

# CONTENT

Authors .....	IX
<b>A. Outline .....</b>	<b>1</b>
A.1 Authors' Aim .....	1
A.2 Basic Concepts, Definitions, Terminology .....	2
A.3 Formal Sources .....	10
<b>B. Fundamental Principles of Czech Health Law .....</b>	<b>15</b>
B.1 Organisation of Health Care, Actors Involved in Health Care .....	16
B.1.1 Patient (the Insured Person) .....	17
B.1.2 Health Service Providers .....	20
B.1.3 Public Health Insurance .....	22
B.1.4 Public Authorities, Public Administration and Its Role .....	23
B.2 Health Professionals and Their Qualifications .....	24
B.2.1 Basic Duties of Health Professionals .....	25
B.2.2 Basic Rights of Health Professionals .....	25
B.2.3 Qualifications — Medical Practitioners, Dentists, Pharmacists ..	26
B.2.4 Qualifications — Other Health Professionals .....	27
B.3 Contract for Health Care, Professional Standards .....	27
B.3.1 Contract for Health Care .....	28
B.3.2 Professional Standards .....	33
B.4 Informed Consent; Capacity; Representatives .....	40
B.4.1 Legal Concept .....	41
B.4.2 Content of Information .....	43
B.4.3 Communication of Information .....	47
B.4.4 Form of Consent .....	48
B.4.5 Capacity and Representatives .....	49
B.4.6 Deficiencies in Consent .....	50
B.4.7 Refusal of Consents .....	51
B.5 Care Without Consent, Restrictive Measures, Detentions .....	52
B.6 Rights and Duties of Patients .....	54
B.7 Rights and Duties of Health Service Providers .....	56
B.8 Duty to Maintain Confidentiality .....	58
B.9 Medical Records .....	59
B.10 Medical Associations .....	61
B.10.1 Role and Organisation .....	62
B.10.2 Disciplinary Authority and Proceedings .....	64

B.11	Public Health Insurance	65
B.11.1	Health Insurance Companies	65
B.11.2	Contracts for the Provision and Reimbursement of Health Services Covered by Public Health Insurance	68
B.11.3	Insured Persons	70
B.12	Medicines and Medical Devices	73
B.12.1	Definition and Regulation of Medicines and Medical Devices	73
B.12.2	Reimbursement from Public Health Insurance	74
B.12.3	Selected Other Areas of Regulation	75
B.13	Protection of Public Health	76
<b>C.</b>	<b>Specific Topics</b>	<b>79</b>
C.1	Human Body and its Parts	79
C.1.1	Legal Status of the Human Body	79
C.1.2	Work and Skill Exception	82
C.1.3	Exception for Deceased Bodies: the Criterion of Individual Person	83
C.1.4	Procurement and Use of Human Body Parts	86
C.1.5	Autopsies	88
C.2	Medical Research	89
C.2.1	Medical Research in General	89
C.2.2	Clinical Trials of Medicinal Products (Pharmaceuticals)	92
C.2.3	Clinical Trials of Medical Devices	103
C.2.4	Evaluation of Non-Established Methods	111
C.2.5	Stem Cells, Human Embryos	116
C.3	Assisted Reproduction	123
C.3.1	Conditions for Assisted Reproduction	125
C.3.2	Donor Anonymity	127
C.3.3	Surplus Embryos	128
C.3.4	Surrogacy	129
C.4	Abortion	130
C.4.1	Case Law of the European Court of Human Rights	131
C.4.2	Conditions for Abortion	132
C.4.3	Abortion in the Case of Minors	134
C.4.4	Abortion in the Case of Foreign Nationals	134
C.4.5	Dealing with the Body of a Foetus	135
C.5	Transplantation	136
C.5.1	Organ Allocation Criteria	138
C.5.2	Organ Donors	139
C.5.3	Special Requirements on Living Donor Transplants	142
C.5.4	Special Requirements on Donation from Minors, Persons with Limited Legal Capacity and Persons Unable to Grant Consent	144

C.6	Vaccination .....	145
C.6.1	Scope of Compulsory Vaccination .....	146
C.6.2	Sanctions .....	148
C.6.3	Exemptions from the Vaccine Mandate .....	150
C.6.4	Civil Liability for a Personal Injury Resulting from Compulsory Vaccination .....	151
C.7	Termination of Life-Sustaining Treatment .....	153
C.7.1	Terminology .....	154
C.7.2	Surrogate Informed Consent .....	155
C.7.3	Decision-Making Without Consent .....	157
C.7.4	Withdrawal of Life Support: Action or Omission? .....	158
C.7.5	Czech Medical Chamber Recommendation .....	161
C.7.6	Previously Expressed Wishes .....	162
C.7.7	Termination of Life-Sustaining Treatment of Minors .....	164
C.8	Euthanasia .....	167
C.8.1	Forms of Euthanasia and Assisted Suicide .....	168
C.8.2	Killing a Patient and the Applicable Law .....	170
C.8.3	Proposals for Legalising Euthanasia .....	172
<b>D.</b>	<b>Liability .....</b>	<b>175</b>
D.1	Principles of Civil Liability .....	175
D.1.1	Who Can Be Held Liable? .....	176
D.1.2	Contractual and Non-Contractual Liability .....	178
D.1.3	Wrongful Action or Omission .....	179
D.1.4	Culpability .....	181
D.1.5	Causation .....	183
D.1.6	Harm .....	184
D.1.7	Secondary Victims .....	185
D.1.8	Wrongful Birth and Wrongful Life .....	188
D.1.9	Strict Liability .....	190
D.1.10	Manner and Extent of Compensation .....	191
D.2	Principles of Criminal Liability .....	193
D.2.1	Who Can Be Held Liable? .....	194
D.2.2	Elements of Liability .....	195
D.2.3	Selected Criminal Offences .....	198
D.2.4	Procedural Aspects .....	199
D.3	Principles of Disciplinary Liability .....	200
D.4	Case Studies .....	203
D.4.1	Introduction .....	203
D.4.2	Medical Errors .....	204
D.4.3	Deficiencies in Informed Consent .....	208
D.4.4	Deficiencies in Medical Records and Shifting the Burden of Proof .....	213

D.4.5 Causation ..... 216

D.4.6 Loss of Chance ..... 219

D.4.7 Secondary Victims ..... 221

D.4.8 Vaccination ..... 224

Bibliography ..... 229

Index ..... 237