

# Health Records as an Object of Czech Personal Data Protection and Intellectual Property Law

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## Abstract

**Objectives:** The handling of health records is closely tied with in the last years very much discussed topic of personal data protection. It is still possible to encounter fears if the legal regulation of personal data protection allows some of these deployments and in which way. Less often, but still, it is possible to encounter concerns also regarding possible intellectual property claims. In the light of these questions the authors decided to do an analysis of the existing legal framework.

**Methods:** In this article we analyse the relevant content of Czech Personal Data Protection Act (though as this area is already highly harmonized by EU directives, the demonstrated principles can be applied more generally, not only in the context of the specific country). In similar way we analyse also the Czech Copyright Act.

**Results:** When comparing both regulations we see that their principles and the subjects they concentrate on are largely different and the personal data protection is more

prominent in our context, but the intellectual property regulation can also apply in some cases and complements the regulation. Legal frameworks we discussed here can be judged as developed and relatively mature. This appears to be the result of the harmonisation by EU directives and other supranational legislation.

**Conclusions:** Legal regulation discussed in this article seems to be generally ready for development and deployment of e-health services. This does not, however, mean that the described regulation should not be a major concern of health care providers. Quite the opposite. The data Protection Act prescribes critical obligations, such as the adoption of measures preventing unauthorised access to personal data. Also for certain types of databases the intellectual property rights cannot be ignored.

## Keywords

Health record, database, legal framework, personal data, intellectual property

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## 1 Introduction

The keeping of health records is closely tied with in the last years very much discussed topic of personal data protection. It is a critical aspect which is necessary to have in mind in the process of deploying various e-health applications and which still arouses various questions. It is still possible to encounter fears if the legal regulation of personal data protection allows some of these deployments and in which way. Less often, but still, it is possible to encounter such questions also regarding possible intellectual property claims.

The authors are dealing with this topic in the context of the Czech system of law. Nevertheless, as this area is already highly harmonized by EU directives, the demon-

strated principles can be applied more generally, not only in the context of the specific country.

The goal of this article is to provide a review of the legal framework in this area and of obligations prescribed by it, to identify possible issues and to help understand its role in the regulation of health records and other medical data.

## 2 Personal Data Protection

The Act n. 101/2000 Sb. on the Protection of Personal Data (hereinafter referred only as "Personal Data Protection Act" or "Act") [1] is a reflection of the article 10 sub-article, 3 of the Czech Charter of Fundamental Rights and Basic Freedoms [2] according to which "Everyone has the

*right to be protected from the unauthorized gathering, public revelation, or other misuse of his/her personal data.*" It also reflects the Council of Europe's Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (also known as the "Convention 108") [3]. And from the point of European law it implements [4, 5] the Directive n. 95/46/ES on the protection of individuals with regard to the processing of personal data and on the free movement of such data [6].

## 2.1 The Scope of the Personal Data Protection Act

The Personal Data Protection Act is in the field of personal data protection *lex generalis*, that is, it will be used if there is no special law with different rules (*lex specialis*). In this article we are going to concentrate on situations where this *lex generalis* will be used (the Czech regulation *lex specialis* in the field of health records has already been discussed by the authors in their previous article [7]).

The scope of the Personal Data Protection Act is large; it covers the processing of personal data by both the public authority bodies (the state authorities and territorial self-administration bodies) and by the natural and legal persons. It also applies to personal data processing both by automatic or other means. However, the Personal Data Protection Act does not cover all processing; outside its scope are the cases of personal data processing carried out by a natural person for personal needs exclusively and of accidental personal data collection, if these data are not subject to further processing.

The Act defines the term „personal data”. According to its definition *“personal data shall mean any information relating to an identified or identifiable data subject. A data subject shall be considered identified or identifiable if it is possible to identify the data subject directly or indirectly in particular on the basis of a number, code or one or more factors specific to his/her physical, physiological, psychological, economic, cultural or social identity”*.

In literature, there is no consensus if the Act does regulate only the personal data of the living people or also the personal data of the deceased [4, 5]. The Act itself does not explicitly states anything about it. The authors though consider logical that the interpretation of the law should be such that the protection granted by the Act should be enjoyed, especially in the field of healthcare, even by the deceased.

## 2.2 The Status of Health Records

The data about health status of a person the Act considers to be “sensitive personal data”. Their processing

<sup>1</sup>An implementation of the article 17 subarticle 3 of the Directive n. 95/46/ES.

is nevertheless allowed in healthcare by the § 9 letter c) of the Act, according to which it is possible to process sensitive personal data *“if the processing in question is in relation with ensuring health care, public health protection, health insurance, and the exercise of public administration in the field of health sector pursuant to a special Act, or it is related to assessment of health in other cases provided by a special Act.”*

The legal framework in this context does not distinguish the keeping of health records in paper and electronic form. The important thing is, that it must be a processing in relation with ensuring health care or some of the other quoted cases.

From practice the authors are aware of cases when medical facilities require patients to sign up forms where they agree with the electronic way of keeping their health records, while they would not require any signature from these patients for the same processing of the data in case of paper form of the health records. This, however, has no legal basis in Czech law. To the authors it also does not seem to be a meritorious effort to respect the rights of the data subject but instead, in a better case, an unnecessary bureaucracy, or, in worse case, an attempt to dodge responsibility in case of a problem. It is up to the health care providers to guarantee the proper functioning and security of the health records and in case of for example data leak, it cannot exculpate itself by an argument that the patient agreed with the form in which the record will be kept.

## 2.3 The Controller, the Processor and the Obligations

The subject that determines the purpose and means of personal data processing carries out such processing and is responsible for such processing is called the controller. The controller may through agreement charge another subject to process personal data - the processor.

Such an agreement must be made in writing and shall explicitly stipulate the scope, purpose and period of time for which it is concluded and must contain guarantees by the processor related to technical and organisational securing of the protection of personal data (§ 6 of the Act<sup>1</sup>). The contractor may in this way charge multiple processors. The processors themselves, however, cannot charge another subject with the processing. These are the agreements that are being made between medical facilities and subjects that are providing for them the data storage and other services. Thus although this legal regulation is only generic and brief, it can be stressed out, that it applies to lot of projects in the field of e-health<sup>2</sup>.

<sup>2</sup>Such as the e-Health project MeDiMed (<http://www.medimed.cz>).

For the data subject, that is, the natural person to whom the personal data pertain, the Act does not prescribe any obligations. It does prescribe many of them though to the controllers and processors. We will discuss them here later, though not all of them will be of deeper interest to us because of the existence of the regulation in *lex specialis* or specific provisions in the Act itself.

Foremost, the Personal Data Protection Act prescribes to the controllers an obligation to specify the purpose for which personal data are to be processed and the means and manner of such processing; these obligations are however in the case of health records already in essence fulfilled by their legal regulation in *lex specialis* [8]. What the controller always must have in mind is the obligation to process only accurate personal data and, if necessary, to take adequate measures to block the processing and to correct or supplement the personal data. Further it is allowed to collect only personal data corresponding exclusively to the specified purpose and in an extent that is necessary for the fulfilment of such purpose. Therefore it is not possible to collect personal data in health records that are not related to the purpose of these records. The personal data can be processed only in accordance with the purpose for which they were collected. Furthermore it is forbidden to group personal data that were obtained for different purposes. The obligations we described in this paragraph are binding likewise for the processor.

The controller and the processor are also (§ 13 of the Act) “obliged to adopt measures preventing unauthorised or accidental access to personal data, their alteration, destruction or loss, unauthorised transmission, other unauthorised processing, as well as other misuse of personal data. This obligation shall remain valid after terminating personal data processing.”

The Act does not define in detail which measures these are supposed to be. It is not even possible as the security risks are always developing. It states, however, that the measures must be a result of an assessment of risks from both the persons with immediate access to the personal data, and the persons attempting an unauthorized access, concerning prevention of unauthorized reading, creating, copying, transferring, modifying or deleting of records containing personal data and measures enabling to determine and verify to whom the personal data were transferred. In the area of automatic processing of personal data, the controller or processor is also obliged to

1. ensure that the systems for automatic processing of personal data are used only by authorized persons,
2. ensure that the natural persons authorized to use systems for automatic processing of personal data have access only to the personal data corresponding

to their authorization, and this on the basis of specific user authorizations established exclusively for these persons,

3. make electronic records enabling to identify and verify when, by whom and for what reason the personal data were recorded or otherwise processed, and
4. prevent any unauthorized access to data carriers.

It is also worth to mention that the Office for Personal Data Protection is asking in its forms about the existence of locks, bars, central security desk, electronic security, security directive, and, in the case of automatic processing, also about access rights, security backups, anti-virus and encryption. In this area, also the technical norms can be of use<sup>3</sup>. The controller or the processor is obliged to document the technical-organisational measures adopted and implemented.

A special obligation of the processor is, if he finds out that the controller breaches the obligations provided by the Act, to notify the controller of this fact without delay and to terminate personal data processing.

The Personal Data Protection Act also prescribes obligations for the employees of the controllers and processors or other natural persons who process personal data on the basis of an agreement concluded with the controller or processor and other persons who, in the scope of fulfilling rights and obligations provided by law, come into contact with personal data at the premises of the controller or processor. These persons are obliged to maintain confidentiality of personal data and security measures whose publishing would endanger the security of personal data. This obligation is binding for them even after the termination of their employment or the relevant work. The obligation to maintain confidentiality, however, does not apply in cases where some other act would prescribe information obligation (such as the obligation to report crime).

## 3 Intellectual Property Rights

### 3.1 Author's Work

The authors consider clear that the individual health records created by doctors cannot be considered author's work in the sense of § 2 article 1 of the Act n. 121/2000 Sb. on Copyright and Rights Related to Copyright (hereinafter referred only as “Copyright Act” or “Act”) [9], as they do not fulfil the necessary criterion of uniqueness. They do not represent an original exceptional outcome of the creative activity of the author.

We consider it necessary though to discuss more the copyright to databases. It is because the Copyright Act also states that the quoted criterion of uniqueness does

<sup>3</sup>Such as ISO/IEC 17799:2000 Information technology – Code of Practice of Information Security Management or Czech ČSN

ISO/IEC TR 13335 Informační technologie – Směrnice pro řízení bezpečnosti IT 1 - 3

not apply to computer programs and databases (§ 2 article 2). For them it is sufficient if they are original in the sense that they are by the way of the selection or arrangement of their content the author's own intellectual creation. For databases it is also required that their individual parts are arranged in a systematic or methodical way and are individually accessible.

Database by the definition in the Act is a collection of independent works, data, or other items arranged in a systematic or methodical manner and individually accessible by electronic or other means, irrespective of the form of the expression thereof (§ 88 of the Act). The collections of health records can be in the light of this definition considered databases in the context of the Act. Before we discuss the relevance of this fact it is necessary though to mention another legal regulation in the same Act which is the regulation of the right of a database maker to his database.

### 3.2 The Right of a Database Maker to His Database

The Copyright Act in its § 88 and following regulates the right of a database maker to his database. This is an implementation of the Directive n. 96/9/EC on the legal protection of databases [10]. It is a type of protection sui generis which is in its nature closer to the protection against unfair competition than copyright protection [11]. The protection of the right of a database maker to his database is not a protection of a right of the author to his work, nor of a right related to copyright, but a special protection regulated in the Copyright Act existing outside these categories.

The maker of the database is the natural or legal person who, on his own responsibility, has compiled the database, or on whose impulse is the database compiled by another person (§ 89 of the Act). The maker of the database may transfer his right.

The right of a database maker to his database arises only when there is a contribution in the form of formation, verification or presentation of the content of the database, which is substantial in terms of quality or quantity.

The protection covers databases in any form, that is both electronic and non-electronic. Protected is the content of the database and also the elements necessary for the operation and searching in databases such as thesaurus and indexing system. On the other hand this protection does not include computer programs used for creating and running the database [11].

The content of the right of a database maker to his database is the right to extraction or re-utilisation of the content of the database and the right to grant to another

person the authorisation to execute such a right. Extraction means a transfer of the database (all or a substantial part thereof) to another medium, re-utilisation means making it available to the public. Lending of the original or a copy of a database is not considered extraction or re-utilization.

The Copyright Act also states that the right in question is not infringed by the lawful user who extracts or re-utilises:

1. qualitatively or quantitatively insubstantial segments of a database that has been made available to the public as long as he is doing so in a normal and appropriate manner, not systematically or repeatedly, and without damaging the legitimate interests of the maker of the database,
2. a substantial part of the content of the database but only
  - (a) for his personal use in case of non-electronic database, or
  - (b) for scientific or educational purposes, if he indicates the source, or
  - (c) for the purposes of public security or an administrative or judicial procedure.

The right of a database maker to his database runs for 15 years from the making of the database. If, however, the database is made available during that period, the right of the maker of the database expires 15 years from the date when the database is made available (§ 93 of the Act).

In case of a violation of the right of a database maker to his database the civil law proceeding as well as the public law sanctions (§105a article 1 letter a) of the Copyright Act, § 270 of the Penal Code [n. 40/2009 Sb.] [12]) can be used.

### 3.3 Usability of Intellectual Property Law Regulation

Such is the protection of databases in the Copyright Act. The question remains, to what extent is it possible to use the copyright to the database and the right of a database maker to his database for protection of medical databases.

We believe that the principles of these rights are not very much in line with the needs of legal protection of medical databases containing health records of individual patients. The character of such data and the requirements for their keeping are completely different from those which are typically in the scope of the intellectual property law. The very roots of databases with health records differ from others by strong public law elements compared to private law elements of the other databases.

Opposite is also the logic of the compared acts. While the author's works are typically distributed commercially, the exchange of information contained in health records should be burdened by financial questions as little as possible. While the author's works can be in certain cases accessed freely (see free uses in § 30 of the Act), in the latter this is out of the question. Also the length of the legal protection set in the Copyright Act (15 years for the right of a database maker to his database) is not corresponding. And it can be stated that the legal regulation of health records, medical confidentiality and personal data protection is so complex that the protection by means of intellectual property law would be even superfluous.

From there reasons we believe that the copyright to databases in case of medical databases with health records of patients does not exist as they must be considered official works within the meaning of § 3 letter a) of the Act. This provision defines an exemption according to which the copyright protection does not apply to official works.

In the case of a right of a database maker to his database it was before possible to get to the same conclusions in exactly the same way. However, since May 22, 2006 by the changes introduced by an amendment n. 216/2006 the § 3 letter a) of the Act does not apply to the right of a database maker to his database anymore (except databases which are part of statutes, which is not our case) [13]. Therefore it can be argued that this right exists even for databases with health records. The existence of such right in our opinion though has little practical impact, as the rules for who can and who cannot access the data in such database are strictly set in the regulation *lex specialis* [8]. This right thus seems to have a bare character.

What we said above does not necessarily mean that the described intellectual property rights are irrelevant in the field of healthcare. In medicine, there are other databases than those with personal data of patients. For example if the personal data from health records get anonymised (by which they are stopping to be personal in the sense of the Personal Data Protection Act) and transformed into a database designed for educational purposes, both the copyright and the right of a database maker to his database could apply. These rights thus can be used for protection of various databases with medical knowledge stored for educational and scientific purposes.

## 4 Conclusion

Above we dealt with medical data in the light of legislation for protection of personal data and for protection of intellectual property. As we can see from the analysis, because of the character of health data the personal data

regulation appears to be more important, however, the protection of the intellectual property rights also has its place and both somewhat complement each other. The health databases with personal data of patients are regulated by legislation for personal data protection. Then, in case of their anonymization for usage for educational purposes, these databases fall into the scope of intellectual property legislation.

Unlike the regulation *lex specialis* analysed in previous article of the authors [7] both legal frameworks we discussed here can be judged as developed and relatively mature. This appears to be the result of the harmonisation by EU directives<sup>4</sup> and other supranational legislation. The part of legal regulation discussed in this article seems to be generally ready for development and deployment of e-health services.

By the previous paragraph the authors did not want to say though, that the described regulation should not be a major concern of health care providers. Quite the opposite. The Data Protection Act prescribes critical obligations, such the adoption of measures preventing unauthorised access to personal data. Also for certain types of databases the intellectual property rights cannot be ignored.

The discussed legal framework represents obligations and certain limitations but these are necessary for building trust in the environment. Lack of trust makes people hesitate to adopt new services. This risks slowing down the development of innovative uses of new technologies. We should thus think about legal framework as an important part of a foundation of every e-health project.

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<sup>4</sup>The Directive n. 95/46/ES might get replaced with a regulation in the future though [14].

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