

the **Code of Ethics of Biochemists**¹⁶⁶ contains a general definition of the duty of professional secrecy (**Articles 24, 51 and 52**).

d. Practice examples

Example(s) of Compliance

The obligation of confidentiality and professional secrecy in recent years is in focus in Serbia. In addition to the described regulations, it is insisted that this area is further detailed by Laws and by-laws. Thus, the Commissioner for Information of Public Importance and Personal Data Protection publishes its practices and recommendations in order to contribute to a better understanding of this problem by relying on the Law on personal data protection.¹⁶⁷

Example(s) of Violation

The Commissioner for Information of Public Importance and Personal Data Protection sent a letter to the Ministry of Health which indicates the responsibilities of the Ministry in connection with the implementation of the Law on exercising of rights to health care of children and women during pregnancy, delivery and postnatal period¹⁶⁸. The Constitutional Court submitted a proposal for establishing the unconstitutionality of Article 5 of this Law because it does not guarantee protection of personal data, does not specify the purpose of collecting data on pregnancy, termination of pregnancy, stillborn children, or child mortality in the first year of life and because the way of keeping and processing data is not regulated in the National Health Insurance Fund (NHIF). In this way, it can cause irreparable consequences both for the individuals whose personal data will be on-hand in NHIF, as it is uncertain how it will be used and collected, as well as for physicians and medical institutions that may be asked (Article 44 and 46 of the Law on Protection of Patients' Rights) if the data from medical records is available. The Constitutional Court rejected the proposal for a finding of unconstitutionality, although one judge dissented based on the grounds of the claim.¹⁶⁹

Actual Case(s)

MM addressed the Municipal Court in Zajecar with a lawsuit for compensation for non-material damages for emotional harm, due to unauthorized disclosure of her medical records. After examining the case, the Court decided in favor of the plaintiff because the health care providers of the Health care center in Zajecar discovered the information about the blood tests of the plaintiff in which they have discovered the HIV virus. Subsequent analysis showed that the plaintiff does not have HIV, but health care providers had expanded the information on the HIV virus through the place where the plaintiff lives. This has led to the isolation of the plaintiff, her family, her child has been rejected from the kindergarten and her husband had problems in the workplace. The Court granted compensation that the Health care center should provide to MM.¹⁷⁰

¹⁶⁶ Official Gazette RS 106/2006.

¹⁶⁷ Official Gazette 97/2008 and 104/2009.

¹⁶⁸ Official Gazette RS 104/2013.

¹⁶⁹ Official Gazette RS 73/2014.

¹⁷⁰ The verdict of the Supreme Court of Serbia, Belgrade, Rev. 392/03.

e. Practice Notes for Lawyers

Administrative, civil and criminal procedure may be opened in response to violations of this right; all procedures are described in details in Chapter 8 of this Guide.

A specific problem may arise in practice when a physician has a prostitute for a patient who is infected with HIV, but who nevertheless continue to engage in this occupation without warning people who come into contact with about her HIV positivity. Such a behavior could be considered as a potential criminal offense specified in paragraph 2 of the Article 250 of the Criminal Code („Whoever, knowing that he/she was infected with HIV, knowingly transmits the infection to another shall be punished with imprisonment from two to twelve years“). Due to the fact that this offense is punishable by imprisonment of two to twelve years, the reporting is mandatory, and failure to report is also punishable under paragraph 2 of Article 332 of the Criminal Code. On the other hand, according to paragraph 3 of the same Article of the Criminal Code, the physician of the perpetrator (who in this particular case is the patient of that physician) will not be punished for failing to report. The question is how a physician is to act in this situation. Given the fact that the patient is required to perform on proposed measures and procedures in the treatment by physicians for protection of the environment, if the patient does not follow the advice of physicians, he/she violates the unwritten contract between himself/herself and the physician; and the physician is thus, relieved of further liability for failure to keep secrecy and shall report this behavior of his/her patient in order to protect other potentially vulnerable individuals.

7.2.9. RESPONSIBILITY FOR KEEPING HEALTH RECORDS AND COMPULSORY NOTIFICATION

a. Keeping health records and the preparation and submission of prescribed reports are integral parts of the work of health care institutions

Health care institutions must keep records and prepare and submit prescribed reports by implementation of uniform methodological principles and statistical standards for keeping records prescribed by the legislation. A health care provider is legally obligated to report the existence of infectious disease or suspected infectious disease and to report preparation of crime, performance of the crime or its executive.

b. Right as Stated in the Country Constitution / Legislation

Law on Health Care Records

Article 2 of the **Law on Health Care Records**¹⁷¹ determines that the records in the field of health care (hereinafter: the records) are used for monitoring and studying of the health status of the population, for the planning and programming of health care, and for monitoring and evaluating of the implementation of plans and health care programs for statistical and scientific research in the field of health care and other purposes.

Health care institutions, private practice, institutions of social welfare, prisons, colleges for health professionals who perform certain duties regarding health care services, as well as other legal entities that perform particular tasks of health care services in accordance with the Law, are required to keep

¹⁷¹ Official Gazette SR 14/1981 and Official Gazette RS 44/1991.

medical records and evidence and to submit them within the prescribed deadlines for individual, collective and periodic reports to the competent institution or the Institute of Public Health, as well as other organizations in the manner prescribed by special Law. Confidentiality of these data is required and guaranteed by the health care institution, with the obligation to protect medical records from unauthorized access, copying, and abuse, regardless of the form in which the data from medical records is preserved.

Keeping health records and entering data into the medical record are exclusively performed by authorized persons only, in accordance with the Law.

The Law on Health Care Records regulates:

- the type and content of medical documentation and records,
- the manner and method of documenting and recording,
- the persons authorized to conduct medical documentation and data entry,
- deadlines for submission and processing of data
- methods of data retrieval from patient medical records used for data processing,
- other issues of importance for medical documentation and record-keeping is.

According to the Law on Health Care Records, **Article 7**, the basic medical documentation includes:

1. health record,
2. patient protocol,
3. a protocol for recording the results of medical work, of the operated patients and patients who died,
4. register of persons accommodated in inpatient health care department, medical history,
5. temperature-therapeutical-dietetic list,
6. discharge list with epicrisis,
7. list of anesthesia,
8. log book,
9. list of medicines (drugs) spent for treatment.

Aids for keeping records include:

1. registry of records,
2. daily records of visits and work,
3. current records of diagnosed illnesses and conditions,
4. daily records of the movement of patients in the hospital - inpatient health care department.

In records of general information of interest to the whole country on the examined, diseased, injured, treated and other persons who were provided with health care services, the following general information is entered for every person:

1. First name and surname of the person from which derived the right to health care,
2. The name of one of the parents,
3. The personal identification number.

Special records are kept in cases of temporary incapacity or inability to work. From the first day of temporary incapacity, particular attention is due to: diseases and injuries (other than occupational injury), occupational injury, pregnancy, childbirth and care of the sick family member.

Criminal Code of the Republic of Serbia

The **Criminal Code**¹⁷² in **Article 251** (concept of crime of *Negligent provision of medical assistance*) stipulates as one of the possible forms of malpractice the inadequate management of medical records, which also happens in practice.

Other Laws Mentioning Medical Records

Laws that also mention medical records are as follows: **Health Insurance Law**¹⁷³, the **Law on Protection of Patients' Rights**¹⁷⁴ and the **Law on Occupational Safety and Health**.¹⁷⁵ In general, these Laws state that medical record has to contain all necessary data for proper diagnostic and therapeutic treatment.

Legislation Containing Requirements for Physician or Health Care Institution Reporting

There is also obligation of reporting in the legislation in Serbia, namely: the existence of an infectious disease or suspected infectious disease, preparing/ planning the criminal act, executing the criminal actor reporting about offender. In performing his/her daily activities, the physician is exposed to various interests which may arise from questions about his responsibilities.

- According to **Article 332 of the Criminal Code**, if the physician knows that a person has committed a criminal offense for which the Law may impose imprisonment of thirty to forty years or if the physician knows that such offense was committed and fails to report it before the offense and/or the offender are discovered, the physician shall be punished by imprisonment of up to two years. The punishment referred to in **paragraph 1** of this Article shall also apply to an official or responsible person who knowingly fails to report a criminal offense which it discovered while performing his/her duties, if the offense is punishable under Law by imprisonment of five years or more of severe punishment. **Paragraph 3** states that the law will not punish the attorney, physician or religious confessor of the perpetrator of the crime.
- **The Criminal Code, (Article 194)** defines the obligation of reporting in cases of the following; serious bodily injury; injuries that are caused by projectiles from firearms or similar means that can cause severe body injury; sexual crime (rape, sodomy, etc.); and domestic abuse.
- **the Law on Protection of Population against Infectious Diseases**¹⁷⁶ (**Article 14**) requires reporting, in accordance with this Law, in the following cases:
 1. illness or death from infectious diseases;
 2. death from infectious disease that is not listed in Article 2 of this Law;

172 Official Gazette RS 85/2005, 88/2005 - corr., 107/2005 - corr., 72/2009, 111/2009, 121/2012, 104/2013 and 108/2014.

173 Official Gazette RS 107/2005, 109/2005 - corr., 57/2011, 110/2012 - decision of the Constitutional Court, 119/2012, 99/2014, 123/2014

174 Official Gazette RS 45/2013.

175 Official Gazette RS 101/2005.

176 Official Gazette RS 125/2004 i 36/2015

3. suspicion of cases of cholera, plague, smallpox, yellow fever, viral hemorrhagic fever, poliomyelitis, diphtheria, measles, botulism;
 4. epidemics of infectious diseases;
 5. secretion that causes typhoid fever, paratyphoid, salmonella, shigella, yersinia, campylobacter infection, as well as carriers of antigens of viral hepatitis B, the presence of antibodies to viral hepatitis C, antibodies to HIV, and carriers of parasites - the cause of malaria;
 6. the possibility of rabies virus infection;
 7. infections within health care institutions (hospital infections);
 8. bacterial resistance to antimicrobial drugs;
 9. laboratory- identified agents of infectious diseases;
 10. acute flaccid paralysis;
 11. suspected use of biological agents.
- **Article 15** of the same Law provides a similar obligation for infectious disease of zoonosis or death of a person caused by this contagious disease.

c. Supporting Regulations/Bylaws/Orders

There are numerous accompanying regulations governing the area of health records, including electronic forms (electronic health records and electronic patient records). These include the following:

- Regulation on voluntary health insurance¹⁷⁷;
- Regulation on the manner of exercising the right to health insurance of military insured and members of their families¹⁷⁸;
- Regulation on the national program of health care for women, children and youth¹⁷⁹;
- Regulation on the national program of prevention, treatment and control of cardiovascular diseases in the Republic of Serbia until 2020¹⁸⁰;
- Regulation on the national program for prevention and early detection of type 2 diabetes¹⁸¹;
- Regulation on the national program of prevention, treatment, improvement and control of the development of renal failure and dialysis in the Republic of Serbia until 2020¹⁸²;
- Regulation on medical documentation, records and reports on personnel, equipment, facilities and medicines in health care institutions¹⁸³;
- Rules on data provided in the special register kept by health care institutions and deadlines for submission of data and information¹⁸⁴;
- Rules on the content of technological and functional requirements for the establishment of an integrated health care information system¹⁸⁵;

177 Official Gazette RS 108/2008 and 49/2009.

178 Official Gazette SRJ 36/1994.

179 Official Gazette RS 28/2009.

180 Official Gazette RS 11/2010.

181 Official Gazette RS 17/2009.

182 Official Gazette RS 11/2011.

183 Official Gazette RS 29/2000.

184 Official Gazette SFRJ 64/1991 and Official Gazette SCG 1/2003 - Constitutional Charter

185 Official Gazette RS 95/2009.

- Regulation on the procedure for issuing registration of birth of the child and the application form for the birth of a child in a health care institution¹⁸⁶.

The Statute of the National Health Insurance Fund¹⁸⁷ also regulates the issue of keeping medical records.

d. Providers' Codes of Ethics

The Code of Ethics of the Serbian Medical Chamber¹⁸⁸ in Articles 49 and 75 requires regular and up-to-date health records.

e. Practice examples

Example(s) of Compliance

KM was admitted as an emergency case, accompanied by police officers, on suspicion that he swallowed a packet of drugs. Since the KM refused to give a written consent to the intervention of removing packets of drugs by inducing vomiting, doctor BM did not perform the intervention but he entered all necessary data into medical records. Despite the initiation of the criminal procedure by the Ministry of Internal Affairs, after examining the facts, doctor BM was acquitted. It was found that the doctor BM acted lawfully and properly because following the entire procedure, entering a note in the medical record of the patients' refusal to provide informed consent for the medical intervention, which, for this reason, was not carried out.

Example(s) of Violation

1. The medical record of anesthesia is not up to date in surgical interventions in general anesthesia, which creates problems in later forensic expertise, if a patient dies during general anesthesia.
2. In the medical history of the patient, who died after several days or even weeks of the medical treatment, there is entered only findings on admission to the health care institution and conclusions on the cause of death, without any information on the progress of the disease or the condition of the patient during treatment.

Actual Case(s)

1. In a criminal case, brought by state prosecutor against physician as defendant for malpractice to the Supreme Court, the clinical picture of the patient after a tonsillectomy clearly indicated the presence of sepsis, without any signs and symptoms of shigellosis. However, a physician indicated in the patient's medical records at the time that most likely it was case of shigellosis and that the patient should not be given antibiotics. A few days later the patient died. Using blood cultures taken during the patient's life and autopsy, findings demonstrated a streptococcal sepsis as a cause of death. During expertise two opposing arguments emerged on the state of the patient's health at discharge from the hospital after completion of the surgery. The doctor argued that the patient was discharged in good general condition and afebrile; the family of the patient stated that he then had hyperthermia. In the reported medical documentation, the patient's condition at discharge is not stated and a temperature chart on the treatment of the patient after tonsillectomy was completely empty, ie

186 Official Gazette RS 25/2001.

187 Official Gazette RS 81/2011, 57/2012, 89/2012, 1/2013 and 32/2013.

188 Official Gazette RS 121/2007.

without any data on postoperative movement of the body temperature. The outcome of the case was imprisonment of the physician.

2. In one autopsy case processed at the Supreme Court through the criminal procedure, a 55-year-old female patient received otorinolaryngology intervention of removal of polyps from the nasal cavity (*polypectomia endonasalis bilat. et ethmoidectomy anterior bilat*). The records about the surgery included the following: „In general anesthesia the cleanse of both nasal polyps hallway from the front and the cells ethmoidal sinuses is done. Front tamponade.“ After this intervention, the patient did not wake up from general anesthesia. The next day the patient died. An autopsy revealed that during surgery a breach occurred to the skull base from a surgical instrument and its penetration through the right frontal lobe of the cerebrum in the front horn of right lateral ventricle, which led to fatal bleeding in the brain ventricles and the subarachnoid space. The outcome of the case was imprisonment of the physician.
3. AP died at a gynecology clinic after childbirth. The patient, unaccompanied by doctors, was directed to this clinic from the Health Centre because of high blood pressure, although according to the findings of the health inspection, the patient had a headache and occasionally lost consciousness. Doubt is expressed publicly that the supporting medical documentation was not sent from the city of the patient, which further aggravated the work of doctors at birth. Nevertheless, despite the orders of the Commissioner for Information and Personal Data Protection to the Health Centre to hand over copies of the documents to her husband, the Health Center refuses, referring to the incompetent, and inaccessible opinion of the Ministry of Health or the inspection of the Ministry of Health.

f. Practice Notes for Lawyers

Administrative, civil and criminal procedure may be opened in response to violations of this right; all procedures are described in details in Chapter 8 of this Guide.

7.2.10. RESPONSIBILITY FOR LICENSING, CONTINUING MEDICAL EDUCATION AND RE-LICENSING

a. Health care providers must constantly improve their professional skills

Serbian law requires that in constantly improving their professional skills, health care providers also must apply diagnostic methods and therapeutic procedures of contemporary medicine.

The requirement for licensing and re-licensing is tied to the regulated professions, which include health care providers.

b. Right as Stated in the Country Constitution / Legislation

Law on Health Care

The issuance, renewal and revocation of the license for independent work is regulated by the **Law on Health Care**¹⁸⁹, with a part which relates to the obligation of licensing and re-licensing, **Articles 190 to 198.b.**

The issuance of the license

Article 194 of the Law on Health Care regulates the issuance of the license to work as a health care provider. It states once a future health care provider successfully completes the professional exam, the competent Chamber (Director of the Chamber) will issue a decision and a license for a period of seven years.

According to **Article 195** of Law, the license is issued when a health care provider candidate:

- meets the educational requirements of the health profession;
- has successfully completed an internship;
- has passed the exam;
- is registered in the directory of the Chamber;
- proves that there is no court decision of a criminal offense that makes him/her unworthy of performing health care activities, and that there is no court decision to sentence him/her to imprisonment for a serious crime against the public health.

The renewal of the license

This is regulated by **Article 196** of the Law on Health Care. This states that a health care provider should submit the request for renewal of the license to the competent Chamber, 60 days before the expiration of the period for which the current license was issued, together with evidence of the completion of required continuing education, as well as evidence of competences to continue work in his/her profession. The certificate of continuing medical education with specific number of accredited points by Health Council of Serbia is proven evidence of competences. The renewal of the license is done every seven years.

Failure to Receive or Renew a License

If a health care provider does not receive, or does not renew his/her license, he/she cannot perform independent work in any health care institution or private practice (**Article 191 of the Law on Health Care**). **Article 192** states that a health care provider to whom the competent Chamber has not renewed the license, or whose license is revoked, under the conditions stipulated by this Law, shall, within eight days of the receipt of the decision, to submit the previously issued license to the relevant Chamber.

Temporary revocation of the license

Temporary revocation is regulated by **Article 197** of the Law on Health Care. It provides that the Chamber of health care providers under certain conditions, can temporarily (from six months to five years) revoke the license of health professionals if:

- they do not renew the license;
- they perform an activity for which their license was not granted;
- they make a professional error which distorted or deteriorated the health condition of a patient;
- they were sentenced to one of the measures of temporary prohibition of independent work by the competent authority of the Chamber, due to a serious breach of professional duty and reputation of the Chamber, in accordance with the Law and the Statute of Chamber;

189 Official Gazette RS 107/2005, 72/2009 – State Law, 88/2010, 99/2010, 57/2011, 119/2012 and 45/2013 – State Law