or of a third party, in so far as the subject is unable to give his consent for physical or legal reasons;  
*implementing art. 8 par. 1 c of directive 95/46/EC*

n° 4 if such collection concerns data which the data subject has evidently made public;  
*implementing art. 8 par. 1 e of directive 95/46/EC*

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<sup>78</sup> Comments (in Italics) are cited from BT-Drs. 14/4329, p. 39 if not announced to the contrary.

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n° 5 if such collection is necessary in order to avert a substantial threat to public safety;

n° 6 if such collection is necessary in order to avert substantial detriment to the common weal or to protect substantial interests of the common weal;

*In order to implement art. 8 par. 4 properly, not any kind of public interest is enough to make the exception.*

n° 7 if such collection is necessary for the purposes of preventive medicine, medical diagnosis, health care or the administration of health services and the processing of these data is carried out by medical personnel or other persons who are subject to an obligation to maintain secrecy;

*implementing art. 8 par. 3 of directive 95/46/EC - Because there are no similar exceptions on state level law in Lower Saxony, regarding this exception, the Federal data protection law is not subsidiary to state level law.*

*The other Länder have implemented similar rules, some of them going beyond by demanding to hear the data protection official's opinion.<sup>79</sup> The duty to observe legal obligations to maintain secrecy on the collected data afterwards is not ruled by n° 7, but by art. 1 par. 3 sentence 2.*

*This rule is also applicable to pharmacists. On the contrary, health insurance companies shall not refer to this exception, but has to be given the data subject's consent<sup>80</sup> or process the data within n° 1, 1<sup>st</sup> alternative.*

*The second part of the rule has to be interpreted in line with directive 95/46/EC.*

*Therefore, not only the processing of data has to be carried out by medical personnel, but also the collection of the data.<sup>81</sup>*

n° 8 if such collection is necessary for the purposes of scientific research, where the scientific interest in carrying out the research project substantially outweighs the data subject's interest in excluding collection and the purpose of the research cannot be achieved in any other way or would otherwise necessitate disproportionate effort;

*making use of art. 8 par. 4 of directive 95/46/EC*

According to art. 4 par. 2 sentence 1 BDSG, the health-related personal data shall be collected from the data subject. They may solely be collected from other sources if this is in compliance with sentence 2 of article 4.

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<sup>79</sup> See Gola/Schomerus, BDSG, 9<sup>th</sup> ed., 2007, commentary on art. 13 BDSG, recital 25.

<sup>80</sup> See Gola/Schomerus, BDSG, 9<sup>th</sup> ed., 2007, commentary on art. 13 BDSG, recital 22.

<sup>81</sup> See Simitis, BDSG, 6<sup>th</sup> ed., 2006, commentary on art. 13 BDSG, recital 41.

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**5.3 Information and access rights of data subjects**

According to art. 19 and 34 BDSG, the data subject shall at his request be provided by public and non-public bodies resp. with information on the stored data, the recipients of data transmission and the purpose of storage free of charge.

According to art. 19 par. 3 BDSG the information shall not be provided, if first of all, this would be prejudicial to the proper performance of the duties of the controller, or this would impair public safety or order or otherwise be detrimental to Federation or a *Land*, or the data or the fact must be kept secret in accordance with a legal provision or by virtue of their nature in particular on account of an overriding justified interest of a third party, and secondly, for this reason the interest of the data subject on the provision of information must be subordinated. According to art. 34 sec. 1 BDSG, overriding interests of trade secrets release the non-public bodies and those public bodies competing as public law enterprises from the obligation to give the requested information.

**5.4 Other relevant rules regarding personal data protection****5.4.1 Protection of social data in general**

Detailed provisions in the data protection law within the social code books regulate the further processing of personal data. These data protection rules protect the so-called *social secret*.

The characteristic feature is that numerous exceptions described in detail are made.

Art. 35 SGB I<sup>82</sup> and art. 67 ff. SGB X<sup>83</sup> in generally regulate data protection of social personal data. Those rules are also applicable to statutory health insurance funds by reference in art. 284 SGB V.

Only data which are necessary to perform the authorities' duties may be processed. Personal data shall be collected generally from the data subject. They may be collected without his participation only if the body shall transfer the data to the collecting body according to the law at all, the data collection otherwise necessitate disproportionate effort and overriding interests of the data subject are not impaired. If the transfer of social data is not provided for in the law, the data subject has to be informed on the transfer and its purpose, art. 67a SGB X. Data shall be stored, modified and used only for the same purpose as they were collected for, art. 67c SGB X. According to art. 67d par. 1 SGB X, data shall only be transferred if admitted by special provisions by law, e.g. averting of dangers in general (art. 68 SGB X) and securing state security after a special decision making procedure, art. 72 SGB X, performance of duties of social security law by special bodies like all organizations providing social security benefits and their associations, art. 69 SGB X, protection of public health in case of risks of infection, art 71 par. 1 1<sup>st</sup> sentence, n° 2 SGB X, and conducting trials, art. 74 SGB X, and conducting of scientific research of social security and social security planning, if no

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<sup>82</sup> Social Code Book I – General Part, Act from Dec. 11,1975, BGBl. I 1975, p. 3015, as last amended by Act from Dec. 19, 2007, BGBl. I 2007, p. 3024.

<sup>83</sup> Social Code Book X – Social Administrative Procedure and Protection of Social Data, Act from Aug. 18, 1980, BGBl. I 1980, p. 1469, as amended and promulgated by Act from 18. 1.2001, BGBl. I, 2001, p. 130, as last amended by Act from 31.7.2008, BGBl. I, 2008, p. 1629.

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overriding interests of the data subject were impaired and – in general – the data subject agreed to the data transfer. All these admissions to data transfer are restricted as far as data have been made available by health service providers which are bound by professional secrecy, e.g. if doctors have submitted data to SHI funds. Data must be transferred in accordance to the rules on professional secrecy also by the addressee then, art. 76 SGB X. Transnational data transfer within the EU is admitted under the condition that the performance of duties of a public body necessitates the transborder data transfer, art. 77 SGB X. Access to data is granted to the data subject by art. 83 SGB X. The data subject may claim information on which data are stored, on addressees of data transfers and on the purpose of storage. Damages can be claimed according to art. 82 SGB X. Incorrect data have to be corrected, art. 84 par. 1 SGB X. Data which are stored against the law, have to be erased, art. 84 par. 2 SGB X, or blocked resp. if erasure is not admitted, art. 84 par. 3 SGB X.

**5.4.2 Protection of social data used by SHI-funds and at the Regional Association of SHI-Accredited Physicians**

Art. 284 to 305b SGB V extensively regulate data processing at statutory health insurance funds and at the Regional Association of SHI-Accredited Physicians.

According to art. 284 par. 1 SGB V the collection and storage of data shall be admissible if they are necessary to handle the insurance relationship (e.g. if a person is insured at all, if contributions have to be and have been paid, realizing the issue of the health insurance card and electronic health card, check of obligations to pay for medical service and cost reimbursement as well as settling the billing procedure with health care service providers, preparation and enforcement of contracts with medical health care service providers on ambulant highly specialized service, integrated health care, spot checks of economically efficiency of SHI-authorized health care services). The data shall be used as far as it is necessary to reach the purpose as it was fixed at collection or storage respectively. The use for diverging purposes is only admitted if admitted by other Social Code Book provisions, art. 284 par. 3 SGB V. For purposes of acquisition of new members, data shall be collected, processed and used in case if the data are generally accessible and overriding opposing data subject's interests do not exist, art. 284 par. 4 SGB V. Further provisions on data protection concern data on stored on or accessible by means of the electronic health card, art. 291a SGB V, see ch. 7.2.

The Regional Association of SHI-Accredited Physicians may collect and store data of insured people only in order to settle the billing procedure for SHI-authorized physicians and to check economical efficiency (especially by spot checks according to art. 106 par. 2 and art. 296, 297 SGB V) and realization of quality checks and transfer them to the SHI-funds. Both SHI-funds and the Regional Association of SHI-Accredited Physicians shall interpret case related personal data for purposes of scientific research, especially to gain epidemiological knowledge, and store data for an expanded period of time under the condition that the supervisory authority permits this.

Medical health care service providers shall note all data that are needed by statutory health insurance funds and at the Regional Association of SHI-Accredited Physicians to perform

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their duties, art. 294 SGB V, and shall note and transfer all data that are necessary to settle the billing procedure, namely diagnoses, way and date of treatment, art. 295 SGB V. The transfer of insuree related personal data for purposes of checks of economical efficiency shall be admissible if evaluation of concrete cases is decisive, art. 298 SGB V.

Apothecaries shall transfer the data on drug dispensing to SHI-insurees to the statutory health insurance funds either using the original prescription form or by sending data units electronically, art. 300 SGB V. Hospitals shall transfer data like the insuree's name and date of birth, status of insurance, diagnoses, way and date of treatment encrypted either by means of, data media or electronic data transfer, art. 301 SGB V.

According to art. 305 SGB V, an insuree can require information from the statutory health insurance company about the medical services he has made use of all over the last year. The health insurance company has to provide this information. SHI-related health care service providers, e.g. doctors, only have to provide these information for the past quarter year and if the patient pays the lump sum of 1 EUR plus forwarding expenses.

**5.4.3 Protection of patient data in hospitals**

Data protection in hospitals if a *Land* or a religious organisation is responsible for running the hospital, is ruled within the Hospital Laws of the *Länder*. Those laws slightly differ from each other; nevertheless, the following guidelines can be pointed out:

All data that are necessary to conduct and to bill the medical care may be collected, stored, modified and used. Furthermore, storing, modifying and using are allowed for purposes of quality assurance, avoidance of and struggle against infections in hospitals, supervision and professional training. Data transfer to doctors and institutions of rehabilitative care, domestic or nursing care for purposes of follow-up treatment is admitted. The patient has to give his/her consent in data transfer to the relatives and to domestic or nursing care institutions. Hospitals may outsource their data processing after if this is notified to the data protection agency. If the patient has to give his consent, this consent must not be given within the general consent in treatment but must be given in a separate declaration. An electronic consent is possible, if it is ensured, that the declaration is not manipulable.

**5.4.4 Data protection for data in other sources**

The legal provisions about the use of data extracted from government validated authentic sources are also relevant. Such validated sources on state law level exist e.g. on cancer.<sup>84</sup> The patients may only be named if they consent. The registers may be upheld for purpose of public health protection or scientific research based on public interest. No patient may be provided information on his disease by the register in order to avoid abuse of such an access right by third parties. Only anonymised data are published.

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<sup>84</sup> See *Deutsch/Spickhoff*, Medizinrecht, 6th ed., 2008, recital 623.

## 6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients result from the above mentioned law. There is no specific act ruling on the entire relationship between healthcare providers and patients. But some aspects from the above mentioned law shall be stressed here again.

### 6.1 Duty of the patient to co-operate

There is no special provision that the patient has to co-operate. Nevertheless, one can formulate, that it is the patient's mere *obligation* to co-operate. This results from the system of criminal law and liability for damages. The physician can reject the patient's claim for damaging and can plead not guilty resp. by pleading that the patient is partly responsible for his damages because of his contributory negligence. In order to avoid this defence the patient should inform the physician on all relevant facts, .g. all medicaments he is taking and should follow the physician's therapeutic instructions.

### 6.2 Right to quality care

That the patient has a right to quality care derives from the contract between the patient and his physician and additionally from the professional code of conduct, which names a duty of physicians to treat patients on the standard of medical science. The patient will be awarded damages and additionally, the physician will be fined or punished if the code of conduct is violated.

### 6.3 Ban on Tele-treatment

Art. 7 par. 3 of the Medical Association's professional model code of conduct prescribes that physicians must not treat concrete and individual illnesses of their patients on basis of information they solely got via letter, telephone or telemedia or other people's report. That means that physicians may diagnose and advise their patients how to go on with their aches and pains when they gained an impression of the patient's state of health personally. Exceptions may be made in cases of emergency, when the physician gives advice what to do until the ambulance arrives. Another exception is made for advices in isolated cases given to a patient normally receiving the physician's medical treatment.<sup>85</sup> General advices on questions of medical care are not covered by the ban on tele-treatment, even if those general remarks are answers on questions on individual health problems.<sup>86</sup>

The Medical Association's professional model code of conduct is implemented into the codes of conduct of all 16 German *Länder*. They are part of the professional law. A violation of rules within these codes of conduct results in a law suit before the court of professional conduct. At the same time tele-treatment service infringes the Unfair Competition Act if the service is provided free of charge.

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<sup>85</sup> Kroha, Ärztliche Online-Beratung, 2007, p. 26.

<sup>86</sup> Kroha, Ärztliche Online-Beratung, 2007, p. 26.

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Furthermore, tele-treatment can result in liability for damages, if the patient has not been treated *lege artis*. It is easy for the physician to make mistakes concerning the diagnosis. The physician acts negligent if he does not examine the patient to the necessary extent and does not assess the results according to physicians' standards.

### 6.4 Right to free choice

According to art. 76 par. 1 of the SGB V, the patient has the right to freely choose his health professional and to change that choice, except for some restrictions in determined cases. One of these restrictions is that the SHI-insured patient can only claim his insurance company to be released from the costs of the treatment, if the physician is a SHI-authorized physician. In general, this free choice also applies to the choice if the patient visits a practitioner first or directly goes to see a specialist. In the course of reorganization of the state health system, a rule was established that the patient has to pay a practice fee (10 EUR), when first seeing a doctor in a quarter. Furthermore, the free choice can be restricted for participants in certain bonus programmes of the health insurance companies, so called general practitioner-centred model<sup>87</sup>.

### 6.5 Rights related to information about the state of health

The patient's right to get information about the state of his health derives from the right of informational self-determination in art. 1 and 2 of the Basic Law.<sup>88</sup> The information has to be adjusted to each patient and his psychical situation. In exceptional cases the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient (so-called "therapeutic privilege" or "humanitarian principle"). Information must not be provided to the patient if the latter explicitly requests not to know. The explicit request not to know can be given in writing or orally.

### 6.6 Right to give consent

Again, the patient's right to get information about the state of his health derives from the physicians' criminal liability. If the physician wants to avoid liability, he must ensure that the patient has given his consent to the treatment. This consent has to be an *informed consent*, which means, that the patient has to be informed on all the facts concerning his state of health, risks and chances of therapy. This demand of consent derives from art. 1 and 2 of the Basic Law.<sup>89</sup>

A physician (not necessarily the one who is treating the patient himself) must inform the patient. If solely the nurse or administrative staff has informed the patient, the consent is invalid.

The information does not have to be and should not be upheld in a written manner. Paper based information can support and complement the session of information and can be used as

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<sup>87</sup> Hausarztzentrierte Versorgung in German.

<sup>88</sup> See *Deutsch/Spickhoff*, Medizinrecht, 6<sup>th</sup> ed., 2008, recital 632.

<sup>89</sup> See *Deutsch/Spickhoff*, Medizinrecht, 6<sup>th</sup> ed., 2008, recitals 306 ff.

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proof for the information and the patient's consent. But a solely paper based information is invalid. If forms are used, courts can check them on observing the rules on general terms of business according to art. 305 ff. of the Civil Code. The information must contain the physician's explanations, and should be a conversational dialogue of the physician's explanations, the patient's questions and the physician's answers. The information has to be adjusted to each patient and his psychical situation. In exceptional cases the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient (so-called "therapeutic exemption").

The patient's consent has to be given expressly, but not necessarily in a written manner.

Nevertheless, for purposes of proof it has to be noted in the medical record, when the information and the consent took place, by whom, and of which content they were. If the patient refuses to be informed, the physician should note this fact.

If the patient himself is unable to consent for legally reasons, the legal representatives have to be informed and give their consent. If the patient himself is unable to consent for physical reasons, e.g. because he is unconscious, the treatment can be justified on the basis of a presumed consent.

**6.7 Rights related to the patient's medical record**

The patient has the right to a medical record, carefully updated and safely stored by the health professional. This right derives as a secondary obligation directly from the medical health care contract.<sup>90</sup> Patients have the right to access their own medical records. This derives from the rules of the professional code of conduct (art. 10<sup>91</sup>) and from art. 1, 2 of the Basic Law and as secondary obligation in the medical health care contract and from art. 29 and 34 BDSG<sup>92</sup>. The right contains the access to reports on diagnosis and therapy, but does not include the physician's personal statements.<sup>93</sup> The patient is entitled to read the original file and can claim copies if he pays for them. At and after the end of the treatment, the patient can claim the (at least temporary) hand-over of x-rays and magnetic resonance images etc. in order to prevent renewed exposures to radiation if further treatments.<sup>94</sup> The physician may solely hand over the patient's medical record to another physician or his successor in practice if the patient has given his consent.

These medical records differ from those that are related to the electronic health card. The patient keeps authority over all his data stored by means of the eGK. The patient's right to access directly derives from this authority and is mentioned in art. 291a par. 4 sentence 2 SGB V.

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<sup>90</sup> See *Wenzel*, in: *Wenzel, Handbuch des Fachanwalts Medizinrecht*, 2007, Ch. 4, recital 301, p. 302.

<sup>91</sup> Musterberufsordnung, MBO, available at <http://www.baek.de/page.asp?his=1.100.1143> (last visited Sept. 2, 2008).

<sup>92</sup> See *Deutsch/Spickhoff*, *Medizinrecht*, 6<sup>th</sup> ed., 2008, recital 625.

<sup>93</sup> See *Deutsch/Spickhoff*, *Medizinrecht*, 6<sup>th</sup> ed., 2008, recital 626.

<sup>94</sup> See *Deutsch/Spickhoff*, *Medizinrecht*, 6<sup>th</sup> ed., 2008, recitals 630 f.

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**6.8 Right to protection of privacy and intimacy**

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health. Again this derives from the constitutional weal of informational self-determent.

**6.9 Right to representation in case of incompetence**

Patients who are legally (because of their minority) or factually not capable of exercising their rights as a patient, are represented by their parents asserting authority over the minor or by the patient's guardians. The minor patient will be involved in exercising his rights, bearing in mind his age and level of maturity which make up the criteria for capacity to consent. This capacity does not stick to a certain age. Minor patients shall at least be included in all decisions.<sup>95</sup>

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<sup>95</sup> See *Deutsch/Spickhoff*, *Medizinrecht*, 6<sup>th</sup> ed., 2008, recital 317.

## 7 Identity management in the health sector

A co-ordinated identity management system for the German healthcare sector including the identities of patients, healthcare professionals and other stakeholders is not yet available. It is part of the planned telematic platform and connected to the introduction of the electronic health cards.

The information in chapter 7.1. is based on IDABC-report referenced under [RD9].

### 7.1 Overview

The current situation is characterized by biometrical passports (first and second generation, meaning the older ones containing biometrical photos and the newer ones additionally containing electronical fingerprints) and the identity cards of ID2-size.<sup>96</sup> The new electronic passport includes a chip with some personal data including biometric data. But it is not intended for use in electronic communication beyond border control.<sup>97</sup>

The new ID-1-sized eID card (elektronischer Personalausweis, ePA) shall be used for visual inspection and, in addition, for universal identification and authentication on the Internet for eGovernment and eCommerce services. For this purpose, the ePA contains a chip where the printed information and certificates to prove these data are stored. The data are protected by a PIN, and a digitized picture of the face as well as finger prints will be included.<sup>98</sup> A parallel e-ID project is the eAT<sup>99</sup>-Smartcard, which is supposed to replace the paper based certificates on residence permits. The eAT will contain biometric features and additional features to provide electronic authentication and signature to be used for electronic commerce.<sup>100</sup>

Concerning the health service providing, the electronic health card has already been started within tests. To identify the patient, the card shall be provided with a photo. The patient can decide to store an electronic signature, so that he can use his eGK for all electronic applications which require electronic signing. The electronic health card is intended to facilitate processes in the health care system and to make the patient data digitally available to the physician. For this purpose, physicians, pharmacists etc. shall authenticate themselves by their special chip card, the health professional card.<sup>101</sup>

In a cabinet decision of June 25, 2008, the cabinet passed the bill of the ELENA-Verfahrensgesetz.<sup>102</sup> ELENA is the Electronic Certificate of Income. ELENA makes it possible, that employers can stop printing forms for their ex-employees that according to art. 312 SGB X certify all facts and provide all the information which decide if the ex-employee may claim unemployment benefits. The employer will send the data to a central server, where

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<sup>96</sup> See <http://www.heise.de/newsticker/meldung/101957> (last visited Sept. 2, 2008).

<sup>97</sup> [RD 9], p. 18.

<sup>98</sup> [RD 9], p. 18.

<sup>99</sup> eAT is the abbreviation of elektronischer Aufenthaltstitel.

<sup>100</sup> See <http://www.heise.de/newsticker/meldung/print/101957> (last visited Sept. 2, 2008).

<sup>101</sup> [RD 9], p. 18.

<sup>102</sup> <http://www.bmwi.de/BMWi/Navigation/Presse/pressemitteilungen,did=254652.html> (last visited Sept. 2, 2008).

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the data are stored in an encrypted version. The authorities can only recall these data by means of a smart card and if the citizen who has applied for the benefits has authorised the recall by identifying himself by means of a signature card, e.g. his electronic health card or a maestro card issued by his bank. The procedure will be started in 2010.<sup>103</sup>

Citizens' portals (Bürgerportale) may become a further relevant component in the German Identity Management System. They are supposed to provide an authentication service, a communication gateway which allows the citizens to receive signed documents with a confirmation of receipt, and a data safe. First studies have been started; final opening dates are not yet available.<sup>104</sup>

**7.2 Patient identifier – electronic Health card**

According to art. 290 par. 1 of SGB V, the patients are identified by their health insurance number. This number contains of different parts: one long life and unchangeable part to identify the patient, and one variable part containing information on the health insurance company and insurance status (member, member because of being a family member of the insurance member or pensioner). The health insurance number is not identical with the pension insurance number. This number is printed on the patient's health insurance card and will be stored on the electronic health card, as soon as this card replaces the health insurance card (see art. 291 SGB V). Each health insurance company hands out the health insurance card or the ehealth card resp. to its own members. The company also sees to replace the patients' health insurance card by the electronic health cards.

In order to avoid abuse of the electronic health card, a photo of the card holder shall be printed on the card and further administrative information (sex, status regarding extra payments) are stored either solely on the insurance health card-chip or on the card and additionally online with the card granting access. Furthermore, a PIN helps to ensure that only the insured person himself permits access to certain data: The access to the medical data that are stored within the electronic health card system as part of voluntary applications requires that the patient types his PIN. An exemption from this is made for emergency situations. Then, access to a limited swift of data (so called *Notfalldatensatz*) is possible without the patient's PIN.

**7.3 Authentication of healthcare professionals - elektronischer Heilberufsausweis (eHBA)/electronic Health Professional Card (eHPC)**

In order to be able to process and access the patient's health data, according to art. 291a par. 5 SGB V, the health care professionals will have to use the electronic health professional card.<sup>105</sup> It is ID-1-sized, contains a photo and the professional's cryptographic keys for electronic signature, authentication and encryption. This enables the healthcare professionals to the following acts:

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<sup>103</sup> <http://www.bmwi.de/BMWi/Navigation/Presse/pressemitteilungen,did=254652.html> (last visited Sept. 2, 2008).

<sup>104</sup> [RD 9], p. 19 f.

<sup>105</sup> See <http://www.bundesaerztekammer.de/page.asp?his=1.134.3416> (last visited Sept. 7, 2008).

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They can authenticate in order to get access to the minimum set of medical data, namely the data that are necessary in case of emergency which will be stored on the patients' electronic health cards and to those medical data which are stored online. In the contrary, the eHPC is not necessary to get access to the administrative data stored on the card. The certificates on the eHPC contain information that enable one to distinguish the health professionals so that only certain professionals who belong to the group which is listed in art. 291 par. 4 SGB V can access certain sorts of data.

Additionally, they are able to sign documents electronically in line with the act on signature. This enables them to handle electronic patient files and electronic prescriptions and other electronic documents that require an electronic signature. For control of the signature process, a PIN (PIN for signature) is to be typed.

Finally, they can use the electronic health professional card to encrypt and decrypt data when they send or receive resp. data from telematic data platforms. In order to activate this functions, the professional has to type a different (cardholder-) PIN for activation) when the card is put into the card readers.

The electronic health professional card is officially issued by the regional Medical Associations after the applicant's identity and his status as a health professional has been verified. This verification is realised either by the *Post-Ident-Verfahren* or direct check of data at the regional Medical Association's office. The doctors receive their card and the PINs directly from the technical provider who validates the card by unblocking it after card and PINs have reached the addressee.<sup>106</sup>

Most doctors work together with their assisting personnel in surgeries or other institutions. The personnel is not issued an own electronic health professional card. Nevertheless, the personnel must be able to read and process data stored the eGK and accessible via eGK. Therefore, each health institution, e.g. the surgery or the medical care unit is provided Secure Module Cards (SMC). Two types of cards exist: Type A only authenticates the personnel, admits access to administrative data and establishes secure communication with the health professional card, if plugged into another card reading terminal within the same institution. SMC Type B fulfils not only these functions within the same institution, but is important for all online applications because it functions as an encrypter and decrypter of all incoming and outgoing data packages and identifies the medical institution when communicating with the telematic infrastructure.<sup>107</sup> The SMC is issued to SHI-related and non-SHI-related physicians by the National Association of Statutory Health Insurance Physicians for application of a health professional, e.g. a physician.<sup>108</sup>

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<sup>106</sup> See [http://www.aeksh.de/2mitglieder/AVZ/eHBA/hpc\\_anmeld.htm](http://www.aeksh.de/2mitglieder/AVZ/eHBA/hpc_anmeld.htm) (last visited Sept. 5, 2008); <http://www.gesundheitskarte-sh.de/archiv/start.html> (last visited Sept. 5, 2008).

<sup>107</sup> See <http://www.telematik-modellregionen.de/content/e231/e584/e613/> (last visited Sept. 4, 2008), Laatz, *Das Rückgrat der Gesundheitskarte*, Jäckel (ed.) *Telemedizinführer Deutschland*, 2007, p. 14.

<sup>108</sup> See Decree on tests concerning the launching of the electronic health card (*Verordnung über Testmaßnahmen für die Einführung der elektronischen Gesundheitskarte*), art. 5a par. 3, 5, BGBl. I 2006, p. 2199; [http://www.gematik.de/upload/gematik\\_BETR\\_Betrieb\\_Policy\\_V1\\_0\\_0\\_1547.pdf](http://www.gematik.de/upload/gematik_BETR_Betrieb_Policy_V1_0_0_1547.pdf) (last visited Sept. 5, 2008).

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### 7.4 Exchange of health-related data

As far as the exchange of health-related data is concerned, one has to differentiate between the exchange of data by means of the electronic health card and the electronic health professional card on the one hand and data exchange using other techniques on the other hand.

#### 7.4.1 Exchange by means of eGK

The first scenario, the exchange by means of the eGK, is ruled in art. 291a, 291b SGB V. The basis for exchange of data by means of eGK is the infrastructure developed by the GEMATIK. According to art. 291b par. 1 sentence 1 SGB V, the GEMATIK, is responsible to formulate the standards for the telematic infrastructure in order to ensure the interoperability of the used technique.<sup>109</sup> The used technique, e.g. terminals for reading in the cards, is developed, constructed and distributed not by the GEMATIK, but by private enterprises.

Only administrative data shall be stored on the chip of the card as well as emergency related data, if the card holder decides to have them stored at all. All other data i.e. those used for an electronic patient file, electronic medical report, images from special diagnoses like x-ray, will not be stored on the chip, but on a central data server, if the patient agrees to have them stored at all. Everybody who wants to access these data has to be connected to a network. Data stored on or with the help of the eGK are under the insurances' authority. Therefore, data exchange by means of the eGK is data exchange with or via the insurances. That is why one can only read and process data stored on or with the help of the eGK, if one can read in the eGK at the same time and – at least in general - the patient types his PIN.

If it comes to the question who may read data stored directly on the electronic health card or online by means of the electronic health card, it is important to differentiate between the data: Administrative data (like name, date of birth, insurance health body identification number etc. can be read and processed without using further cards. The pharmaceuticals and their assistants can read and process data related to the electronic prescription by means of their health professional card.

If the patient decides that more of his health related data are to be accessible via his/her eGK, one has to differentiate again: Data that are to be accessible in cases of emergency can be recalled by means of the health professional card, art. 291a par. 4 sent. 1 SGB V. It is not necessary that the patient types his PIN for admitting the data recall.<sup>110</sup>

Other data, e.g. those used for an electronic patient file, electronic medical report, images from special diagnoses like x-ray, are only accessible if the patient has admitted this. The access can be restricted to single health professionals. . . .

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<sup>109</sup> For an overview over the standards set by the GEMATIK, see [http://www.gematik.de/\(S\(oz2zq0ni4qpkns555sj00f55\)\)/Zulassungsverfahren\\_Komponenten\\_und\\_Dienste.Gematik](http://www.gematik.de/(S(oz2zq0ni4qpkns555sj00f55))/Zulassungsverfahren_Komponenten_und_Dienste.Gematik) (last visited Sept. 3, 2008). *The documents name explicitly all demands on the elements of the infrastructure.*

<sup>110</sup> See [http://www.bmg.bund.de/cn\\_110/SharedDocs/Downloads/DE/Neu/Elektronische-Gesundheitskarte\\_\\_Notfalldaten,templateId=raw,property=publicationFile.pdf/Elektronische-Gesundheitskarte\\_\\_Notfalldaten.pdf](http://www.bmg.bund.de/cn_110/SharedDocs/Downloads/DE/Neu/Elektronische-Gesundheitskarte__Notfalldaten,templateId=raw,property=publicationFile.pdf/Elektronische-Gesundheitskarte__Notfalldaten.pdf), p. 4 (last visited Sept. 4, 2008).

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The health related data which are stored online shall be transmitted from the reader to the server and vice versa only if the signals are encrypted. Therefore, all healthcare providers need a special connector which uses the SMC Type B. The connector is an electronic interface – a small box – which encrypts and decrypts the data.<sup>111</sup>

**7.4.2 Exchange of health related data without using the eGK**

Health related data can also be exchanged directly between physicians. Their electronic health professional card and the infrastructure within their medical institution will allow them encrypted data communication via secured web-connections.<sup>112</sup>

The exchange of health related data is already practised. One example is the *Patient-Partner-Verbund*, a system integrating patients and other partners in Bavaria. The medical data of those patients who take part in the programme of their free will, are posted online and all explicitly named physicians and other health care service providers get access to these data. Special features are minutes of meetings with all health care service providers of a certain patient with his practitioner presenting the complete medical case and the minutes of nursing care. E.g. in Bavaria, the online data communication is part of a general practitioner-centred model set up to reduce cost for SHI-financed medical care.<sup>113</sup>

Another project exchanging health related data without using the eGK is a project concerning the statutory occupational accident insurance. The organizations providing the benefits for this accident insurance, namely the professional associations and the accident insurance funds, have come up with special communication platform named DALE-UV. Physicians which decide to take part in this project transmit medical and administrative data which formerly had to be transmitted by paper-based forms via this platform. Physicians collect the data and send them encrypted to a data collecting platform which forwards the data to the organizations providing the benefits, the statutory health insurance funds and the physician of further treatment. Smart Cards ensure the identification of the transmitting physicians.<sup>114</sup>

Furthermore, health related data have to be exchanged between physicians and Regional Associations of Statutory Health Insurance Physicians on the one hand and the latter and the Statutory health insurance funds on the other hand for purposes of billing health care. An electronic transmission is possible, art. 295 par. 1b and 2 SGB V.

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<sup>111</sup> See <http://www.telematik-modellregionen.de/content/e231/e584/e613/> (last visited Sept. 4, 2008).

<sup>112</sup> See <http://www.telematik-modellregionen.de/content/e231/e584/e613/> (last visited Sept. 4, 2008).

<sup>113</sup> See <http://www.openpr.de/pdf/64102/Elektronischer-Datenaustausch-in-bayerischem-Arztnetz-Patient-Partner-Verbund-nutzt-web-basierte-Gesundheitsakte-LifeSensor.pdf> (last visited Sept. 5, 2008).

<sup>114</sup> See [http://www.dale-uv.de/dale/pages/down/pdf\\_bilder/flyer.pdf](http://www.dale-uv.de/dale/pages/down/pdf_bilder/flyer.pdf) (last visited Sept. 6, 2008).

## 8 Electronic prescription

Up to now, the electronic prescription, called *eRezept*, is only realised in the model regions for the electronic health card. In this regard, the following rules are applicable<sup>115</sup>:

The necessary information for a prescription are stored by the practitioner on or with the help of the patient's electronic health card (at the moment, only the first option is tested as the online-applications have not already been realized). As a supplement and bare for the patient's information, the practitioner can print an informal sheet of paper with the relevant information about which drugs and how much of each to take when. This sheet of paper is not a valid prescription.

The general data protecting rules call for either the patients consent or a legislative permit to store the patient's personal data. In so far, the storage of prescription-relevant data is permitted by article 291a par. 2 n° 1 SGB V. The patient's consent is not required and the patient cannot revoke the storage of his data. Nevertheless, remains the patient's own decision to hand in the prescription or not. Thus the patient keeps the authority over his data. If the patient decides to hand in the prescription, he/she is free to take it to the healthcare provider of his/her own choice.

The rules on the running of pharmacies<sup>116</sup> already consider the electronic prescriptions. If chemists hand out drugs, they have to add the information in the electronic prescription and complete this information with their qualified electronic signature, art. 17 par. 5 ApBetrO. In regard of the electronic prescription, special electronic transmission rules shall be developed in order to enable the mail-ordering of drugs by using the electronic prescription. If SHI-associated physicians (148.000) want to use software to write electronic prescriptions, the software used to write electronic prescriptions has to fulfil certain standards and has to be certified by the National Association of Statutory Health Insurance Physicians<sup>117</sup>, art. 73 par. 8 SGB V and art. 29 Bundesmantelvertrag-Ärzte (BMV-Ä) resp. art. 15 Bundesmantelvertrag-Ärzte/Ersatzkassen (EKV)<sup>118</sup>. Central demand is that the software guarantees that the prescriptions cannot be manipulated. A special catalogue summarizing technical demands to the software has been made.<sup>119</sup>

Within the amendments to the Bundesmantelvertrag the parties have agreed on special forms for prescriptions. Up to now, they are used as binding model for the paper based prescriptions. The ePrescription (the set of data accessible for the purpose to hand out medicine resp.) will at least contain those information that are now also part of the paper based model: name and health insurance company, date of birth and of expiration of the card, patient's and insurance company number, the prescribed drug including how and when to take it, codes on the amount

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<sup>115</sup> See [http://www.bmg.bund.de/cln\\_117/nn\\_1168300/SharedDocs/Publikationen/DE/Gesundheit/g-07016,templateId=raw,property=publicationFile.pdf/g-07016.pdf](http://www.bmg.bund.de/cln_117/nn_1168300/SharedDocs/Publikationen/DE/Gesundheit/g-07016,templateId=raw,property=publicationFile.pdf/g-07016.pdf) (last visited Sept. 7, 2008).

<sup>116</sup> Verordnung über den Betrieb von Apotheken (Apothekenbetriebsordnung - ApBetrO), last changed July, 20<sup>th</sup> 2007, BGBl. I 2007, p. 1574, available at [http://www.gesetze-im-internet.de/apobetro\\_1987/index.html](http://www.gesetze-im-internet.de/apobetro_1987/index.html) (last visited Sept. 7, 2008).

<sup>117</sup> Kassenärztliche Bundesvereinigung in German.

<sup>118</sup> Available at <http://www.kbv.de/rechtsquellen/2310.html> (last visited Sept. 7, 2008).

<sup>119</sup> See Anforderungskatalog AVWG, available at <http://www.kbv.de/rechtsquellen/2310.html> (last visited Sept. 7, 2008).

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the patient has to pay. Finally, the hand-written signature of the practitioner who prescribes the medicine will be replaced by generating a qualified electronic signature by using his electronic health professional card.

## 9 General assessment

The German regulatory framework offers the basis for the implementation of eHealth projects such as the patient's summaries, telemedicine or electronic prescriptions.

The main problem from the current point of view is that some actors within the health care system are still combating the introduction of telemedical applications and even threaten to boycott the telematic applications<sup>120</sup>. Parts of the professionals' associations and assemblies argue that the infrastructure for the telematic applications cannot ensure that unauthorized third persons cannot access the data. They point out once that storage of citizens' health data has build up, it could serve as a data source for any purposes not at all being related to health service delivering later.<sup>121</sup> Others point out that the chip-based smartcard is antiquated and they reject the concept of central storage as expensive and unsafe. Using other memories, e.g. USB Flash, instead of the chip based smart cards could avoid this central storage.<sup>122</sup>

Nevertheless, the telematic applications via ehealth card are to be started early in 2009.<sup>123</sup>

The implementation of the European data protection directive into German law has been fulfilled. Only some additional requirements, compared to the EU Directive, have been added for the processing of personal data concerning health.

Finally, one has to state that up to now the cross-border interoperability of certain telemedical applications, is in the focus of interest: The infrastructure which is to be established as a basis for the use of the eGK will serve as an interoperable platform which can be used not only by national health care service providers but also by cross-border ehealth applications. In order to ensure and to develop the interoperability of the telemedical infrastructure, Germany takes part in the Project Smart Open Services (S.O.S.)<sup>124</sup>. The aim is that at the end of the project, foreign health care service providers can get access to the patient's medical data stored within the German ehealth system by electronic means using their own ehealth systems if a patient needs medical treatment outside of Germany. The development of the telematic infrastructure will be completed with the eGK-issue in 2009, so that the outcome of the S.O.S. project can be implemented within the further development of the ehealth infrastructure.

Katharina Anton  
September 7, 2008

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<sup>120</sup> See <http://www.heise.de/newsticker/meldung/107713>, May 10, 2008, last visited Sept. 6, 2008.

<sup>121</sup> See <http://www.heise.de/newsticker/meldung/108038>, May 18, 2008, last visited Sept. 6, 2008.

<sup>122</sup> See <http://www.heise.de/newsticker/meldung/107713>, May 10, 2008, last visited Sept. 6, 2008.

<sup>123</sup> See above ch. 3.3 National eHealth strategy, p. 12.

<sup>124</sup> See commission press release IP/08/1075, July 2, 2008, available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1075&format=HTML&aged=0&language=EN&guiLanguage=en>. For further information on S.O.S. see [http://ec.europa.eu/information\\_society/newsroom/cf/document.cfm?action=display&doc\\_id=511](http://ec.europa.eu/information_society/newsroom/cf/document.cfm?action=display&doc_id=511) (last visited Sept. 6, 2008).

## Annex: Contact details of National Correspondents

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