

HUMAN RIGHTS IN

Patient Care:

A PRACTITIONER GUIDE

MACEDONIA



**Human Rights
in Patient Care:**
A Practitioner Guide
Macedonia

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Not listed, but still deserving our thanks, are the many others who supported our working group and its work.

1 This chapter builds on material in *Health and Human Rights: A Resource Guide*, published by Open Society Institute and Equitas and edited by J. Cohen, T. Ezer, P. McAdams, and M. Miloff. An HTML version of this resource guide is available at: <http://equalpartners.info/>. The appendix to the international and regional procedures chapter is excerpted, with permission, from the Human Rights Centre, University of Essex, publication *Reported Killing as Human Rights Violations*, by Kate Thompson and Camille Giffard, pages 127–130.

Preface

The right to health has long been treated as a “second generation right”, which implies that it is not enforceable at the national level, resulting in a lack of attention and investment in its realization. However, this perception has significantly changed as countries increasingly incorporate the right to health and its key elements as fundamental and enforceable rights in their constitutions and embody those rights in their domestic laws. Significant decisions by domestic courts, particularly in Asia, Africa, and Latin America, have further contributed to the realization of the right to health domestically and to the establishment of jurisprudence in this area.

Although these and other positive developments toward ensuring the highest attainable standard of physical and mental health represent considerable progress, the right to health for all without discrimination is not fully realized, because, for many of the most marginalized and vulnerable groups, the highest attainable standard of health remains far from reach. In fact, for many, interaction with health care settings and providers involves discrimination, abuse, and violations of their basic rights. As I explored in my report to the UN General Assembly on informed consent and the right to health, violations to the right to privacy and to bodily integrity occur in a wide range of settings. Patients and doctors both require support to prevent, identify, and seek redress for violations of human rights in health care settings, particularly in those cases in which power imbalances—created by reposing trust and by unequal levels of knowledge and experience inherent in the doctor-patient relationship—are further exacerbated by vulnerability due to class, gender, ethnicity, and other socioeconomic factors.

Although there are a large number of publications on the principles of human rights, very little has been available in the area of the application of human rights principles in actual health care settings. In this context, the present guide fills a long-felt void. The specific settings detailed in this guide are Eastern European countries, but the guide is useful beyond this context in the international settings. I hope it will encourage the establishment of protective mechanisms and legislative action relating to violations within health care settings. Not only will it help to support health care providers, legal practitioners, and health activists to translate human rights norms into practice, it will also ultimately help communities to raise awareness, mobilize, and claim the rights they are entitled to.

The authors have done a huge service in furthering the right to health. They deserve full credit for undertaking this arduous task. The Open Society Institute also needs to be thanked for funding and publishing this very important work. I have no doubt that this practitioner's guide will generate a greater appreciation for the role of human rights in the delivery of quality health care in patient care settings and will also prove to be an invaluable resource for those working to realize the right to health.

Anand Grover,
United Nations Special Rapporteur on the Right to Health

Preface to the Macedonian Edition

Human rights in health care is a legal area that in Republic of Macedonia is fully regulated with the national legislation, as well as with the signed and ratified international instruments. Since gaining its independence, in Republic of Macedonia the right to health and the responsibility for one's health and the health of others is incorporated into the Constitution of the Republic of Macedonia and into the current legislation, and since then it evolved with patients' rights and responsibilities, as well as with rights and responsibilities of the health workers and the health care facilities.

The application of these regulations and the realization of the rights and responsibilities in health care are complex processes that involve many stakeholders and factors. On a global level, the standpoint regarding the patient-health worker i.e. patient-health care facility relation is being substituted in the past couple of decades; the paternalistic approach is being slowly substituted by a more active role of the patient in the decision making process regarding his/her health, and in selecting most appropriate and expedient services with minimal risks for the patients' health and life. This requires broader health education of patients, as well as better information on patients' rights and responsibilities and health workers' rights and responsibilities.

The Faculty of Medicine - Skopje and the Centre for Regional Policy Research and Cooperation "Studiorum", with financial and technical support from the Foundation Open Society Institute Macedonia, as well as the expertise of a number of academic professors and practitioners, created this Practitioners' Guide, in which the compulsory international and regional legal framework and the national legislation of Republic of Macedonia in this field are processed. With the intention to reflect on the existing relations between the law and the health care, the authors tried to illustrate the infringement of the patients' and health workers' rights i.e. to transpose the legal matter into common language, by placing a number of hypothetical examples and case studies. By using hypothetical examples and case studies of various NGOs, the authors tried to point out that a systematic monitoring and recording of legal practice in the patients' rights field is necessary and it is an important source of knowledge towards the advancement of the legislation and its use in this field, as well as that the cooperation with the NGO sector should intensify accordingly in order to respond to the complex practical needs for the realization of the right to health in Republic of Macedonia. In this manner, in the development of this Practitioners' Guide as a practical tool for realization of the right to health, the contribution of the Ombudsman needs to be pointed out.

This Guide has been developed by March 31, 2010. All amendments to the laws and bylaws, as well as other novelties of the applied policies in the health care field that directly or implicitly influence the patients' and health workers' rights and responsibilities, will be issued in additional addendums of the Guide, as well as on the web page constructed for this purpose.¹

The authors, publishers, supporters and all the others that gave their contribution in the creation of this Guide, sincerely hope that the Guide will be a useful tool for

lawyers, health care workers, health care facilities managers, and other practitioners that come face to face with these issues in their professional daily routines.

From the authors

1 The web page can be accessed through the following links: <http://www.pravanapacienti.mk>, <http://www.healthrights.mk>, <http://www.tedrejtatepacienteve.mk>, <http://www.patientsrights.mk>

1

Introduction

1.1 Introduction

This guide is part of a series published in cooperation with the Law and Health Initiative of the Open Society Institute (OSI) Public Health Program, OSI's Human Rights and Governance Grants Program, OSI's Russia Project, and the Soros Foundations of Armenia, Georgia, Kazakhstan, Kyrgyzstan, Macedonia, Moldova, and Ukraine. Designed as a practical "how to" manual for lawyers, it aims to provide an understanding of how to use legal tools to protect basic rights in the delivery of health services. The guide systematically reviews the diverse constitutional provisions, statutes, regulations, bylaws, and orders applicable to patients and health care providers and categorizes them by right or responsibility. It additionally highlights examples and actual cases argued by lawyers.

The aim of the guide is to strengthen awareness of existing legal tools that can be used to remedy abuses within patient care. If adequately implemented, current laws have the potential to address pervasive violations of rights to informed consent, confidentiality, privacy, and nondiscrimination. As this effect can be accomplished through both formal and informal mechanisms, this guide covers litigation and alternative forums for resolving claims, such as enlisting ombudspersons and ethics review committees. It is hoped that lawyers and other professionals will find this book a useful reference in a post-Soviet legal landscape, which is often in rapid flux.

This guide addresses the concept of "human rights in patient care", which brings together the rights of both patients and health care providers. The concept of human rights in patient care refers to the application of general human rights principles to all stakeholders in the delivery of health care. These general human rights principles can be found in international and regional treaties such as the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the European Convention on the Protection of Human Rights and Fundamental Freedoms, and the European Social Charter. These rights are universal and can be applied in the context of health care delivery just as they can be in any other context.

1.2 Overview of the Guide

Chapters 2 and 3 of the guide respectively cover the international and regional law governing human rights in patient care. They examine relevant “hard” and “soft” law and provide examples of cases and interpretations of treaty provisions. These two chapters are identically organized around the established human rights applicable to both patients and providers. These are the rights to liberty and security of the person; privacy; information; bodily integrity; life; highest attainable standard of health; freedom from torture, cruel, inhuman, and degrading treatment; participation in public policy; and nondiscrimination and equality for patients; decent work conditions; freedom of association; and due process for providers. Chapter 4 then provides information on the international and regional procedures for protecting these rights.

Chapters 5, 6, 7, and 8 are country-specific. Chapter 5 clarifies the legal status of international and regional treaties ratified, signed or adopted by the Republic of Macedonia, explains the country’s use of precedent, and includes a brief description of the legal and health system. Chapter 6 deals with patient rights and responsibilities. The patient rights section is organized according to the rights in the European Charter of Patients’ Rights, with the addition of any country-specific rights not specifically covered by the Charter. Drawn up in 2002 by the Active Citizenship Network—a European network of civic consumer, and patient organizations—the European Charter of Patients’ Rights is not legally binding, but is generally regarded as the clearest and most comprehensive statement of patient rights. The Charter attempts to translate regional documents on health and human rights into 14 concrete provisions for patients: rights to preventive measures, access, information, informed consent, free choice, privacy and confidentiality, respect of patients’ time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain, personalized treatment, the filing of complaints, and compensation. These rights have been used as a reference point to monitor and evaluate health care systems across Europe and as a model for national laws. Chapter 6 thus uses the rights enumerated in the European Charter of Patients’ Rights as an organizing principle, but along with each right, the applicable binding provisions under the national laws are presented and analyzed. These rights are then cross-referenced with the more general formulation of rights in the international and regional chapters. Chapter 7 focuses on provider rights and responsibilities, including the right to work in decent conditions, the right to freedom of association, the right to due process, and other relevant country-specific rights.

Chapter 8 covers the national mechanisms for enforcement of both patient and provider rights and responsibilities. These mechanisms include administrative, civil, and criminal procedures and alternative mechanisms, such as the Office of the Public Prosecutor, ombudspersons, ministries of internal affairs, ethics review committees, and inspectorates of health facilities. The chapter additionally contains an annex of sample forms and documents for lawyers to file.

The final section is a glossary of terms that are relevant to the field of human rights in patient care. Some versions of the guide also include a section of the glossary

with country-specific terminology. The glossary will enable greater accessibility of law, health, and human rights material.

Uses of the Guide

The guide has been designed as a resource for both litigation and training. It may be particularly useful in clinical legal-education programs. Although designed for lawyers, the guide may additionally be of interest to medical professionals, public health managers, Ministries of Health and Justice personnel, patient advocacy groups, and patients who desire a firmer understanding of the legal basis for patient and provider rights and responsibilities and the available mechanisms for enforcement.

Companion Websites

The field of human rights in patient care is constantly changing and evolving, necessitating the need for regular updates to the guide. Electronic versions of the guides will be periodically updated at: <http://www.health-rights.org/>. This international home page links to country websites, which include additional resources gathered by the country working groups that prepared each guide. The Macedonian country website is www.healthrights.mk. These resources include relevant laws and regulations, case law, tools and sample forms, and practical tips for lawyers. The websites also provide a way to connect lawyers, health providers, and patients concerned about human rights in health care. Each of the websites provides a mechanism for providing feedback on the guides.

Note from the Authors

The material in this guide represents the views of an interdisciplinary working group composed of legal and medical experts. The guide does not carry judicial or legislative authority, and it does not substitute for legal advice from a qualified lawyer. Rather, it represents the authors' attempt to capture the current state of the law and legal practice in the field of human rights in patient care in the Republic of Macedonia. The authors welcome any comments concerning errors or omissions, suggested additions to the guide, and questions about how the law might apply to a particular factual scenario.

As this guide illustrates, in the Republic of Macedonia, the field of human rights in patient care is still new and evolving. Many of the statutory provisions cited in the guide have not been authoritatively interpreted by courts, and those that have still remain open to additional application and interpretation. There remain huge gaps in understanding how, in practice, to apply human rights in patient care. This guide is, therefore, a starting point for legal inquiry, not a final answer. It is hoped that this guide will attract new professionals to the field of human rights in patient care, and that future editions will be much richer in their elaboration of legal protections.

1.3 Abbreviations

AC	Advisory Committee
CAT	Convention Against Torture and Other Forms of Cruel, Inhuman, or Degrading Treatment or Punishment
CE	ILO Committee of Experts
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women
CERD	Committee on the Elimination of Racial Discrimination
CESCR	Committee on Economic, Social, and Cultural Rights
CHR	Commission on Human Rights
CMW	International Convention on the Protection of the Rights of All Migrants Workers and Members of their Families
COE	Council of Europe
CRC	Committee Convention on the Rights of the Child
DRC	Convention on the Rights of Persons with Disabilities
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
ECOSOC	UN Economic and Social Council
ECSR	European Committee of Social Rights
EPHA	European Public Health Alliance
ESC	European Social Charter
EU	European Union
FCNM	Framework Convention for the Protection of National Minorities
HRC	Human Rights Committee
IAPO	International Alliance of Patients' Organizations
ICCPR	International Covenant on Civil and Political Rights
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social, and Cultural Rights
ICN	International Council of Nurses
ILO	International Labour Organization
OHCHR	Office of the High Commissioner for Human Rights
SR	Special Rapporteur on the Right to Health
UDHR	Universal Declaration of Human Rights
UN	United Nations
UPR	Universal Periodic Review
WHO	World Health Organization
WMA	World Medical Association

1.4 Table of Ratifications

Table with ratified international and regional documents

<i>Documents</i>	Date of Accession	Date of Signature	Date of Ratification	Entry into Force	Applicable in-country Legislation	Reservation Entered
International						
International Covenant on Civil and Political Rights (ICCPR)			18.01.1994	17.11.1991		
Optional Protocol to the International Covenant on Civil and Political Rights (ICCPR – OP)		12.12.1994	12.12.1994	17.11.1991		
International Covenant on Economic, Social and Cultural Rights (ICESCR)			18.01.1994	17.11.1991		
Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)			18.01.1994	17.11.1991		
Convention for the Elimination of All Forms of Racial Discrimination (CERD)			18.01.1994	17.11.1991		
Convention Against Torture and Other Forms of Cruel, Inhuman, or Degrading Treatment or Punishment (CAT)		14.06.1996	06.06.1997	01.10.1997		
Optional Protocol to the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT – OP)			01.09.2006	13.02.2009		
Convention on the Rights of the Child (CRC)			02.12.1993	17.11.1991		
International Convention on the Protection of the Rights of All Migrants Workers and Members of their Families (C114)						
Convention on the Rights of Persons with Disabilities (DRC)		30.03.2007				
European (Regional)						
Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997		04.04.1997	03.09.2009	01.01.2010		
Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, concerning Prohibition of Cloning Human Beings		12.01.1998	03.09.2009	01.01.2010		
Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Transplantation of Organs and Tissues of Human Origin		15.03.2002	03.09.2009	01.01.2010		
Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research						
Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes						
Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights)		09.11.1995	10.04.1997	10.04.1997		
European Social Charter 1961		05.05.1998	31.03.2005	30.04.2005		
European Social Charter 1996		27.05.2009				
Framework Convention for the Protection of National Minorities 1995		25.07.1996	10.04.1997	01.02.1998		
EU Charter of Fundamental Rights						
Other treaties related to Health Law signed by country						
Name of the treaty						

2

International Framework for Human Rights in Patient Care

2.1 Introduction

This chapter presents the main standards that safeguard human rights in patient care internationally and examines how United Nations (UN) treaty-monitoring bodies have interpreted these standards. The chapter is divided into three parts. The first part describes the key international sources governing human rights in patient care. The second examines patients' rights, and the third focuses on the rights of providers. Each part includes subsections that discuss the standards and relevant interpretations connected to a particular right (e.g., the Right to Liberty and Security of the Person) and also provide some examples of potential violations. The standards addressed include binding treaties, such as the International Covenant on Civil and Political Rights (ICCPR), and nonbinding policies developed by the UN and nongovernmental organizations (NGOs), such as the World Medical Association's Declaration on Patients' Rights.

2.2 Key sources

UNATED NATIONS

Universal Declaration of Human Rights 1948 (UDHR)

The UDHR is not a treaty but it is highly authoritative. It has shaped the evolution of modern human rights law, and many of its provisions are effectively reproduced in international treaties (see below). Many of its provisions have also achieved the status of customary international law – they are universal and indisputable.

Key provisions include:

- Article 3 (right to life)
- Article 5 (prohibition on torture and cruel, inhuman, or degrading treatment)
- Article 7 (protection against discrimination)
- Article 12 (right to privacy)
- Article 19 (right to seek, receive, and impart information)
- Article 25 (right to medical care)

TREATIES

All of the seven major international human rights treaties contain guarantees relating to the protection of human rights in patient care. While these treaties are binding on those states that have ratified them, their standards have strong moral and political force even for nonratifying countries. Many, such as the two international covenants and the Convention on the Rights of the Child (CRC), have been widely (and, in the case of the latter, almost universally) ratified.¹

The treaty monitoring bodies have issued numerous General Comments (GCs) to serve as authoritative guides for interpretation of the treaty standards. For example, the

Committee on Economic, Social and Cultural Rights (CESCR) issued GC 14 on Article 12 of the International Covenant on Civil and Political Rights (ICESCR), interpreting the right to health as the right to control one's own health and body.

All of the treaty bodies monitor compliance through the consideration of periodic state reports and then issue concluding observations.² The majority - including the Human Rights Committee (HRC), Committee on the Elimination of Discrimination Against Women (CEDAW), Committee Against Torture (CAT), Committee on the Elimination of Racial Discrimination (CERD) and the Committee on the Rights of Persons with Disabilities (CRPD) – may now also consider individual complaints provided

1 Office of the UN High Commissioner for Human Rights. Status of the Ratifications of the Principle International Human Rights Treaties. <http://www2.ohchr.org/english/bodies/docs/status.pdf>. Accessed November 14, 2009.

2 Office of the UN High Commissioner for Human Rights. Human Rights Bodies.

<http://www.ohchr.org/EN/HRBodies/Pages/HumanRightsBodies.aspx>. Accessed November 14, 2009.

that, in most cases, the State has ratified the appropriate optional protocol to the treaty.³ Together, these materials can be used to further interpret the standards.

► **International Covenant on Civil and Political Rights (ICCPR)⁴**

Together with the UDHR and the ICESCR, the ICCPR forms part of the International Bill of Human Rights. The ICCPR is monitored by the HRC.

Relevant provisions include:

- Article 2(1) (prohibition on discrimination)
- Article 6 (right to life)
- Article 7 (prohibition on torture)
- Article 9 (right to liberty and security)
- Article 10 (right to dignity for detainees)
- Article 17 (right to privacy)
- Article 19(2) (right to information)
- Article 26 (equality before the law)

► **International Covenant on Economic, Social and Cultural Rights (ICESCR)⁵**

The ICESCR is monitored by the CESCR.

Key provision:

- Article 12 (right to highest attainable standard of health) – (See General Comment 14)⁶

The Special Rapporteur (currently Anand Grover, who replaced Professor Paul Hunt in August 2008) is an independent expert who is mandated by the UN to investigate how the right to the highest attainable standard of health can be effectively realized. The SR conducts country visits, produces annual reports and carries out in-depth studies into particular issues. For example, in September 2007, the SR produced draft guidelines for pharmaceutical companies on access to medicines.⁷

Other relevant provisions include:

- Article 2(1) (prohibition on discrimination)
- Article 10(3) (protection of children)
- Article 11 (adequate standard of living)

3 Office of the UN High Commissioner for Human Rights. Human Rights Bodies: Complaint Procedures. <http://www2.ohchr.org/english/bodies/petitions/index.htm>. Accessed November 14, 2009.

4 International Covenant on Civil and Political Rights. United Nations General Assembly Resolution 2200A [XXI]. 16 December 1966. <http://www2.ohchr.org/english/law/ccpr.htm>. Accessed November 14, 2009.

5 International Covenant on Economic, Social and Cultural Rights. United Nations General Assembly Resolution 2200A[XXI]. 16 December 1966. <http://www2.ohchr.org/english/law/cescr.htm>

6 Official Documents Center of the United Nations. <http://daccessdds.un.org/doc/UNDOC/GEN/G00/439/34/PDF/G0043934.pdf?OpenElement>. Accessed November 14, 2009.

7 <http://www2.ohchr.org/english/issues/health/right/docs/draftguid.doc>

Note: Special Rapporteur (SR) on the Right to Health⁸**► Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)⁹**

Monitored by the Committee on the Elimination of Discrimination against Women (CEDAW).

Key provisions:

- Article 12 (elimination of discrimination against women in health care)
- Article 14(2)(b) (right of women in rural areas to have access to adequate health care facilities)

(See also General Recommendation 24 on Article 12 (women and health)¹⁰, a comprehensive analysis of women's health needs and recommendations for government action.)¹¹

► International Convention for the Elimination of All Forms of Racial Discrimination (CERD)¹²

Monitored by the Committee on the Elimination of Racial Discrimination.

Key provision:

- Article 5(1)(e) (prohibition on racial discrimination in public health and medical care)

► Convention Against Torture and Other Forms of Cruel, Inhuman, or Degrading Treatment or Punishment (CAT)¹³

Monitored by the Committee Against Torture, the CAT introduced a new optional protocol in 2002 that focuses on prevention of torture.¹⁴

8 Office of the UN High Commissioner for Human Rights. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

<http://www2.ohchr.org/english/issues/health/right/>. Accessed November 14, 2009.

<http://www2.ohchr.org/english/issues/health/right/docs/draftguid.doc>

9 Convention on the Elimination of All Forms of Discrimination Against Women. United Nations General Assembly. 18 December 1979. <http://www2.ohchr.org/english/law/cedaw.htm>. Accessed November 14, 2009.

10 UN Committee on the Elimination of Discrimination against Women. CEDAW General Recommendation No. 24: Article 12 of the Convention (Women and Health) <http://www.un.org/womenwatch/daw/cedaw/recommendations/recomm.htm#recom24>. Accessed November 14, 2009.

11 International Convention for the Elimination of all Forms of Racial Discrimination. UN General Assembly Resolution 2106 [XX]. 21 December 1965. <http://www2.ohchr.org/english/law/cerd.htm> Accessed November 14, 2009.

12 Convention against Torture and other Cruel, Inhuman, or Degrading Treatment or Punishment. UN General Assembly Resolution 39/46. 10 December 1984. <http://www2.ohchr.org/english/law/cat.htm>. Accessed November 14, 2009.

13 Optional Protocol to the Convention against Torture and other Cruel, Inhuman, or Degrading Treatment or Punishment. UN General Assembly Resolution A/RES/57/199 18 December 2002. <http://www2.ohchr.org/english/law/cat-one.htm>. Accessed November 14, 2009.

14 Convention on the Rights of the Child. UN General Assembly Resolution 44/25. 20 November 1989. <http://www2.ohchr.org/english/law/crc.htm>, Accessed November 14, 2009.

► **Convention on the Rights of the Child (CRC)**¹⁵

Monitored by the Committee on the Rights of the Child, the CRC contains a comprehensive range of civil, political, economic, social, and cultural rights guarantees.

Key provision:

- Article 24 (right to highest attainable standard of health)

► **International Convention on the Protection of the Rights of All Migrants Workers and Members of Their Families (CMW)**¹⁶

Monitored by the Committee on Migrant Workers, the CMW contains a comprehensive range of civil, political, economic, social, and cultural rights guarantees.

Key provisions:

- Article 28 (right to medical care)
- Articles 43 and 45(1)(c) (equal treatment in health care)

► **Convention on the Rights of Persons with Disabilities (CRPD)**¹⁷

The CRPD applies to people with “long-term physical, mental, intellectual or sensory impairments,” and seeks to “ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities and to promote respect for their inherent dignity.”¹⁸ The CRPD contains a comprehensive range of civil, political, economic, social, and cultural rights guarantees. It was entered into force on May 12, 2008.

Key provision:

- Article 25 (health)

Other relevant provisions include:

- Article 5 (equality and nondiscrimination)
- Articles 6 and 7 (women and children)
- Article 9 (access to medical facilities and services)
- Article 10 (right to life)
- Article 14 (liberty and security)
- Article 15 (freedom from torture, etc.)
- Article 16 (freedom from exploitation, violence, and abuse)
- Article 17 (protection of physical and mental integrity)

15 International Convention on the Protection of the Rights of all Migrant Workers and Members of Their Families, UN General Assembly Resolution 45/158. 18 December 1990. <http://www2.ohchr.org/english/law/cmw.htm>. Accessed November 14, 2009.

16 Convention on the Rights of Persons with Disabilities. UN General Assembly Resolution. 13 December 2006. <http://www2.ohchr.org/english/law/disabilities-convention.htm>. Accessed November 14, 2009.

17 Conventions on the Rights of Persons with Disabilities, Article 1.

18 Standard Minimum Rules for the Treatment of Prisoners. Economic and Social Council Resolution 663 C (XXIV). 31 July 1957. <http://www2.ohchr.org/english/law/treatmentprisoners.htm>. Accessed November 14, 2009.

- Article 19 (independent living)
- Article 21 (access to information)
- Article 22 (respect for privacy)
- Article 26 (habilitation and rehabilitation)
- Article 29 (participation in public life)

NONTREATY INSTRUMENTS

- ▶ **UN Standard Minimum Rules for the Treatment of Prisoners**¹⁹
- ▶ **UN Body of Principles for the Protection of All Persons Under Any Form of Detention or Imprisonment**²⁰
- ▶ **UN Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care**²¹

Additional international documents

There are also a number of other important international consensus documents that do not have the binding force of a treaty but exert considerable political and moral force.

▶ **WHO Alma-Ata Declaration 1978**²²

This declaration reaffirms that health is a state of complete physical, mental and social well-being, not merely the absence of disease or infirmity, and is a fundamental human right (Article 1). It focuses on the importance of primary health care.

▶ **Charter on the Right to Health 2005 (International Union of Lawyers)**²³

This charter addresses issues such as privacy and informed consent.

▶ **Declaration on the Rights of the Patients 2005 (revised) (World Medical Association (WMA))**²⁴

This declaration addresses issues such as the rights to confidentiality, information, and informed consent. The following is an excerpt from the *preamble*:

19 Body of Principles for the Protection of All Persons Under Any Form of Detention. UN General Assembly Resolution 43/173. 9 December 1998. <http://www2.ohchr.org/english/law/bodyprinciples.htm>. Accessed November 14, 2009.

20 Principles for the Protection of Persons with Mental Illness and Improvement of Mental Health Care. UN General Assembly Resolution 46/119. 17 December 1991. <http://www2.ohchr.org/english/law/principles.htm>. Accessed November 14, 2009.

21 Declaration of Alma-Ata. 6 September 1978. http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf. Accessed November 14, 2009.

22 Charter on the Right to Health. International Union of Lawyers. UIA General Assembly. 31 August 2005. www.uanet.org/documents/qquia/resolutions/Sante4GB.pdf. Accessed November 14, 2009.

23 Declaration on the Rights of the Patient. World Medical Association. WMA Assembly September/October 1981. <http://www.wma.net/en/30publications/10policies/14/index.html>. Accessed November 14, 2009.

24 Declaration on Patient-Centered Health Care. International Alliance of Patients' Organizations (IAPPO). www.patientsorganizations.org/. Accessed November 14, 2009.

The relationship between physicians, their patients and broader society has undergone significant changes in recent times. While a physician should always act according to his/her conscience, and always in the best interests of the patient, equal effort must be made to guarantee patient autonomy and justice. The following Declaration represents some of the principal rights of the patient that the medical profession endorses and promotes. Physicians and other persons or bodies involved in the provision of health care have a joint responsibility to recognize and uphold these rights. Whenever legislation, government action or any other administration or institution denies patients these rights, physicians should pursue appropriate means to assure or to restore them.

► **Declaration on Patient-Centered Healthcare 2007, International Alliance of Patients' Organizations (IAPO)²⁵**

This declaration was produced by IAPO as part of its effort to advocate internationally, with a strong voice for patients, on relevant aspects of healthcare policy, with the aim of influencing international, regional, and national health agendas and policies.

The document espouses five principles:

- **Respect:**
Patients and carers have a fundamental right to patient-centered healthcare that respects their unique needs, preferences and values, as well as their autonomy and independence.
- **Choice and empowerment:**
Patients have a right and responsibility to participate, to their level of ability and preference, as a partner in making healthcare decisions that affect their lives. This requires a responsive health service which provides suitable choices in treatment and management options that fit in with patients' needs, and encouragement and support for patients and carers that direct and manage care to achieve the best possible quality of life. Patients' organizations must be empowered to play meaningful leadership roles in supporting patients and their families to exercise their right to make informed healthcare choices.
- **Patient involvement in health policy:**
Patients and patients' organizations deserve to share the responsibility of healthcare policy-making through meaningful and supported engagement in all levels and at all points of decision-making, to ensure that they are designed with the patient at the centre. This should not be restricted to healthcare policy but include, for example, social policy that will ultimately impact on patients' lives.

²⁵ Jakarta Declaration on Leading Health Promotion into the 21st Century. World Health Organization (WHO). 21-25 July 1997.

www.who.int/hpr/NPH/docs/jakarta_declaration_en.pdf. Accessed November 14, 2009.

- Access and support:

Patients must have access to the healthcare services warranted by their condition. This includes access to safe, quality and appropriate services, treatments, preventive care and health promotion activities. Provision should be made to ensure that all patients can access necessary services, regardless of their condition or socio-economic status. For patients to achieve the best possible quality of life, healthcare must support patients' emotional requirements, and consider non-health factors such as education, employment and family issues which impact on their approach to healthcare choices and management.

- Information:

Accurate, relevant and comprehensive information is essential to enable patients and carers to make informed decisions about healthcare treatment and living with their condition. Information must be presented in an appropriate format according to health literacy principles considering the individual's condition, language, age, understanding, abilities and culture.

► **Jakarta Declaration on Leading Health Promotion into the 21st Century (1997)** ²⁶

This declaration is the final outcome document of the Fourth International Conference on Health Promotion. It lays down a series of priorities for health promotion in the twenty-first century, including social responsibility, increased investment and secured infrastructure, and empowerment of the individual.

► **Position Statement: Nurses and Human Rights 1998, International Council of Nurses (ICN)** ²⁷

The ICN views health care as the right of all individuals, regardless of financial, political, geographic, racial, or religious considerations. This right includes the right to choose or decline care, including the rights to acceptance or refusal of treatment or nourishment; informed consent; confidentiality; and dignity, including the right to die with dignity.

The ICN addresses the rights of both those seeking care and the providers. Nurses have an obligation to safeguard and actively promote people's health rights at all times and in all places. This obligation includes assuring that adequate care is provided within the scope of the available resources and in accordance with nursing ethics. In addition, the nurse is obliged to ensure that patients receive appropriate information in understandable language prior to giving their consent for treatment or procedures, including participation in research.

²⁶ Position Statement: Nurses and Human Rights. International Council of Nurses. www.icn.ch/pshumrights.htm, Accessed November 14, 2009.

²⁷ UN Human Rights Committee (HRC), A. v. New Zealand, Communication No. 754/1997: (CCPR/C/66/D/754/1997). Views adopted 15 July 1999. See also UN Human Rights Committee (HRC), Fijalkowska v. Poland, Communication No. 1061/2002: Poland. (CCPR/C/84/1061/2002). Views adopted 26 July 2005.

2.3 Patients' Rights

This section explores international protection of nine critical patients' rights: the rights to liberty and security of the person; privacy and confidentiality; information; bodily integrity; life; highest attainable standard of health; freedom from torture, cruel, inhuman, and degrading treatment; participation in public policy; and nondiscrimination and equality for patients.

The CESCR has provided the most significant international legal commentary on the rights of patients. Its elaboration on UN General Comment 14 on the right to the highest attainable standard of health (under Article 12 of the ICESCR) has been particularly influential. In addition, the CESCR has frequently condemned governments for failing to devote adequate resources to healthcare and services for patients. At this writing, however, the lack of an individual complaint mechanism has hampered the ability of the CESCR to examine specific violations beyond the systemic failures identified in country reports. The expected introduction of such a mechanism should provide the CESCR with an opportunity to mirror the work of its sister body, the HRC, in developing significant case law on human rights in patient care.

Although the CESCR has elaborated on the right to health with the most detail, other UN monitoring bodies have also provided significant comments on patients' rights. The HRC has frequently cited Articles 9 and 10 of the ICCPR to condemn the unlawful detention of mental health patients and the denial of medical treatment to detainees, respectively. It has also upheld the need to protect confidential medical information under Article 17 of the ICCPR and has used the right to life under Article 6 of the ICCPR to safeguard medical treatment during pretrial detention. Additionally, as detailed below, UN bodies concerned with monitoring racial and sex discrimination have examined equal access to health care.

In addition to binding treaty provisions, other international standards such as the Standard Minimum Rules for the Treatment of Prisoners also provide significant reference points regarding patients' rights. Although these standards cannot be directly enforced against states, patients and their advocates can use them to progressively interpret treaty provisions.

Right to Liberty and Security of the Person

EXAMPLES OF POTENTIAL VIOLATIONS

- A person is detained indefinitely on mental health grounds without any medical opinion being sought
- Residents of an institution are not informed about their right to apply to a court or tribunal to challenge their involuntary admission
- A female drug user is detained in hospital after giving birth and is denied custody of her child

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 9(1) ICCPR:** *Everyone has the right to liberty and security of person. No one shall be subjected to arbitrary arrest or detention. No one shall be deprived of his liberty except on such grounds and in accordance with such procedure as are established by law.*

- The HRC has stated that treatment in a psychiatric institution against the will of the patient constitutes a form of deprivation of liberty that falls under the terms of Article 9 of the ICCPR.²⁸ In this context, the HRC has considered a period of 14 days of detention for mental health reasons without review by a court incompatible with Article 9(1) of the ICCPR.²⁹

- The HRC has stated that, in relation to arbitrary committal under mental health legislation, in a case in which the victim was at the time considered to be legally capable of acting on her own behalf³⁰:

*[T]he State party has a particular obligation to protect vulnerable persons within its jurisdiction, including the mentally impaired. It considers that as the author suffered from diminished capacity that might have affected her ability to take part effectively in the proceedings herself, the court should have been in a position to ensure that she was assisted or represented in a way sufficient to safeguard her rights throughout the proceedings....The Committee acknowledges that circumstances may arise in which an individual's mental health is so impaired that so as to avoid harm to the individual or others, the issuance of a committal order, without assistance or representation sufficient to safeguard her rights, may be unavoidable. In the present case, no such special circumstances have been advanced. For these reasons, the Committee finds that the author's committal was arbitrary under article 9, paragraph 1, of the Covenant.*³¹

► **Article 25 CRC:** *States Parties recognize the right of a child who has been placed by the competent authorities for the purposes of care, protection or treatment of his or her physical or mental health, to a periodic review of the treatment provided to the child and all other circumstances relevant to his or her placement.*

► **Article 14 CRPD:**

1. *States Parties shall ensure that persons with disabilities, on an equal basis with others:*

(a) *Enjoy the right to liberty and security of person;*

28 UN Human Rights Committee (HRC), Concluding Observations of the Human Rights Committee: Estonia, 2003. (CCPR/CO/77/EST).

29 UN Human Rights Committee (HRC), Fijalkowska v. Poland, Communication No. 1061/2002 (CCPR/C/84/1061/2002). Views adopted 26 July 2005.

30 Ibid para. 8.3

31 UN Human Rights Committee (HRC), Concluding Observations of the Human Rights Committee: Chile, 1999. (CCPR/C/79/Add.104). UN Human Rights Committee (HRC), Concluding Observations of the Human Rights Committee: Venezuela, 2001. (CCPR/CO/71/VEN).

(b) Are not deprived of their liberty unlawfully or arbitrarily, and that any deprivation of liberty is in conformity with the law, and that the existence of a disability shall in no case justify a deprivation of liberty.

2. States Parties shall ensure that if persons with disabilities are deprived of their liberty through any process, they are, on an equal basis with others, entitled to guarantees in accordance with international human rights law and shall be treated in compliance with the objectives and principles of this Convention, including by provision of reasonable accommodation.

► **UN Body of Principles for the Protection of All Persons Under Any Form of Detention or Imprisonment**

► **UN Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care**

► **Article 6 Charter on the Right to Health:** *No one may be deprived of liberty on the ground of medical danger to oneself or others unless this danger is certified by competent and independent physicians and by a judicial ruling made in accordance with the due process of law.*

Right to Privacy and Confidentiality

EXAMPLES OF POTENTIAL VIOLATIONS

- A doctor discloses a patient's history of drug use or addiction without his or her consent
- Government requires disclosure of HIV status on certain forms
- Health care workers require young people to obtain parental consent as a condition of receiving sexual health services
- Residents of an institution have no place to keep their personal possessions

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- **Article 17(1) ICCPR:** *No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honor and reputation.*
- **Article 16(1) CRC:** *No child shall be subjected to arbitrary or unlawful interference with his or her privacy, family, home or correspondence, nor to unlawful attacks on his or her honor and reputation.*
- **Article 12 ICESCR:** The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
 - **CESCR GC 14, para. 12:** *Accessibility of information should not impair the right to have personal health data treated with confidentiality.*

- **CESCR GC 14, para. 23:** The realization of the right to health of adolescents is dependent on the development of youth-friendly health care, which respects confidentiality and privacy and includes appropriate sexual and reproductive health services.
- ▶ **Article 22 CRPD:** (1) *No person with disabilities, regardless of place of residence or living arrangements, shall be subjected to arbitrary or unlawful interference with his or her privacy, family, or correspondence or other types of communication or to unlawful attacks on his or her honor and reputation. Persons with disabilities have the right to the protection of the law against such interference or attacks.* (2) *States Parties shall protect the privacy of personal, health and rehabilitation information of persons with disabilities on an equal basis with others.*
- ▶ **Article 8 Charter on the Right to Health:** *Physicians are bound by professional confidentiality to ensure due respect for patient privacy. This confidentiality... contributes to the effectiveness of medical care. Exceptions to medical confidentiality, strictly limited by law, may serve only the goals of protection of health, safety or public hygiene. Patients are not bound by medical confidentiality. Physicians may be relieved of their obligation to maintain professional confidentiality if they become aware of attacks on the dignity of the human person...*
- ▶ **Principle 8 WMA Declaration on the Rights of the Patients**
Right to confidentiality
 - a. All identifiable information about a patient’s health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death. Exceptionally, descendants may have a right of access to information that would inform them of their health risks.
 - b. Confidential information can only be disclosed if the patient gives explicit consent or if expressly provided for in the law. Information can be disclosed to other health care providers only on a strictly “need to know” basis unless the patient has given explicit consent.
 - c. All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of its storage. Human substances from which identifiable data can be derived must be likewise protected.

Note: Confidentiality of Sexual and Reproductive Health Information

Clearly the need to protect the confidentiality of medical information can have an impact across a range of health issues. Confidentiality is particularly vital in relation to sexual and reproductive health, however. Examinations by UN treaty-monitoring bodies in the context of right to privacy have included (i) condemnation of a legal duty imposed on health personnel to report cases of abortions as part of a general criminalization of the procedure without exception, thereby inhibiting women from seeking medical treatment and jeopardizing their lives;³² (ii) the need

32 HRC. Concluding Observations of the Human Rights Committee: Chile, 1999. (CCPR/C/79/Add.104). Concluding Observations: Venezuela, 2001. (CCPR/CO/71/VEN).

to investigate allegations that women seeking employment in foreign enterprises are subjected to pregnancy tests and are required to respond to intrusive personal questioning followed by the administering of antipregnancy drugs;³³ and (iii) the need to address the concerns and need for confidentiality of adolescents with respect to sexual and reproductive health, including those married at a young age and those in vulnerable situations.³⁴

Right to Information

EXAMPLES OF POTENTIAL VIOLATIONS

- Government bans publications about drug use or harm reduction, claiming it promotes illegal activity
- Young people are deliberately denied information about sexually transmitted diseases (STDs) and the use of condoms
- Roma women lack access to information on sexual and reproductive health

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 19(2) ICCPR:** *Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive, and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice.*
 - A member of the HRC noted that in the case of *Zheludkov v. Ukraine*:³⁵

*“A person’s right to have access to his or her medical records forms part of the right of all individuals to have access to personal information concerning them. The State has not given any reason to justify its refusal to permit such access, and the mere denial of the victim’s request for access to his medical records thus constitutes a violation of the State’s obligation to respect the right of all persons to be ‘treated with humanity and with respect for the inherent dignity of the human person,’ regardless of whether or not this refusal may have had consequences for the medical treatment of the victim.”*³⁶
- ▶ **Article 12 ICESCR:** *The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*
 - **CESCR GC 14, para. 12(b)(iv):** *[Health care accessibility] “includes the right to seek, receive and impart information and ideas concerning health issues.*

33 HRC. Concluding Observation of the Human Rights Committee: Mexico, 1999. (CCPR/C/79/Add.109). Requirement for women to have access to appropriate remedies where their equality and privacy rights had been violated.

34 CRC. Concluding Observations of the Committee on the Rights of the Child: Djibouti, 2000. (CRC/C/15/Add.131).

35 HRC. *Zheludkov v. Ukraine*. Communication No. 726/1996. (CCPR/C/76/D/726/1996). Views adopted October 29, 2002.

36 Individual opinion by Ms. Cecilia Medina Quiroga (concurring).

- **CESCR GC 14, para. 23:** *States Parties should provide a safe and supportive environment for adolescents, that ensures the opportunity to participate in decisions affecting their health, to build life skills, to acquire appropriate information, to receive counselling and to negotiate the health behaviour choices they make.*
 - **Article 17 CRC:** *States Parties recognize the important function performed by the mass media and shall ensure that the child has access to information and material from a diversity of national and international sources, especially those aimed at the promotion of his or her social, spiritual, and moral well-being and physical and mental health.*³⁷
- ▶ **Article 21 CRPD:** *States Parties shall take all appropriate measures to ensure that persons with disabilities can exercise the right to freedom of expression and opinion, including the freedom to seek, receive, and impart information and ideas on an equal basis with others and through all forms of communication of their choice, as defined in article 2 of the present Convention, including by: (a) Providing information intended for the general public to persons with disabilities in accessible formats and technologies appropriate to different kinds of disabilities in a timely manner and without additional cost.*
- ▶ **Principle 7 WMA Declaration on the Rights of the Patients:**
- a. *The patient has the right to receive information about himself/herself recorded in any of his/her medical records, and to be fully informed about his/her health status including the medical facts about his/her condition. However, confidential information in the patient's records about a third party should not be given to the patient without the consent of that third party.*
 - b. *Exceptionally, information may be withheld from the patient when there is good reason to believe that this information would create a serious hazard to his/her life or health.*
 - c. *Information should be given in a way appropriate to the patient's culture and in such a way that the patient can understand.*
 - d. *The patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life.*
 - e. *The patient has the right to choose who, if anyone, should be informed on his/her behalf.*
- ▶ **Principle 5 IAPO Declaration on Patient-Centred Healthcare:**³⁸
Accurate, relevant, and comprehensive information is essential to enable patients and carers to make informed decisions about healthcare treatment and living with their condition. Information must be presented in an appropriate format according to health literacy principles considering the individual's condition, language, age, understanding, abilities, and culture.

Note: Access to Sexual and Reproductive Health Information

³⁷ CRC. General Comment 4 of the Committee on the Rights of the Child: Adolescent Health and Development in the Context of the Convention on the Rights of the Child. (CRC/GC/2003/4).

³⁸ IAPO. IAPO Policy Statement on Health Literacy. <http://www.patientsorganizations.org/showarticle.pl?id=126&n=962> Accessed November 6, 2009.

- ▶ The provision of appropriate and timely information with respect to sexual and reproductive health is particularly crucial. UN treaty-monitoring bodies have urged States to improve access in light of increasing teenage abortions and sexually transmitted diseases,³⁹ including HIV/AIDS,⁴⁰ with such information also extending to children⁴¹ and to people in areas with prevalent alcohol and tobacco use.⁴²

Right to bodily integrity

EXAMPLES OF POTENTIAL VIOLATIONS

- A Roma woman is sterilized against her will
- Doctors compel a drug-using pregnant woman to undergo an abortion
- Treatment is routinely given to residents of an institution without their consent as they are assumed to lack the capacity to make decisions about their treatment and care
- Patients at a psychiatric hospital are treated as part of a clinical medication trial without being informed that they are included in the research
- Patients are given electroconvulsive therapy (ECT) that is described to them as “sleep therapy”

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

Note: Right to Bodily Integrity

The right to bodily integrity is not specifically recognized under the ICCPR or ICESCR, but it has been interpreted to be part of the right to security of the person (ICCPR 9), the right to freedom from torture and cruel, inhuman, and degrading treatment (ICCPR 7), the right to privacy (ICCPR 17), and the right to the highest attainable standard of health (ICESCR 12).

- ▶ **Article 12(1) CRC:** *States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters*

39 UN Committee on Economic Social and Cultural Rights (CESCR), Concluding Observations of the Committee on Economic, Social and Cultural Rights: Lithuania, 2004. (E/C.12/1/Add.96). UN Committee on Elimination of Discrimination Against Women (CEDAW), Concluding Observations of the Committee on Elimination of Discrimination Against Women: Costa Rica, 2003. (A/58/38(SUPP)) See also UN Committee on Economic Social and Cultural Rights (CESCR), Concluding Observations of the Committee on Economic, Social and Cultural Rights: China, 2005. (E/C.12/1/Add.107).

40 CESCR, Concluding Observations of the Committee on Economic Social and Cultural Rights: Chile, 2004. (E/C.12/Add.105). See also CESCR, Concluding Observations of the Committee on Economic Social and Cultural Rights: Cameroon, 1999. (E/C.12/Add.40). . See also CEDAW, Concluding Observations of the Committee on the Elimination of Discrimination Against Women: Ethiopia, 2004. (A/59/38(SUPP)).

41 CRC, Concluding Observations of the Committee on the Rights of the Child: Mozambique, 2002. (CRC/C/15/Add.172). See also CRC, Concluding Observations of the Committee on the Rights of the Child: Indonesia, 2004. (CRC/C/15/Add.203).

42 CESCR, Concluding Observations of the Committee on Economic, Social and Cultural Rights: Ukraine, 2001. (E/C.12/1/Add.65).

affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.

- ▶ **Article 39 CRC:** *States Parties shall take all appropriate measures to promote physical and psychological recovery and social reintegration of a child victim of: any form of neglect, exploitation, or abuse; torture or any other form of cruel, inhuman or degrading treatment or punishment; or armed conflicts. Such recovery and reintegration shall take place in an environment which fosters the health, self-respect, and dignity of the child.*
- ▶ **Article 17 CRPD:** *Every person with disabilities has a right to respect for his or her physical and mental integrity on an equal basis with others.*
- ▶ **Article 12 ICESCR:** *The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*
 - **CESCR GC 14, para. 8:** [The right to health includes] the right to be free from nonconsensual medical treatment and experimentation.

▶ **International Ethical Guidelines for Biomedical Research Involving Human Subjects** ⁴³

- ▶ **Article 5 Charter on the Right to Health:** *Consent of the patient must be required before any medical treatment, except in case of emergency only as strictly provided by law.*

▶ **Principles 2-6 WMA Declaration on the Rights of the Patients:**

2. Right to freedom of choice

- a. The patient has the right to choose freely and change his/her physician and hospital or health service institution, regardless of whether they are based in the private or public sector.*
- b. The patient has the right to ask for the opinion of another physician at any stage.*

3. Right to self-determination

- a. The patient has the right to self-determination, to make free decisions regarding himself or herself. The physician will inform the patient of the consequences of his/her decisions.*
- b. A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the*

⁴³ Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva 2002. http://www.cioms.ch/frame_guidelines_nov_2002.htm. Accessed November 15, 2009.

information necessary to make his/her decisions. The patient should clearly understand the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent.

- c. *The patient has the right to refuse to participate in research or the teaching of medicine.*
4. *The unconscious patient*
- a. *If the patient is unconscious or otherwise unable to express his/her will, informed consent must be obtained whenever possible, from a legally entitled representative.*
 - b. *If a legally entitled representative is not available, but a medical intervention is urgently needed, consent of the patient may be presumed, unless it is obvious and beyond any doubt on the basis of the patient's previous firm expression or conviction that he/she would refuse consent to the intervention in that situation.*
 - c. *However, physicians should always try to save the life of a patient unconscious due to a suicide attempt.*
5. *The legally incompetent patient*
- a. *If a patient is a minor or otherwise legally incompetent, the consent of a legally entitled representative is required in some jurisdictions. Nevertheless the patient must be involved in the decision-making to the fullest extent allowed by his/her capacity.*
 - b. *If the legally incompetent patient can make rational decisions, his/her decisions must be respected, and he/she has the right to forbid the disclosure of information to his/her legally entitled representative.*
 - c. *If the patient's legally entitled representative, or a person authorized by the patient, forbids treatment which is, in the opinion of the physician, in the patient's best interest, the physician should challenge this decision in the relevant legal or other institution. In case of emergency, the physician will act in the patient's best interest.*

6. *Procedures against the patient's will*

Diagnostic procedures or treatment against the patient's will can be carried out only in exceptional cases, if specifically permitted by law and conforming to the principles of medical ethics.

Note: Genital Mutilation and the Right to Bodily Integrity

Treaty-monitoring bodies have recognized that practices such as genital mutilation can infringe girls' right to personal security and their physical and moral integrity by threatening their lives and health.⁴⁴

⁴⁴ CEDAW, Concluding Observations of the Committee on the Elimination of Discrimination Against Women: Burkina Faso, 2000. (A/55/38(SUPP)). See also CEDAW, Concluding Observations of the Committee on the Elimination of Discrimination Against Women: Cameroon, 2000. (A/55/38(SUPP)).

Right to Life

EXAMPLES OF POTENTIAL VIOLATIONS

- Doctors refuse to treat a person who is experiencing a drug overdose because drug use is illegal, resulting in the person's death
- Drug users die as a result of poor fire safety in a locked hospital ward
- Government places arbitrary legal restrictions on access to life-saving HIV-prevention or treatment
- The mortality rate of an institution is particularly high during the winter months due to the poor condition of the building, inadequate sanitation and heating, and poor quality of care
- A patient at a psychiatric hospital known to be at risk of committing suicide is not monitored adequately and subsequently takes her own life

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 6(1) ICCPR:** *Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.*

- **HRCGC 6, paras. 1 and 5:** *The right to life “should not be interpreted narrowly” or “in a restrictive manner,” and its protection “requires that States adopt positive measures ... to increase life expectancy.”*
- The HRC, in finding a violation of Article 6 and Article 10(1) of the ICCPR, in a case in which a healthy young man who fell ill in a pretrial detention center did not receive any medical treatment despite repeated requests for assistance and subsequently died, noted that:

*It is incumbent on States to ensure the right to life of detainees, and not incumbent on the latter to request protection...it is up to the State party by organizing its detention facilities to know about the state of health of the detainees as far as may be reasonably be expected. Lack of financial means cannot reduce this responsibility.*⁴⁵

Because the detention center had a properly functioning medical service within and should have known about the dangerous change in the victim's state of health, the state was required to take immediate steps to ensure that the conditions of detention were compatible with its obligations under Articles 6 and 10. Such obligations are retained even where private companies run such institutions.⁴⁶

45 HRC. *Lantsova v The Russian Federation*, Communication No. 763/1997. (CCPR/C/74/763/1997). Views adopted March 26, 2002.

46 HRC. General Comment 20 of the Human Rights Committee. (A/47/40/[SUPP]).

- While not explicitly recognizing the right to an abortion, the HRC has stated that states have a duty to take measures to ensure the right to life of pregnant women whose pregnancies are terminated, thereby ending the blanket ban on the procedure.⁴⁷

► **Article 10 CRPD:** *States Parties reaffirm that every human being has the inherent right to life and shall take all necessary measures to ensure its effective enjoyment by persons with disabilities on an equal basis with others.*

Right to the Highest Attainable Standard of Health

EXAMPLES OF POTENTIAL VIOLATIONS

- State fails to take progressive steps to ensure access to antiretroviral drugs for people living with HIV or to prevent mother-to-child HIV transmission
- Doctors and health facilities are not located in proportionate proximity to certain poor neighborhoods
- State systematically fails to provide training in palliative care for its medical personnel
- A child in a social care home becomes bedridden due to malnutrition
- Adults and children are placed on the same wards in a psychiatric hospital
- Women with mental disabilities are denied reproductive health services

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 12 ICESCR:** *(1) The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: . . . (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.*

- **CESCR GC 14, para. 4:** The right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.
- **CESCR GC 14, para. 12:** Health care and services must be available, in sufficient quantity, accessible (physically and economically) to all without discrimination, culturally acceptable and of good quality.

⁴⁷ HRC. Concluding Observations of the Human Rights Committee: Chile, 1999. (CCPR/C/79/Add.104) See also UN Committee on the Elimination of Discrimination Against Women (CEDAW). General Comment 19 of the Committee on the Elimination of Discrimination Against Women: Violence against Women. (A/47/38 [SU PP]).

- **CESCR GC 14, paras. 30-37:** In delivering such services, states are under a duty to progressively realize the right to health while ensuring that they respect people's own resources,⁴⁸ protect them against the negative actions of third parties, and fulfill or provide sufficient resources where there are none.
 - **CESCR GC 14, paras. 46-52:** Violations of the right to health can be caused by deliberate acts or failures to act by the state.
 - In the context of obligations under Article 12 of the ICESCR, the CESCR has frequently condemned states for failing to devote adequate resources to health care and services because of the obviously detrimental impact of that failure on patients.⁴⁹
 - The CESCR has required that states should introduce appropriate legislation to safeguard patient rights, including redress for medical errors.⁵⁰
- **Article 3(3) CRC:** *States Parties shall ensure that the institutions, services and facilities responsible for the care or protection of children shall conform with the standards established by competent authorities, particularly in the areas of safety, health, in the number and suitability of their staff, as well as competent supervision.*
- **Article 24 CRC:** *(1) States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. (2) States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures: (a) To diminish infant and child mortality; (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;... (d) To ensure appropriate pre-natal and post-natal health care for mothers.*
- In the context of the right to health, the Committee on the Rights of the Child has criticized the incompatibility of a proposed free trade agreement being negotiated by three Latin American countries and the United States and, in particular, the right to access low-cost drugs and social services by poor people.⁵¹ The committee went on to recommend that a study on the impact of trade standards should be carried out.⁵²

48 Some obligations such as nondiscrimination are immediately realizable without qualification.

49 CESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Uruguay, 1997. (E/C.12/1/Add.18). Alarm expressed at fact that very low wages paid to nurses led to a low ratio of nurses to doctors (lower than 1:5), tending to diminish the quality and accessibility of medical care available to the community. See also UN Committee on Economic, Social and Cultural Rights (CESCR), Concluding Observations of the Committee on Economic, Social and Cultural Rights: Congo, 2000. (E/C.12/1/Add.45). Grave concern expressed at decline of standard of health, due in part to ongoing financial crisis, which resulted in a serious shortage of funds for public health services; UN Committee on Economic Social and Cultural Rights (CESCR). Concluding Observations of the Committee on Economic, Social and Cultural Rights: Mongolia, 2000. (E/C.12/1/Add.47). Deteriorating health situation for population since 1990 in light of decreasing government expenditure on health from 5.8 percent of GDP in 1991 to 3.6 percent in 1998.

50 CESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Russia, 2003. (E/C.12/1/ADD.94).

51 CRC. Concluding Observations of the Committee on the Rights of the Child: Ecuador, 2005. (CRC/C/15/Add.262).

52 In so doing, the committee was reiterating the recommendations issued by the CESCR in June 2004 (E/C.12/1/Add.100), which urged Ecuador to "conduct an evaluation of the effects of international trade standards on the right

► **Article 25 CRPD:** *States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation. In particular, States Parties shall:*

- (a) *Provide persons with disabilities with the same range, quality and standard of free or affordable health care and programs as provided to other persons, including in the area of sexual and reproductive health and population-based public health programs;*
- (b) *Provide those health services needed by persons with disabilities specifically because of their disabilities, including early identification and intervention as appropriate, and services designed to minimize and prevent further disabilities, including among children and older persons;*
- (c) *Provide these health services as close as possible to people's own communities, including in rural areas;*
- (d) *Require health professionals to provide care of the same quality to persons with disabilities as to others, including on the basis of free and informed consent by, inter alia, raising awareness of the human rights, dignity, autonomy and needs of persons with disabilities through training and the promulgation of ethical standards for public and private health care;*
- (e) *Prohibit discrimination against persons with disabilities in the provision of health insurance, and life insurance where such insurance is permitted by national law, which shall be provided in a fair and reasonable manner;*
- (f) *Prevent discriminatory denial of health care or health services or food and fluids on the basis of disability.*

Freedom from Torture and Cruel, Inhuman, and Degrading Treatment

EXAMPLES OF POTENTIAL VIOLATIONS

- Fearing prosecution by the state, a doctor refuses to prescribe morphine to relieve a patient's pain
- A person is denied mental health treatment while in detention and instead is locked in solitary confinement
- Staff of an AIDS ward permit television cameras to film patients without patients' consent and broadcast the footage on local television
- Female residents of an institution are required to shower together, supervised by male staff

to health of all persons and to make ample use of the flexibility clauses allowed by the Agreement on Trade-Related Aspects of Intellectual Property of the World Trade Organization (WTO), so as to provide access to generic drugs and, more generally, to enable the universal enjoyment of the right to health in Ecuador.”

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 7 ICCPR:** *No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.*
- ▶ **Article 10(1) ICCPR:** *All persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person.*
 - The HRC has made clear that Article 10(1) of the ICCPR applies to any person deprived of liberty under the laws and authority of the State, who is held in prisons or hospital - particularly, in a psychiatric hospital - or in a detention camp, correctional institution, or elsewhere, and that States Parties should ensure that the principle stipulated therein is observed in all institutions and establishments within their jurisdiction where persons are being held.⁵³

The HRC has reaffirmed on a number of occasions that the obligation under Article 10(1) of the ICCPR to treat individuals with respect for the inherent dignity of the human person encompasses the provision of, inter alia, adequate medical care during detention.⁵⁴ Often in conjunction with Article 7, has gone on to find breaches of this obligation on numerous occasions.⁵⁵ Specifically,

53 HRC. General Comment 21 of the Human Rights Committee. (A/47/40[SUPP]).

54 HRC. *Kelly v. Jamaica*. Communication No. 256/1987. (CCPR/C/41/D/253/1987). Views adopted April 8, 1991. Breach of Article 10(1), where a prisoner contracted health problems as a result of a lack of basic medical care and was only allowed out of his cell for 30 minutes each day. See also UN Human Rights Committee (HRC). *Linton v. Jamaica*. Communication No. 255/1987. (CCPR/C/46/D/255/1987). Views adopted October 22, 1992. Denial of adequate medical treatment for injuries sustained during aborted escape attempt breached Articles 7 and 10(1); UN Human Rights Committee (HRC). *Bailey v. Jamaica*. Communication No. 334/1988. (CCPR/C/47/D/334/1988); UN Human Rights Committee (HRC). *Thomas v. Jamaica*. Communication No. 321/1988. (CCPR/C/49/D/321/1988). Views adopted October 19, 1993; UN Human Rights Committee (HRC). *Mika Miha v. Equatorial Guinea*. Communication No. 414/1990. (CCPR/C/51/D/414/1990). Views adopted July 8, 1994; UN Human Rights Committee (HRC). *Colin Johnson v. Jamaica*. Communication No. 653/1995. (CCPR/C/64/D/653/1995). Views adopted October 20, 1998; UN Human Rights Committee (HRC). *Kalenga v. Zambia*. Communication No. 326/1988. (CCPR/C/48/D/326/1988). Views adopted July 27, 1993.

55 HRC. *Whyte v. Jamaica*. Communication No. 732/1997. (CCPR/C/63/D/732/1997). Views adopted July 27, 1998. Failure to treat asthma attacks and injuries sustained through beatings. See also UN Human Rights Committee (HRC). *Leslie v. Jamaica*. Communication No. 564/1993. (CCPR/C/63/D/564/1993). Views adopted July 31, 1998. Lack of adequate medical treatment for beatings and stabbing on basis that Leslie was due to be executed imminently; UN Human Rights Committee (HRC). *Henry v. Jamaica*. Communication No. 610/1995. (CCPR/C/64/D/610/1995). Views adopted October 20, 1995. Lack of medical treatment despite a recommendation from a doctor that prisoner be operated on; UN Human Rights Committee (HRC). *Pennant v. Jamaica*. Communication No. 647/1995. (CCPR/C/64/D/647/1995). Views adopted October 20, 1998; UN Human Rights Committee (HRC). *Levy v. Jamaica*. Communication No. 719/1996. (CCPR/C/64/D/719/1996). Views adopted November 3, 1998; UN Human Rights Committee (HRC). *Marshall v. Jamaica*. Communication No. 730/1996. (CCPR/C/64/D/730/1996). Views adopted November 3, 1998; UN Human Rights Committee (HRC). *Morrison v. Jamaica*. Communication No. 663/1995. (CCPR/C/64/D/663/1995). Views adopted November 3, 1998; UN Human Rights Committee (HRC). *Brown v. Jamaica*. Communication No. 775/1997. (CCPR/C/65/D/775/1997). Views adopted March 23, 1999; UN Human Rights Committee (HRC). *Bennett v. Jamaica*. Communication No. 590/1994. (CCPR/C/65/D/590/1994). Views adopted March 25, 1999; UN Human Rights Committee (HRC). *Smith and Stewart v. Jamaica*. Communication No. 668/1995. (CCPR/C/65/D/668/1995). Views adopted April 8, 1999; UN Human Rights Committee (HRC). *Mulezi v. Democratic Republic of the Congo*. Communication No. 962/2001. Views adopted July 6, 2004; UN Human Rights Committee (HRC). *Saidov v. Tajikistan*. Communication No. 964/2001. Views adopted July 8, 2004.

in relation to the mentally ill in detention facilities (both in prisons and mental health institutions), the HRC has required improvements in hygienic conditions and the provision of regular exercise and adequate treatment.⁵⁶ Failure to adequately treat a mental illness condition that is exacerbated by being on death row can also amount to a breach of Articles 7 and/or 10(1).⁵⁷

In relation to Article 10(1) the HRC has found a violation where a prisoner on death row was denied medical treatment⁵⁸ and where severe overcrowding in a pretrial detention center resulted in inhumane and unhealthy conditions, eventually leading to the detainee's death.⁵⁹

Other examples of violations of Articles 7 and 10(1) include a case in which a detainee had been held in solitary confinement in an underground cell, was subjected to torture for three months, and was denied the medical treatment his condition required⁶⁰ and a case where the combination of the size of the cells, hygienic conditions, poor diet and lack of dental care resulted in a finding of a breach of Articles 7 and 10(1).⁶¹

Denying a detainee direct access to his medical records, particularly where this may have consequences for his treatment, can constitute a breach of Article 10(1).⁶²

Where a violation has occurred, the obligation to provide an effective remedy under Article 2(3)(a) of the ICCPR can include the provision of appropriate medical and psychiatric care.⁶³

56 HRC. Concluding Observations of the UN Human Rights Committee: Bosnia and Herzegovina, 2006. (CCPR/C/BIH/CO/1).

57 HRC. Williams v. Jamaica, Communication No. (609/1995), (CCPR/C/61/D/609/1995) at para. 6.5. Views adopted November 4, 1997.

58 HRC. Lewis v. Jamaica. Communication No. 527/1993. Views adopted July 18, 1996. Appointments to treat skin condition not kept over period of 25 years. See also Pinto v. Trinidad and Tobago. Communication No. 232/1987. (CCPR/A/45/40 [vol. II SUPP]). Views adopted July 20, 1990. The HRC reaffirmed that the obligation to treat individuals deprived of their liberty with respect for the inherent dignity of the human person encompasses the provision of adequate medical care during detention and that this obligation, obviously, extends to persons under the sentence of death. However, the facts did not disclose a violation where the allegations of ill treatment and lack of medical care were uncorroborated and made at a late stage in the application; UN Human Rights Committee (HRC). Henry and Douglas v. Jamaica. Communication No. 571/1994. (CCPR/A/51/40 [vol. II SU PP]), CCPR/C/57/D/571/1994). Views adopted July 25, 1996. Keeping Henry in a cold cell after he was diagnosed for cancer breached Articles 7 and 10(1); UN Human Rights Committee (HRC). Leehong v. Jamaica. Communication No. 613/1995. (CCPR/A/54/40 [vol. II],(CCPR/C/66/D/613/1995). Views adopted July 13, 1999. Prisoner on death row only allowed to see a doctor once, despite sustained beatings by warders and request for medical attention.

59 HRC. Lantsova v. The Russian Federation. Communication No. 763/1997. Views adopted March 26, 2002.

60 HRC. Setelich/Sendic v. Uruguay. Communication No. R.14/63. (CCPR/A/37/40). Views adopted October 28, 1981.

61 HRC. Howell v. Jamaica. Communication No. 798/1998. (CCPR/A/59/40 [vol. II], C/79/D/798/1998). Views adopted October 21, 2003).

62 HRC. Zheludkov v. Ukraine. Communication No. 726/1996. (CCPR/A/58/40 [vol. II], CCPR/C/76/D/726/1996). Views adopted October 29, 2002. See concurring opinion of Quiroga, which states that committee's interpretation of Article 10(1) relating to access to medical records is unduly narrow and that mere denial of records is sufficient to constitute a breach, regardless of consequences.

63 HRC. Sahadath v. Trinidad and Tobago. Communication No. 684/1996. (CCPR/A/57/40 [vol. II], CCPR/C/684/1996). Views adopted April 2, 2002.

- ▶ **Article 1 CAT:** (1) For the purposes of this Convention, the term “torture” means any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions. (2) This article is without prejudice to any international instrument or national legislation which does or may contain provisions of wider application.
- ▶ **Article 2 CAT:** (1) Each State Party shall take effective legislative, administrative, judicial or other measures to prevent acts of torture in any territory under its jurisdiction. (2) No exceptional circumstances whatsoever, whether a state of war or a threat of war, internal political instability or any other public emergency, may be invoked as a justification of torture. (3) An order from a superior officer or a public authority may not be invoked as a justification of torture.
- ▶ **Article 4 CAT:** (1) Each State Party shall ensure that all acts of torture are offences under its criminal law. The same shall apply to an attempt to commit torture and to an act by any person which constitutes complicity or participation in torture. (2) Each State Party shall make these offences punishable by appropriate penalties which take into account their grave nature.
- ▶ **Article 10 CAT:** (1) Each State Party shall ensure that education and information regarding the prohibition against torture are fully included in the training of law enforcement personnel, civil or military, medical personnel, public officials and other persons who may be involved in the custody, interrogation or treatment of any individual subjected to any form of arrest, detention or imprisonment.
- ▶ **Article 13 CAT:** Each State Party shall ensure that any individual who alleges he has been subjected to torture in any territory under its jurisdiction has the right to complain to, and to have his case promptly and impartially examined by, its competent authorities. Steps shall be taken to ensure that the complainant and witnesses are protected against all ill-treatment or intimidation as a consequence of his complaint or any evidence given.
- ▶ **Article 14 CAT:** (1) Each State Party shall ensure in its legal system that the victim of an act of torture obtains redress and has an enforceable right to fair and adequate compensation, including the means for as full rehabilitation as possible. In the event of the death of the victim as a result of an act of torture, his dependants shall be entitled to compensation. (2) Nothing in this article shall affect any right of the victim or other persons to compensation which may exist under national law.
- ▶ **Article 16 CAT:** (1) Each State Party shall undertake to prevent in any territory under its jurisdiction other acts of cruel, inhuman or degrading treatment or punishment which do not amount to torture as defined in article 1, when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. In particular, the obligations contained in articles 10, 11, 12 and 13 shall apply with the substitution for references to torture of references to other forms of cruel, inhuman or degrad-

ing treatment or punishment. (2) The provisions of this Convention are without prejudice to the provisions of any other international instrument or national law which prohibits cruel, inhuman or degrading treatment or punishment or which relates to extradition or expulsion.

The Committee Against Torture has identified overcrowding, inadequate living conditions, and lengthy confinement in psychiatric hospitals as “tantamount to inhuman or degrading treatment.”⁶⁴ It has also condemned, in similar terms, extreme overcrowding in prisons where living and hygiene conditions would appear to endanger the health and lives of prisoners⁶⁵, in addition to lack of medical attention.⁶⁶

The Committee has also emphasized that medical personnel who participate in acts of torture should be held accountable and punished.⁶⁷

Note: Special Rapporteurs on Torture

Successive UN Special Rapporteurs on Torture have found numerous abuses of detainees’ health and access to health services that amount to breaches of prohibitions against torture and/or cruel, inhuman, or degrading treatment. Special Rapporteurs have noted that conditions and the inadequacy of medical services are often worse for pretrial detainees than for prisoners.⁶⁸ Some of the worst abuses include: failure to provide new detainees with access to a medical professional and with sanitary living conditions;⁶⁹ failure to segregate those with contagious diseases such as tuberculosis;⁷⁰ completely unacceptable quarantine procedures;⁷¹ and insufficient provision of food, leading in some instances to conditions approaching starvation.⁷²

Another issue repeatedly raised by UN Special Rapporteurs on Torture is the impact on their mental health of children who enter the justice system and the accompanying threats presented by inhuman and violent conditions.⁷³

64 OHCHR. Concluding Observations: Russia. (CAT /C/RUS /CO/4).

65 OHCHR. Concluding Observations: Cameroon. (CAT /C/CR/31/6).

66 OHCHR. Concluding Observations: Nepal. (CAT /C/NPL/CO/2). See also observations on Paraguay (CAT /C/SR.418) and Brazil (CAT /C/SR.471).

67 OHCHR. Concluding Observations: Argentina. (A/48/44).

68 M. Nowak. Report of the Special Rapporteur on Torture, mission to Jordan (addendum), 2007a. (UN doc. A/HRC/33/Add.3); T. van Boven. Report of the Special Rapporteur on torture, mission to Uzbekistan (addendum), 2003. (UN doc. E/CN.4/2003/68/Add.2).

69 N. S. Rodley. Report of the Special Rapporteur on Torture, mission to the Russian Federation (addendum), 1994. (UN doc. E/CN.4/1995/34/Add.1).

70 Rodley. Report of the Special Rapporteur on Torture, mission to Azerbaijan, 2000. (UN doc. E/CN.4/2001/66/Add.1).

71 Rodley. Report of the Special Rapporteur on Torture, mission to Azerbaijan, 2000. (UN doc. E/CN.4/2001/66/Add.1); Nowak. Report of the Special Rapporteur on Torture, mission to Moldova, 2009. (UN doc. A/HRC/10/44/Add.3).

72 Rodley. Report of the Special Rapporteur on Torture, mission to Kenya (addendum), 2000. (UN doc. E/CN.4/2000/9/Add.4).

73 Nowak. Report of the Special Rapporteur on Torture, mission to Nigeria, 2007. (UN doc. A/HRC/7/3/Add.4.0); Nowak. Report of the Special Rapporteur on Torture, mission to Moldova, 2009. (UN doc. A/HRC/10/44/Add.3); Rodley. Report of the Special Rapporteur on Torture, mission to Kenya (addendum), 2000. (UN doc. E/CN.4/2000/9/Add.4).

- ▶ **Article 37 CRC:** *States Parties shall ensure that: (a) No child shall be subjected to torture or other cruel, inhuman or degrading treatment or punishment.*
- ▶ **Article 39 CRC:** *States Parties shall take all appropriate measures to promote physical and psychological recovery and social reintegration of a child victim of: any form of neglect, exploitation, or abuse; torture or any other form of cruel, inhuman or degrading treatment or punishment; or armed conflicts. Such recovery and reintegration shall take place in an environment which fosters the health, self-respect and dignity of the child.*
- ▶ **Article 15 CRPD:** *(1) No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation. (2) States Parties shall take all effective legislative, administrative, judicial or other measures to prevent persons with disabilities, on an equal basis with others, from being subjected to torture or cruel, inhuman or degrading treatment or punishment.*

Code of Conduct for Law Enforcement Officials

- ▶ **Article 2:** *In the performance of their duty, law enforcement officials shall respect and protect human dignity and maintain and uphold the human rights of all persons.*
- ▶ **Article 5:** *No law enforcement official may inflict, instigate or tolerate any act of torture or other cruel, inhuman or degrading treatment or punishment, nor may any law enforcement official invoke superior orders or exceptional circumstances ...as a justification of torture or other cruel, inhuman or degrading treatment or punishment.*
- ▶ **Principles of Medical Ethics Relevant to the Role of Health Personnel, Particularly Physicians, in the Protection of Prisoners and Detainees against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1982).** ⁷⁴
- ▶ **UN Body of Principles for the Protection of All Persons under Any Form of Detention or Imprisonment**
- ▶ **Principle 1:** *All persons under any form of detention or imprisonment shall be treated in a humane manner and with respect for the inherent dignity of the human person.*
- ▶ **Principle 6:** *No person under any form of detention or imprisonment shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. No circumstance whatever may be invoked as a justification for torture or other cruel, inhuman or degrading treatment or punishment.*

74 OHCHR. <http://www.wfirt.net/humanrts/instreet/h3pmerhp.htm>.

► UN Standard Minimum Rules for Treatment of Prisoners ⁷⁵

Rules 22-26 on Medical Services

Rule 22(1) requires that every institution should have at least one qualified medical officer who has some knowledge of psychiatry. More generally, medical services should be organized in collaboration with the public health system and should include appropriate psychiatric services. Rule 22(2) requires the transfer of sick prisoners to specialist institutions as appropriate while also ensuring that prison hospitals are properly equipped and staffed. Under Rule 22(3) the services of a qualified dental officer shall be available to every prisoner.

Rule 23 focuses on the provision of pre- and postnatal care and nursery care for women and their children and ensures that, whenever practicable, babies will be born in an external hospital.

Rule 24 requires that the medical officer shall see and examine every prisoner as soon as possible after his admission and thereafter as necessary, with a view to diagnose any physical or mental illnesses and to segregate prisoners with infectious or contagious conditions.

Under Rule 25 the medical officer should see all sick prisoners on a daily basis and report to the prison director whenever he determines that a prisoner's physical or mental health is being adversely affected by his detention. In addition, in line with Rule 26 the medical officer shall regularly inspect and report upon prisoners' food, hygiene, sanitation, heating, lighting, clothing, and bedding. The director shall, after considering the reports, take immediate action as required.

► Physicians for Human Rights Principles on the Effective Investigation and Documentation of Torture: the Istanbul Protocol ⁷⁶

Right to Participate in Public Policy

EXAMPLES OF POTENTIAL VIOLATIONS

- An indigenous group is denied any say in policy decisions affecting their health and well-being on the grounds of their perceived lack of competence
- Lesbian, Gay, Bisexual, and Transgender (LGBT) groups are deliberately excluded from participating in the development of policies that address HIV/AIDS

⁷⁵ OHCHR. Standard Minimum Rules for the Treatment of Prisoners. <http://www2.ohchr.org/english/law/treatmentprisoners.htm#wp1018277>.

⁷⁶ Physicians for Human Rights. Istanbul Protocol. www.physiciansforhumanrights.org/library/istanbul-protocol.html.

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 25 ICCPR:** *Every citizen shall have the right and the opportunity, without... distinctions . . . (a) To take part in the conduct of public affairs, directly or through freely chosen representatives.*

- ▶ **Article 7 CEDAW:** *State Parties shall take all appropriate measures to eliminate discrimination against women in the political and public life of the country and, in particular, shall ensure to women, on equal terms with men, the right: . . . (b) [t]o participate in the formulation of government policy and the implementation thereof.*

- ▶ **Article 14(2)(a) CEDAW:** *The right of rural women to participate in development planning.*

- ▶ **Article IV WHO Alma-Ata Declaration:** *The people have the right and the duty to participate individually and collectively in the planning and implementation of their healthcare.*

- ▶ **Principle 2 IAPO Declaration on Patient-Centered Healthcare:** *Choice and Empowerment: Patients have a right and responsibility to participate, to their level of ability and preference, as a partner in making healthcare decisions that affect their lives. This requires a responsive health service which provides suitable choices in treatment and management options that fit in with patients' needs, and encouragement and support for patients and carers that direct and manage care to achieve the best possible quality of life. Patients' organizations must be empowered to play meaningful leadership roles in supporting patients and their families to exercise their right to make informed healthcare choices.*

- ▶ **Principle 3 IAPO Declaration on Patient-Centered Healthcare⁷⁷:** *Patient involvement in health policy: Patients and patients' organizations deserve to share the responsibility of healthcare policy-making through meaningful and supported engagement in all levels and at all points of decision-making, to ensure that they are designed with the patient at the center. This should not be restricted to healthcare policy but include, for example, social policy that will ultimately impact on patients' lives.*

- ▶ **Article 12 ICESCR:** (1) The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: ... (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

⁷⁷ See also IAPO's Policy Statement on Patient Involvement at <http://www.patientsorganizations.org/showarticle.pl?id=590&n=962>.

- **CESCR GC 14, paras. 43 and 54:** *The CESCR has called for countries to adopt “a national public health strategy and plan of action” to be “periodically reviewed, on the basis of a participatory and transparent process.” In addition, “[p]romoting health must involve effective community action in setting priorities, making decisions, planning, implementing and evaluating strategies to achieve better health. Effective provision of health services can only be assured if people’s participation is secured by States.”*

Right to Nondiscrimination and Equality

EXAMPLES OF POTENTIAL VIOLATIONS

- Asylum seekers are denied access to all health care apart from emergency treatment
- Hospitals routinely place Roma women in separate maternity wards
- Drug users are underrepresented in HIV treatment programs despite accounting for a majority of the people living with HIV
- A woman with a diagnosis of schizophrenia is told by nursing staff that her abdominal pains are “all in your mind”; she is later diagnosed as having ovarian cancer

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 26 ICCPR:** *All persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.*
- ▶ **Article 2(2) ICCPR; Article 2(2) ICESCR:** *The States Parties to the present Covenant undertake to guarantee the rights enunciated in the present Covenant shall be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, birth or other status.*
 - **CESCR GC 14, para. 12:** *The CESCR has stated that health facilities, goods, and services have to be accessible to everyone without discrimination “and especially to the most vulnerable and marginalized sections of the population.” In particular, such health facilities, goods, and services “must be affordable for all,” and “poorer households should not be disproportionately burdened with health expenses as compared to richer households.” The CESCR has further urged particular attention to the needs of “ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS.”*
 - **CESCR GC 5, para. 15:** *The CESCR has defined disability-based discrimination as “any distinction, exclusion, restriction or preference, or denial of reasonable accommodation based on disability which has the effect of nullifying or*

impairing the recognition, enjoyment or exercise of economic, social or cultural rights.” It has gone on to emphasize the need “to ensure that not only the public health sector but also private providers of health services and facilities comply with the principle of non-discrimination in relation to persons with disabilities.”⁷⁸

To ensure equality between men and women in accessing health care, the CESCR has stated that it requires, at a minimum, the removal of legal and other obstacles that prevent men and women from accessing and benefiting from health care on the basis of gender. This includes, inter alia, addressing the ways in which gender roles affect access to determinants of health, such as water and food; the removal of legal restrictions on reproductive health provisions; the prohibition of female genital mutilation; and the provision of adequate training for health care workers to deal with women’s health issues.⁷⁹

- ▶ **Article 5 CERD:** *In compliance with the fundamental obligations laid down in article 2 of this Convention, States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of the following rights: ... (e) Economic, social and cultural rights, in particular: ... (iv) The right to public health, medical care, social security and social services.*
- **CERD GR 30, para. 36:** *The CERD has recommended that the States that are party to the Convention, as appropriate to their specific circumstances, ensure that they respect the right of non-citizens to an adequate standard of physical and mental health by, inter alia, refraining from denying or limiting their access to preventive, curative and palliative health services.*
- ▶ **Article 12 CEDAW:** *(1) States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning. (2) Notwithstanding the provisions of paragraph 1 of this article, States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.*
- ▶ **Article 14(2)(b) CEDAW:** *States Parties shall take all appropriate measures to eliminate discrimination against women in rural areas in order to ensure, on a basis of equality of men and women, that they participate in and benefit from ru-*

78 CESCR. General Comment 14 of the Committee on Economic, Social and Cultural Rights: The right to the highest attainable standard of health. (E/C.12/2004/4).

79 CESCR. General Comment 16 of the Committee on Economic, Social and Cultural Rights: The equal right of men and women to enjoyment of all economic, social, and cultural rights (article 3 of the International Covenant on Economic, Social and Cultural Rights). (E/C.12/2005/4).

ral development and, in particular, shall ensure to such women the right: To have access to adequate health care facilities, including information, counselling and services in family planning.

- ▶ **Article 23 CRC:** (1) States Parties recognize that a mentally or physically disabled child should enjoy a full and decent life, in conditions which ensure dignity, promote self-reliance and facilitate the child's active participation in the community. (2) States Parties recognize the right of the disabled child to special care and shall encourage and ensure the extension, subject to available resources, to the eligible child and those responsible for his or her care, of assistance for which application is made and which is appropriate to the child's condition and to the circumstances of the parents or others caring for the child. (3) Recognizing the special needs of a disabled child, assistance extended in accordance with paragraph 2 of the present article shall be provided free of charge, whenever possible, taking into account the financial resources of the parents or others caring for the child, and shall be designed to ensure that the disabled child has effective access to and receives education, training, health care services, rehabilitation services, preparation for employment and recreation opportunities in a manner conducive to the child's achieving the fullest possible social integration and individual development, including his or her cultural and spiritual development. (4) States Parties shall promote, in the spirit of international cooperation, the exchange of appropriate information in the field of preventive health care and of medical, psychological and functional treatment of disabled children, including dissemination of and access to information concerning methods of rehabilitation, education and vocational services, with the aim of enabling States Parties to improve their capabilities and skills and to widen their experience in these areas. In this regard, particular account shall be taken of the needs of developing countries.

- ▶ **Article 28 CMW:** Migrant workers and members of their families shall have the right to receive any medical care that is urgently required for the preservation of their life or the avoidance of irreparable harm to their health on the basis of equality of treatment with nationals of the State concerned. Such emergency medical care shall not be refused them by reason of any irregularity with regard to stay or employment.

- ▶ **Article 43 CMW:** (1) Migrant workers shall enjoy equality of treatment with nationals of the State of employment in relation to: (e) Access to social and health services, provided that the requirements for participation in the respective schemes are met; (2) States Parties shall promote conditions to ensure effective equality of treatment to enable migrant workers to enjoy the rights mentioned in paragraph 1 of the present article whenever the terms of their stay, as authorized by the State of employment, meet the appropriate requirements.

- ▶ **Article 45(1)(c) CMW:** (1) Members of the families of migrant workers shall, in the State of employment, enjoy equality of treatment with nationals of that State in relation to: Access to social and health services, provided that requirements for participation in the respective schemes are met.

- ▶ **Article 1 CRPD:** *The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity.*
- ▶ **Article 12 CRPD:** *((1) States Parties reaffirm that persons with disabilities have the right to recognition everywhere as persons before the law. (2) States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life. (3) States Parties shall take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity. (4) States Parties shall ensure that all measures that relate to the exercise of legal capacity provide for appropriate and effective safeguards to prevent abuse in accordance with international human rights law.*
- ▶ **Article 25 CRPD:** *States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation.*
- ▶ **Article 23 Convention Relating to the Status of Refugees:** *The Contracting States shall accord to refugees lawfully staying in their territory the same treatment with respect to public relief and assistance as is accorded to their nationals.*
- ▶ **Article 3 Charter on the Right to Health:** *Duty of states to institute health services that are available, accessible, and affordable for every individual.*
- ▶ **Principle 1 WMA Declaration on the Rights of the Patients:** *Every person is entitled without discrimination to appropriate medical care.*
- ▶ **Principle 4 IAPO Declaration**
- ▶ *Patients must have access to the healthcare services warranted by their condition. This includes access to safe, quality and appropriate services, treatments, preventive care and health promotion activities. Provision should be made to ensure that all patients can access necessary services, regardless of their condition or socio-economic status. For patients to achieve the best possible quality of life, healthcare must support patients' emotional requirements, and consider non-health factors such as education, employment and family issues which impact on their approach to healthcare choices and management.*
- ▶ **Resolution on Medical Care for Refugees (World Medical Association)⁸⁰**

⁸⁰ World Medical Association. Resolution on Medical Care for Refugees. www.wma.net/e/policy/m10.htm. Accessed November 22, 2009.

- *Physicians have a duty to provide appropriate medical care regardless of the civil or political status of the patient, and governments should not deny patients the right to receive, nor should they interfere with physicians' obligation to administer, adequate treatment; and*
- *Physicians cannot be compelled to participate in any punitive or judicial action involving refugees or IDPs or to administer any non-medically justified diagnostic measure or treatment, such as sedatives to facilitate easy deportation from the country or relocation; and*
- *Physicians must be allowed adequate time and sufficient resources to assess the physical and psychological condition of refugees who are seeking asylum.*

Note: The right to nondiscrimination and equal access to medical services

UN treaty bodies have frequently condemned states for failing to ensure equal access to medical services (often due to a lack of sufficient resources) for marginalized and vulnerable groups. These groups have included indigenous people living in extreme poverty;⁸¹ refugees of a particular nationality;⁸² children, older persons, and persons with physical and mental disabilities;⁸³ and those living in rural areas where the geographical distribution of health services and personnel shows a heavy urban bias.⁸⁴ In one country, the CESCR noted with regret that 90 percent of the population had no access to health services.⁸⁵ In another case, a state was criticized for inadequate medical care provided to low-income patients and was urged to subsidize expensive drugs required by chronically ill and mentally ill patients.⁸⁶

Treaty bodies have emphasized the importance of ensuring that those infected with particular diseases such as HIV/AIDS, should not be the subject of discrimination and stigmatized as a result of their medical condition.⁸⁷

81 CERD. Concluding Observations of the Committee on the Elimination of Racial Discrimination: Bolivia, 1996. (CERD/C/304/Add.10). See also CESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Mexico, 1999. (E/C.12/1/Add.14). State was urged to take more effective measures to ensure access to basic health care services for all children and to combat malnutrition, especially among children belonging to indigenous groups living in rural and remote areas.

82 CERD. Concluding Observations: Japan, 2001. (A/56/18 [SU PP]). Different standards of treatment are applied to Indochinese refugees compared to those from other nationalities.

83 CESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Finland, 2000. (E/C.12/1/Add.52). Failure of certain municipalities to allocate sufficient funds to health care services, resulting in inequality with regard to levels of provision depending on the place of residence.

84 CESCR. Concluding Observations: Mali, 1994. (E/1995/22). See also concluding observations Guatemala, 1996. (E/1997/22); Paraguay, 1996. (E/1997/22 (1996)). Noting the very small number of medical and paramedical personnel in the country; Mongolia, 2000. (E/2001/22). Noting the long-term deterioration in health situation and need to improve access to health care services for the poor and in rural areas.

85 CESCR. Concluding Observations: Nepal, 2001. (E/2002/22). The committee notes that under the current national health plan for 1997–2017, the role of the state in the development of a national health care system, consistent with the structural adjustment programs, is minimized. It further notes that the mental health service was insufficient and that no community mental health program was available.

86 CESCR. Concluding Observations: China, 2005. (E/C.12/1/ADD.107). See also concluding observations Russian Federation, 2003. (E/C.12/1/ADD.94). Committee criticizes Russia for frequent failure of hospitals and clinics in poor regions to stock essential drugs.

87 CEDAW. Report of the Committee on the Elimination of Discrimination against Women, 2001. (A/56/38 [SUPP]). See also CESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Russian Federation, 2003. (E/2004/22).

Two groups that continue to suffer from unequal access to health services are women and young people, which frequently leads to high mortality rates.⁸⁸ Both groups, particularly women living in rural areas⁸⁹ and especially vulnerable groups of children (such as girls, indigenous children and children living in poverty), will often experience multiple discrimination, requiring specific targeted measures and sufficient budgetary allocations.⁹⁰

88 ICESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Peru, 1997. (E/1998/22). See also concluding observations Ukraine, 2001. (E/2002/22). Noting deterioration in the health of the most vulnerable groups, especially women and children, and in the quality of health services. Committee urges state to ensure that its commitment to primary health care is met by adequate allocation of resources and that all persons, especially from the most vulnerable groups, have access to health care.

89 CEDAW. Report of the Committee on the Elimination of Discrimination against Women: Burkina Faso, 2000. (A/55/38).

90 CRC. Convention on the Rights of the Child. Concluding Observations: Bolivia, 1993. (CRC/C/16).

2.4 Providers' Rights

Numerous international treaties and conventions include rights that are designed to protect workers and ensure safe and healthy work environments. The United Nations and its agencies, including the International Labor Organization, have developed some of these international labor standards and monitor their implementation. This section presents several standards and how they have been interpreted in relation to three key rights for health care and service providers. These include the right to (i) work in decent conditions, including the receipt of fair pay; (ii) freedom of association, including association with trade unions and the right to strike; and (iii) due process and related rights to receive a fair hearing and an effective remedy, protection of privacy and reputation, and freedom of expression and information.

Part I of this section covers the right to work in decent conditions. Part II discusses the right to freedom of association. Part III explores the right to due process and related rights. Each section begins with a discussion of the significance of that particular right for health providers and is followed by examples of potential violations. The relevant standards from various UN treaties are reproduced, including those of general application and the standards that refer to particular groups. Key interpretative materials are then summarized, and interpretive guidelines are drawn from the concluding observations, general comments, and case law of official monitoring bodies.

Right to Work in Decent Conditions

UN treaty-monitoring bodies have made it clear that there is no right that requires an individual be provided with work or the occupation of one's choice. States must, however, refrain from unduly hindering the ability of individuals to freely pursue their chosen careers. Furthermore, states are required to ensure the fair treatment of migrant workers, a requirement that is particularly relevant for medical professionals, who are often recruited from other countries to staff hospitals and clinics. The Convention on Migrant Workers emphasizes states' obligation to foreign-born employees.

The UN bodies have conducted surveys of workers' pay and conditions, and these investigations have resulted in specific references to the treatment of health care personnel. The concern for medical professionals is driven in part by the poor remuneration that they receive in some countries.

EXAMPLES OF POTENTIAL VIOLATIONS

- All overseas migrant workers from country X, including a number who are employed as doctors and nurses, are summarily expelled after diplomatic relations are broken off following a trade dispute
- Female employees are subject to frequent sexual harassment by other members of staff with no action taken to stop harassment

- There is no regulation of working hours for medical staff, who are frequently required to work in excess of 80 hours per week

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 23(1) Universal Declaration of Human Rights (UDHR):** *Everyone has the right to work, to free choice of employment, to just and favorable conditions of work and to protection against unemployment.*
- ▶ **Article 6(1) International Covenant on Economic, Social and Cultural Rights (ICESCR):** *(1) The States Parties to the present Covenant recognize the right to work, which includes the right of everyone to the opportunity to gain his living by work which he freely chooses or accepts, and will take appropriate steps to safeguard this right.*
 - **CESCR GC 18, para. 1:** *The right to work is essential for realizing other human rights and forms an inseparable and inherent part of human dignity. Every individual has the right to be able to work, allowing him/her to live in dignity. The right to work contributes at the same time to the survival of the individual and to that of his/her family, and insofar as work is freely chosen or accepted, to his/her development and recognition within the community.*
 - **CESCR GC 18, para. 4:** *The right to work, as guaranteed in the ICESCR, affirms the obligation of States parties to assure individuals their right to freely chosen or accepted work, including the right not to be deprived of work unfairly. This definition underlines the fact that respect for the individual and his dignity is expressed through the freedom of the individual regarding the choice to work, while emphasizing the importance of work for personal development as well as for social and economic inclusion.*
 - **CESCR GC 18, paras. 6, 23 and 25:** *The right to work does not mean there is an absolute and unconditional right to obtain employment but that rather that the state should ensure that neither itself or others (such as private companies) do anything unreasonably or in a discriminatory way to prevent a person from earning a living or practicing their profession.*
 - **CESCR GC 16, para. 23:** *Implementing article 3, in relation to article 6, requires inter alia, that in law and in practice, men and women have equal access to jobs at all levels and all occupations and that vocational training and guidance programmes, in both the public and private sectors, provide men and women with the skills, information and knowledge necessary for them to benefit equally from the right to work.*
 - *In addition to frequent criticisms of states' high levels of unemployment, the CESCR has also condemned (a) the expulsion of HIV-positive foreign workers with valid work permits;⁹¹ (b) the disproportionate number of women in low paid part time work;⁹² and (c) the downsizing of the public sector with significant social repercussions.⁹³*

91 ICESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Libyan Arab Jamahiriya, 1997. (E/1998/22 (1997)).

92 ICESCR. Concluding Observations: United Kingdom of Great Britain and Northern Ireland, 1997. (E/1998/22). See also concluding observations on Ukraine, 1995 (E/1996/22).

93 ICESCR. Concluding Observations: Solomon Islands, 1999. (E/2000/22).

► **International Convention on the Elimination of All Forms of Racial Discrimination (ICERD)**

- The CERD has expressed concern on numerous occasions about the failure of states to address the lack of employment opportunities for ethnic minorities and migrant workers.⁹⁴
- The CERD has held that the examination and quota system for doctors trained overseas did not breach a migrant worker's right, under Article 5(e)(i) of the UN International Convention on the Elimination of All Forms of Racial Discrimination. Article 5(e)(i) guarantees the right to work and freely choose employment without distinction as to race, color, or national or ethnic origin.⁹⁵

Article 11 UN Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms 1998:⁹⁶ *Everyone has the right, individually and in association with others, to the lawful exercise of his or her occupation or profession. Everyone who, as a result of his or her profession, can affect the human dignity, human rights and fundamental freedoms of others should respect those rights and freedoms and comply with relevant national and international standards of occupational and professional conduct or ethics.*

Standards related to women

- **Article 11(1) Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW):** *States Parties shall take all appropriate measures to eliminate discrimination against women in the field of employment in order to ensure, on a basis of equality of men and women, the same rights, in particular:*
- (a) the right to work as an inalienable right of all human beings;...*
 - (c) The right to free choice of profession and employment, the right to promotion, job security and all benefits and conditions of service and the right to receive vocational training and retraining, including apprenticeships, advanced vocational training and recurrent training;...*

Standards related to migrant workers

- **Article 51 International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families:** *Migrant workers who in the State of employment are not permitted freely to choose their remunerated activity shall neither be regarded as in an irregular situation nor shall they lose their authorization of residence by the mere fact of the termination of their remunerated activity*

94 CERD. Concluding Observations of the Committee on the Elimination of Racial Discrimination: Poland, 1997. (A/52/18). See also concluding observations Norway, 1994 (A/49/18); United Kingdom of Great Britain and Northern Ireland, 1991 (A/46/18); Israel, 1998 (A/53/18); The Netherlands, 1998 (A/53/18); Lebanon, 1998 (A/53/18); Azerbaijan, 1999 (A/54/18); Denmark, 2000 (A/55/18); Latvia, 2003 (A/58/18); Iceland, 2005 (A/60/18); and Turkmenistan, 2005 (A/60/18).

95 CERD. Opinion regarding B. M. S. v. Australia, 1996. (C/54/D/8/1996); Procedural Decisions, 1999. (A/54/18).

96 UN General Assembly Resolution 53/144. December 9, 1998.

prior to the expiration of their work permit, except where the authorization of residence is expressly dependent upon the specific remunerated activity for which they were admitted. Such migrant workers shall have the right to seek alternative employment, participation in public work schemes and retraining during the remaining period of their authorization to work, subject to such conditions and limitations as are specified in the authorization to work.

Right to Fair Pay and Safe Working Conditions

EXAMPLES OF POTENTIAL VIOLATIONS

- Nurses and ancillary staff are paid less than the national minimum wage
- A staff canteen remains open despite repeatedly failing to meet basic hygiene standards
- Medical staff in the X-ray department are frequently exposed to dangerously high levels of radiation due to faulty equipment that has not been checked or replaced
- A nurse is infected with HIV due to improperly sterilized medical equipment

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 7 ICESCR:** *The States Parties to the present Covenant recognize the right of everyone to the enjoyment of just and favourable conditions of work which ensure, in particular: (a) Remuneration which provides all workers, as a minimum, with: (i) Fair wages and equal remuneration for work of equal value without distinction of any kind, in particular women being guaranteed conditions of work not inferior to those enjoyed by men, with equal pay for equal work; (ii) A decent living for themselves and their families in accordance with the provisions of the present Covenant; (b) Safe and healthy working conditions; (c) Equal opportunity for everyone to be promoted in his employment to an appropriate higher level, subject to no considerations other than those of seniority and competence; (d) Rest, leisure and reasonable limitation of working hours and periodic holidays with pay, as well as remuneration for public holidays.*
- ▶ **Article 12 ICESCR:** *(1) The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for... (b) [t]he improvement of all aspects of environmental and industrial hygiene. ...*
 - The CESCR has expressed concern about a range of working-condition issues, including: the need to harmonise the labor code with international standards, especially with regard to maternity leave;⁹⁷ disparities in pay and conditions between the private and public sectors (in teaching);⁹⁸ discrimination in employment on the grounds of political opinion;⁹⁹ the lack of a national minimum wage for public sector employees and the serious deterioration of some of those employees' (specifically, teachers') salaries in terms of purchasing

power; the conflictual nature of relations between teachers and the state and the apparent ineffectiveness of the measures taken to remedy that situation;¹⁰⁰ ineffective campaigns to increase awareness of hygiene and safety in the workplace where they are frequently below established standards;¹⁰¹ the fact that standards for the protection of workers concerning limits on the duration of the working day and weekly rest are not always fully met due to some areas of the private sector being dilatory in enforcing the relevant legislation;¹⁰² the lack of legislation to protect workers who are not covered by collective bargaining agreements in relation to a minimum wage, health and maternal benefits, and safe working conditions;¹⁰³ unsafe working conditions and lack of compensation for workplace injury;¹⁰⁴ the privatization of labor inspections and control systems;¹⁰⁵ legislation that favors individual negotiation with employers over collective bargaining;¹⁰⁶ the need for effective implementation of legislative provisions concerning job security;¹⁰⁷ and the allowance of excessive working hours in both the public and private sectors.¹⁰⁸

► **International Covenant on Civil and Political Rights (CCPR)**

- The UN Human Rights Council (HRC) has condemned sexual harassment in the workplace¹⁰⁹ and the lack of implementation of laws concerning labor standards. Laws concerning labor standards include those that call for adequate monitoring of working conditions and sufficient funding for labor inspection workforce.¹¹⁰

► **Article 4 International Labour Organization (ILO) Occupational Safety and Health Convention No. 155, 1981:**¹¹¹

The state is under an obligation to formulate, implement and periodically review a coherent national policy on occupational safety, occupational health and the working environment with the aim of preventing accidents and injury to health arising out of, linked with or occurring in the course of work, by minimising, so far as is reasonably practicable, the causes of hazards inherent in the working environment.

97 ICESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Ecuador, 1990. (E/1991/23).

98 ICESCR. Concluding Observations: Spain, 1991. (E/1992/23); Concluding observations Columbia, 1991 (E/1992/23).

99 ICESCR. Concluding Observations: Germany, 1993. (E/1994/23).

100 ICESCR. Concluding Observations: Uruguay, 1994. (E/1995/22). See also concluding observations Finland, 1996. (E/1997/22).

101 ICESCR. Concluding Observations: Argentina, 1994. (E/1995/22).

102 ICESCR. Concluding Observations: Austria, 1994. (E/1995/22).

103 ICESCR. Concluding Observations: Suriname, 1995. (E/1996/22).

104 ICESCR. Concluding Observations: Russian Federation, 1997. (E/1998/22). The committee later condemned the large number of illegal dismissals and nonpayment of wages.

105 ICESCR. Concluding Observations: Argentina, 1999. (E/2000/22).

106 ICESCR. Concluding Observations: Australia, 2000. (E/2001/22).

107 ICESCR. Concluding Observations: Finland, 2000. (E/2001/22).

108 ICESCR. Concluding Observations: Japan, 2001. (E/2002/22).

109 ICCPR. Chile, 1999. (A/54/40 [vol. I]). See also ICCPR. Trinidad and Tobago, 2001. (A/56/40 [vol. II]).

110 ICCPR. Dominican Republic, 1993. (A/48/40 [vol. II]). See also ICESCR. El Salvador, 1996. (E/1997/22).

111 International Labour Organization (ILO). Occupational Health Services Convention No. 155, 1981. http://www.ilocarib.org.tt/projects/cariblex/conventions_19.shtml.

► **Article 3(1) ILO Occupational Health Services Convention No. 161, 1985**¹¹²

States undertake to develop progressively occupational health services for all workers, including those in the public sector.

► **Article 2(1) ILO Promotional Framework for Occupational Safety and Health Convention No. 187, 2006**¹¹³

States under a duty to promote continuous improvement of occupational safety and health to prevent occupational injuries, diseases and deaths, by the development, in consultation with the most representative organizations of employers and workers, of a national policy, national system and national programme.

Standards related to nursing staff

► **ILO Nursing Personnel Convention¹¹⁴ No. 149, 1977:** ¹¹⁵

Article 1(2): *This Convention applies to all nursing personnel, wherever they work.*

Article 2: (1) *Each Member which ratifies this Convention shall adopt and apply, in a manner appropriate to national conditions, a policy concerning nursing services and nursing personnel designed, within the framework of a general health programme, where such a programme exists, and within the resources available for health care as a whole, to provide the quantity and quality of nursing care necessary for attaining the highest possible level of health for the population. (2) In particular, it shall take the necessary measures to provide nursing personnel with- (a) education and training appropriate to the exercise of their functions; and (b) employment and working conditions, including career prospects and remuneration, which are likely to attract persons to the profession and retain them in it. (3) The policy mentioned in paragraph 1 of this Article shall be formulated in consultation with the employers' and workers' organisations concerned, where such organisations exist. (4) This policy shall be co-ordinated with policies relating to other aspects of health care and to other workers in the field of health, in consultation with the employers' and workers' organisations concerned.*

112 ILO. Occupational Health Services Convention No. 161, 1985.

113 ILO. Promotional Framework for Occupational Safety and Health Convention. <http://www.ilo.org/ilolex/cgi-lex/convde.pl?C187>

114 ILO. Nursing Personnel Convention No. 149, 1977. <http://www.ilo.org/public/english/dialogue/sector/publ/health/c149.pdf>.

The preamble states: Recognising the vital role played by nursing personnel, together with other workers in the field of health, in the protection and improvement of the health and welfare of the population, and Recognising that the public sector as an employer of nursing personnel should play an active role in the improvement of conditions of employment and work of nursing personnel, and Noting that the present situation of nursing personnel in many countries, in which there is a shortage of qualified persons and existing staff are not always utilised to best effect, is an obstacle to the development of effective health services, and Recalling that nursing personnel are covered by many international labour Conventions and Recommendations laying down general standards concerning employment and conditions of work, such as instruments on discrimination, on freedom of association and the right to bargain collectively, on voluntary conciliation and arbitration, on hours of work, holidays with pay and paid educational leave, on social security and welfare facilities, and on maternity protection and the protection of workers' health, and Considering that the special conditions in which nursing is carried out make it desirable to supplement the above-mentioned general standards by standards specific to nursing personnel, designed to enable them to enjoy a status corresponding to their role in the field of health and acceptable to them, and Noting that the following standards have been framed in co-operation with the World Health Organisation and that there will be continuing co-operation with that Organisation in promoting and securing the application of these standards....

115 ILO. Table of ratifications. <http://www.ilo.org/ilolex/cgi-lex/ratfice.pl?C149>.

Article 6: *Nursing personnel shall enjoy conditions at least equivalent to those of other workers in the country concerned in the following fields: (a) hours of work, including regulation and compensation of overtime, inconvenient hours and shift work; (b) weekly rest; (c) paid annual holidays; (d) educational leave; (e) maternity leave; (f) sick leave; (g) social security.*

Article 7: *Each Member shall, if necessary, endeavour to improve existing laws and regulations on occupational health and safety by adapting them to the special nature of nursing work and of the environment in which it is carried out.*

Note: Working Conditions and Health Care Professionals

UN treaty-monitoring bodies have made specific reference to health personnel on numerous occasions. There is general consensus about the need to take measures to increase the salaries of nurses.¹¹⁶ The failure to pay medical staff their salaries for extended periods also presents an issue, as it leads many doctors to seek employment overseas. Monitoring bodies have also noted the pressing need to allocate funds to hospitals and health care services on a priority basis in order to restore health services to an operational level and to ensure that doctors, nurses, and other medical personnel are able to resume work as soon as possible.¹¹⁷ The low wages of the medical staff and the suboptimal living and working conditions in hospitals have also generated concern.¹¹⁸ Finally, the “brain drain” associated with the exodus of health professionals due to poor working conditions in the health sector in their home countries has been cited as problematic.¹¹⁹

Standards related to women

- ▶ **Article 10(2) ICESCR:** *Special protection should be accorded to mothers during a reasonable period before and after childbirth. During such period working mothers should be accorded paid leave or leave with adequate social security benefits.*
- ▶ **Article 7 ICESCR:** *The States Parties to the present Covenant recognize the right of everyone to the enjoyment of just and favourable conditions of work which ensure, in particular: (a) Remuneration which provides all workers, as a minimum, with: (i) Fair wages and equal remuneration for work of equal value without distinction of any kind, in particular women being guaranteed conditions of work not inferior to those enjoyed by men, with equal pay for equal work; (ii) A decent living for themselves and their families in accordance with the provisions of the present Covenant; (b) Safe and healthy working conditions; (c) Equal opportunity for everyone to be promoted in his employment to an appropriate higher level, subject to no considerations other than those of seniority and competence; (d) Rest, leisure*

116 ICESCR. Concluding Observations of the Committee on Economic, Social and Cultural Rights: Uruguay, 1997. (E/1998/22).

117 CRC. Concluding Observations of the Committee on the Rights of the Child: Solomon Islands, 2003. (CRC/C/132).

118 ICESCR. Concluding Observations: Georgia, 2002. (E/2003/22).

119 ICESCR. Concluding Observations: Zambia, 2005. (E/2006/22).

and reasonable limitation of working hours and periodic holidays with pay, as well as remuneration for public holidays.

- **CESCR GC 16, para. 24:** Article 7 (a) of the Covenant requires States parties to recognize the right of everyone to enjoy just and favourable conditions of work and to ensure, among other things, fair wages and equal pay for work of equal value. Article 3, in relation to article 7 requires, *inter alia*, that the State party identify and eliminate the underlying causes of pay differentials, such as gender-biased job evaluation or the perception that productivity differences between men and women exist. Furthermore, the State party should monitor compliance by the private sector with national legislation on working conditions through an effectively functioning labor inspectorate. The State party should adopt legislation that prescribes equal consideration in promotion, non-wage compensation and equal opportunity and support for vocational or professional development in the workplace. Finally, the State party should reduce the constraints faced by men and women in reconciling professional and family responsibilities by promoting adequate policies for childcare and care of dependent family members.

- ▶ **Article 11(1)(f) CEDAW:** States Parties shall take all appropriate measures to eliminate discrimination against women in the field of employment in order to ensure, on a basis of equality of men and women, the same rights, in particular: ... [t]he right to protection of health and to safety in working conditions, including the safeguarding of the function of reproduction.

- ▶ **Article 11(2) CEDAW:** In order to prevent discrimination against women on the grounds of marriage or maternity and to ensure their effective right to work, States Parties shall take appropriate measures: (a) To prohibit, subject to the imposition of sanctions, dismissal on the grounds of pregnancy or of maternity leave and discrimination in dismissals on the basis of marital status; (b) To introduce maternity leave with pay or with comparable social benefits without loss of former employment, seniority or social allowances; (c) To encourage the provision of the necessary supporting social services to enable parents to combine family obligations with work responsibilities and participation in public life, in particular through promoting the establishment and development of a network of child-care facilities; (d) To provide special protection to women during pregnancy in types of work proved to be harmful to them.

- **CEDAW General Recommendation 24 on Article 2, para. 28:** When reporting on measures taken to comply with article 12, States parties are urged to recognize its interconnection with other articles in the Convention that have a bearing on women's health. Those articles include ... article 11, which is concerned, in part, with the protection of women's health and safety in working conditions, including the safeguarding of the reproductive function, special protection from harmful types of work during pregnancy and with the provision of paid maternity leave.

- CEDAW has offered frequent criticism of the disproportionate number of women occupying low-paid, low-skilled and part-time work, including in the health

sector.¹²⁰ The CEDAW committee has also highlighted the relative absence of women from high decision-making professional and administrative positions in both the public and private sectors (evidence of the so-called ‘glass-ceiling’ phenomenon).¹²¹

- CEDAW has also condemned: the lack of regulations to penalize and remedy sexual harassment in the workplace in the private sector;^{122, 123} the poor working conditions of women workers in both the private and the public sectors, particularly with respect to the nonimplementation of minimum wage levels and the lack of social and health benefits;¹²⁴ discrimination against women on the grounds of pregnancy and maternity in spite of policies that prohibit this practice;¹²⁵ the lack of affordable childcare;¹²⁶ and the need to expand the number of crèches available for working mothers.¹²⁷

Standards related to workers with disabilities

► **Article 7 ICESCR:** *The States Parties to the present Covenant recognize the right of everyone to the enjoyment of just and favourable conditions of work which ensure, in particular...*

- **CESCR GC 5, para. 25:** The right to “the enjoyment of just and favourable conditions of work” (Article 7) applies to all disabled workers, whether they work in sheltered facilities or in the open labor market. Disabled workers may not be discriminated against with respect to wages or other conditions if their work is equal to that of non-disabled workers. States parties have a responsibility to ensure that disability is not used as an excuse for creating low standards of labor protection or for paying below-minimum wages.

Standards related to race, non-citizens, and migrant workers

► **Article 5(e)(i) CERD:** *In compliance with the fundamental obligations laid down in Article 2 of this Convention, States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the*

120 CEDAW. Report of the Committee on the Elimination of Discrimination against Women: Belarus, 2004. (A/59/38 [part I]).

121 CEDAW. Report of the Committee: Finland, 1995. (A/50/38). See also reports of the committee on Ethiopia, 1996 (A/51/38) and Albania, 2003 (A/58/38 [part I]).

122 CEDAW. Report of the Committee: Argentina, 1997. (A/52/38/Rev. 1 [part II]). See also report of the committee on Cuba, 2000 (A/55/38 [part II]).

123 CEDAW. Report of the Committee: China, 1999. (A/54/38/Rev.1 [part I]).

124 CEDAW. Report of the Committee: Bangladesh, 1997. (A/52/38/Rev.1 [part II]).

125 CEDAW. Report of the Committee: Guyana, 2001. (A/56/38 [part II]). The committee recommended development of a national policy for the private and public sectors to include minimum mandatory and paid maternity and parental leave and also to include provisions for effective sanctions and remedies for violation of laws regarding maternity leave. It also recommended establishment of training programs for the staff of the labor office to facilitate prosecution and ensure the effective enforcement of existing laws for both the public and private sectors.

126 CEDAW. Report of the Committee: Ireland, 2005. (A/60/38 [part II]).

127 CEDAW. Report of the Committee: Bangladesh, 2004. (A/59/38 [part II]).

law, notably in the enjoyment of the rights to work, to free choice of employment, to just and favourable conditions of work, to protection against unemployment, to equal pay for equal work, to just and favourable remuneration.

- ▶ **CERD GR 30, paras. 33-35:** *[The committee recommends] that the States parties to the Convention, as appropriate to their specific circumstances, adopt the following measures:...(33) Take measures to eliminate discrimination against non-citizens in relation to working conditions and work requirements, including employment rules and practices with discriminatory purposes or effects; (34) Take effective measures to prevent and redress the serious problems commonly faced by non-citizen workers, in particular by non-citizen domestic workers, including debt bondage, passport retention, illegal confinement, rape and physical assault; (35) Recognize that, while States parties may refuse to offer jobs to non-citizens without a work permit, all individuals are entitled to the enjoyment of labor and employment rights, including the freedom of assembly and association, once an employment relationship has been initiated until it is terminated.*
- ▶ **Article 25 International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families:** *(1) Migrant workers shall enjoy treatment not less favourable than that which applies to nationals of the State of employment in respect of remuneration and: (a) Other conditions of work, that is to say, overtime, hours of work, weekly rest, holidays with pay, safety, health, termination of the employment relationship and any other conditions of work which, according to national law and practice, are covered by these terms; (b) Other terms of employment, that is to say, minimum age of employment, restriction on home work and any other matters which, according to national law and practice, are considered a term of employment. (2) It shall not be lawful to derogate in private contracts of employment from the principle of equality of treatment referred to in paragraph 1 of the present article. (3) States Parties shall take all appropriate measures to ensure that migrant workers are not deprived of any rights derived from this principle by reason of any irregularity in their stay or employment. In particular, employers shall not be relieved of any legal or contractual obligations, nor shall their obligations be limited in any manner by reason of such irregularity.*
- ▶ **Article 70:** *States Parties shall take measures not less favourable than those applied to nationals to ensure that working and living conditions of migrant workers and members of their families in a regular situation are in keeping with the standards of fitness, safety, health and principles of human dignity.*

Right to Freedom of Association

The ability of workers to be able to form, join, and run associations without undue interference is critical to their ability to effectively defend their rights. Health care professionals enjoy the same collective action rights as other employees. Although the health sector provides an essential service, this fact only precludes its members from work stoppage in certain exceptional circumstances. Although UN jurispru-

dence on freedom of association has focused on the treatment of NGOs and political parties, the interpretation of the core aspects of the right can also be applied to professional associations and trade unions. The latter are also the subject of relevant ILO standards.

Certain provisions of the UN Human Rights Defenders Declaration emphasize the role of healthcare providers as human rights defenders who implement and protect social rights and fundamental civil rights, such as life and freedom from torture and inhuman or degrading treatment.¹²⁸

Right to Freedom of association and assembly

EXAMPLES OF POTENTIAL VIOLATIONS

- A professional medical association is not approved by the Ministry of Health because its president is a leading member of an opposition political party
- A rally for improved pay and conditions for health workers is prevented from taking place by the authorities without any justification

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

General standards

- ▶ **Article 20 Universal Declaration of Human Rights (UDHR):** (1) Everyone has the right to freedom of peaceful assembly and association. (2) No one may be compelled to belong to an association.
- ▶ **Article 21 International Covenant on Civil and Political Rights (ICCPR):** The right of peaceful assembly shall be recognized. No restrictions may be placed on the exercise of this right other than those imposed in conformity with the law and which are necessary in a democratic society in the interests of national security or public safety, public order (*ordre public*), the protection of public health or morals or the protection of the rights and freedoms of others.
- ▶ Although freedom of assembly is not an absolute right, any restrictions on the ability of people to peacefully protest must be justified in line with the conditions explicitly stated in Article 21 of the ICCPR.¹²⁹
- ▶ **Article 22 ICCPR:** (1) Everyone shall have the right to freedom of association with others, including the right to form and join trade unions for the protection of his interests. (2) No restrictions may be placed on the exercise of this right other than those which are prescribed by law and which are necessary in a democratic society in the interests of national security or public safety, public order (*ordre public*),

¹²⁸ UN Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms. (A/RES /53/144). [http://www.unhcr.ch/huridocda/huridoca.nsf/\(Symbol\)/A.RES.53.144.En](http://www.unhcr.ch/huridocda/huridoca.nsf/(Symbol)/A.RES.53.144.En).

¹²⁹ S. Joseph, J. Schultz, and M. Castan. *The ICCPR: Cases, Materials and Commentary*. (Oxford: Oxford University Press, 2004), 569.

the protection of public health or morals or the protection of the rights and freedoms of others. This article shall not prevent the imposition of lawful restrictions on members of the armed forces and of the police in their exercise of this right. (3) Nothing in this article shall authorize States Parties to the International Labour Organisation Convention of 1948 concerning Freedom of Association and Protection of the Right to Organize to take legislative measures which would prejudice, or to apply the law in such a manner as to prejudice, the guarantees provided for in that Convention.

- It is not clear whether Article 22 of the ICCPR also includes the freedom not to join an association, in which case trade union “closed shop” practices would amount to a breach, although it is probable that the article does include this freedom.¹³⁰
- Procedural formalities for recognition of associations must not be so onerous as to amount to a substantive restriction on Article 22 of the ICCPR.¹³¹
- Although legislation governing the incorporation and status of associations may be, on its face compatible with Article 22, de facto state practice restricting the right to freedom of association through a process of prior licensing and control has been condemned.¹³²

► **Article 2 ILO Convention No. 87 on the Freedom of Association and Protection of the Right to Organise:**¹³³ *Workers and employers, without distinction whatsoever, shall have the right to establish and, subject only to the rules of the organisation concerned, to join organisations of their own choosing without previous authorisation.*

- The right to establish and to join organizations for the promotion and defense of workers’ interests without previous authorization is a fundamental right under Article 2 of ILO Convention No. 87 that should be enjoyed by all workers without any distinction whatsoever; hospital personnel are entitled to take full advantage of this right.¹³⁴
- A law providing that the right of association is subject to authorization granted by a government department purely in its discretion is incompatible with the principle of freedom of association as guaranteed by ILO Convention No. 87.¹³⁵

► **UN Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms (the Human Rights Defenders Declaration) 1998**¹³⁶

130 Ibid., 582. See also HRC. *Gauthier v. Canada*. Communication No. 633/1995. Views adopted May 5, 1999.
 131 HRC. Concluding Observations of the Human Rights Committee: Belarus, 1997. (CCPR/C/79/Add.); Concluding Observations: Lithuania, 1997. (CCPR/C/79/Add.87).
 132 HRC. Concluding Observations: Lebanon, 1997. (A/52/40 [vol. II]).
 133 ILO. Table of ratifications. <http://www.ilo.org/ilolex/cgi-lex/ratifce.pl?C087>.
 134 ILO. Freedom of Association: Digest of Decisions and Principles of the Freedom of Association Committee, 2005.
 135 ILO. Freedom of Association: Digest of Decisions and Principles, 2005; Digest of Decisions and Principles, 1996; and 332nd Report of the Freedom of Association Committee. Case No. 2225.
 136 UN General Assembly Resolution 53/144. December 9, 1998. Full text available at [http://www.unhcr.ch/huridocda/huridocda.nsf/\(Symbol\)/A.RES.53.144.En](http://www.unhcr.ch/huridocda/huridocda.nsf/(Symbol)/A.RES.53.144.En)

Article 1: *Everyone has the right, individually and in association with others, to promote and to strive for the protection and realization of human rights and fundamental freedoms at the national and international levels.*

Article 5: *For the purpose of promoting and protecting human rights and fundamental freedoms, everyone has the right, individually and in association with others, at the national and international levels: (a) To meet or assemble peacefully; (b) To form, join and participate in non-governmental organizations, associations or groups; (c) To communicate with non-governmental or intergovernmental organizations.*

Standards related to women

- ▶ **Article 7(c) CEDAW:** *States Parties shall take all appropriate measures to eliminate discrimination against women in the political and public life of the country and, in particular, shall ensure to women, on equal terms with men, the right to participate in non-governmental organizations and associations concerned with the public and political life of the country.*
- ▶ **Article 3 CEDAW:** *States Parties shall take in all fields, in particular in the political, social, economic and cultural fields, all appropriate measures, including legislation, to ensure the full development and advancement of women, for the purpose of guaranteeing them the exercise and enjoyment of human rights and fundamental freedoms on a basis of equality with men.*
 - **CESCR GC 16 on Article 3: The Equal Right of Men and Women to the Enjoyment of all Economic, Social and Cultural Rights, E/2006/22 (2005) 116, para. 25:** Article 8, paragraph 1 (a), of the Covenant requires States parties to ensure the right of everyone to form and join trade unions of his or her choice. Article 3, in relation to article 8, requires allowing men and women to organize and join workers' associations that address their specific concerns. In this regard, particular attention should be given to domestic workers, rural women, women working in female-dominated industries and women working at home, who are often deprived of this right.

Standards related to race

- ▶ **Article 5(d)(ix) ICERD:** *In compliance with the fundamental obligations laid down in Article 2 of this Convention, States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of [t]he right to freedom of peaceful assembly and association.*

Trade Unions and the Right to Strike

EXAMPLES OF POTENTIAL VIOLATIONS

- Health sector trade unions or professional associations have not been approved by the Ministry of Health to represent members
- A nurse cannot work at a particular hospital unless she joins the only trade union recognized by the management, as part of a “closed shop” agreement
- Some doctors and nurses are dismissed after taking collective action over their poor pay and conditions

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- **Article 22 ICCPR:** (1) Everyone shall have the right to freedom of association with others, including the right to form and join trade unions for the protection of his interests. (2) No restrictions may be placed on the exercise of this right other than those which are prescribed by law and which are necessary in a democratic society in the interests of national security or public safety, public order (ordre public), the protection of public health or morals or the protection of the rights and freedoms of others. This article shall not prevent the imposition of lawful restrictions on members of the armed forces and of the police in their exercise of this right. (3) Nothing in this article shall authorize States Parties to the International Labour Organisation Convention of 1948 concerning Freedom of Association and Protection of the Right to Organize to take legislative measures which would prejudice, or to apply the law in such a manner as to prejudice, the guarantees provided for in that Convention.
- Trade unions have specific protection under Article 22(1) of the ICCPR;¹³⁷ Article 22(3) emphasizes preexisting obligations under ILO Convention 87.
 - The need for multiple trade unions to be lawfully guaranteed has been emphasized by both the HRC and the CESCR,¹³⁸ and the absence of enabling legislation has been condemned.¹³⁹
 - Workers’ rights, including collective bargaining, protection against reprisals for exercising free association rights and freedom from unnecessary interference in trade union activities, have been reaffirmed by both the HRC¹⁴⁰ and CESCR¹⁴¹ on numerous occasions.

137 Article 22(1) of the ICCPR reads: Everyone shall have the right to freedom of association with others, including the right to form and join trade unions for the protection of his interests.

138 ICCPR. Brazil, 1996. (A/51/40 [vol. I]); ICES CR. Rwanda, 1989. (E/1989/22).

139 ICCPR. Georgia, 1997. (A/52/40 [vol. I]).

140 ICCPR. Costa Rica, 1999. (A/54/40 [vol. I]). “Freedom of association, including the right to collective bargaining, should be guaranteed to all individuals. Labour legislation should be reviewed and, where necessary, reformed to introduce measures of protection against reprisals for attempts to form associations and trade unions and to ensure that workers have access to speedy and effective remedies.” See also Dominican Republic, 2001. (A/56/40 [vol. I]); Argentina, 1995. (A/50/40 [vol. I]); Guatemala, 1996. (A/51/40 [vol. I]); Nigeria, 1996. (A/51/40 [vol. I]); Bolivia, 1997. (A/52/40 [vol. I]); Venezuela, 2001.

141 (A/56/40 [vol. I]). ICESCR. Jamaica, 1990. (E/1990/23).

- The HRC has found breaches of both Article 22 and 19 (free expression) for the unlawful detention of individuals because of their trade union activities.¹⁴²
- Trade union protection includes ensuring that foreign workers are not barred from holding official positions and that unions are not dissolved by the executive.¹⁴³
- Article 22(3) does not implicitly guarantee the right to strike.¹⁴⁴
- The denial to civil servants of the right to form associations and to bargain collectively has been condemned as a violation of Article 22 of the ICCPR.¹⁴⁵
- An absolute ban on strikes by public servants who are not exercising authority in the name of the state and are not engaged in “essential services”, as defined by the ILO, may violate Article 22 of the ICCPR.¹⁴⁶

► **Article 23(4) UDHR:** *Everyone has the right to form and to join trade unions for the protection of his interests.*

► **Article 8 ICESCR**

1. *The States Parties to the present Covenant undertake to ensure:*

(a) *The right of everyone to form trade unions and join the trade union of his choice, subject only to the rules of the organization concerned, for the promotion and protection of his economic and social interests. No restrictions may be placed on the exercise of this right other than those prescribed by law and which are necessary in a democratic society in the interests of national security or public order or for the protection of the rights and freedoms of others;*

(b) *The right of trade unions to establish national federations or confederations and the right of the latter to form or join international trade-union organizations;*

(c) *The right of trade unions to function freely subject to no limitations other than those prescribed by law and which are necessary in a democratic society in the interests of national security or public order or for the protection of the rights and freedoms of others;*

(d) *The right to strike, provided that it is exercised in conformity with the laws of the particular country.*

2. *This article shall not prevent the imposition of lawful restrictions on the exercise of these rights by members of the armed forces or of the police or of the administration of the State.*

3. *Nothing in this article shall authorize States Parties to the International Labour Organisation Convention of 1948 concerning Freedom of Association and Protection of the Right to Organize to take legislative measures which would prejudice, or apply the law in such a manner as would prejudice, the guarantees provided for in that Convention.*

142 *Burgos v. Uruguay.* (R.12/52); ICCPR. A/36/40. July 29, 1981; *Pietraoia v. Uruguay.* (R.10/44); ICCPR. A/36/40. March 27, 1981; *Weinberger v. Uruguay.* (R.7/28); ICCPR. A/36/40. October 29, 1980; *Sohn v. Republic of Korea.* (518/1992); ICCPR. (A/50/40 [vol. II]). July 19, 1995. (CCPR/C/54/D/518/

143 HRC. Concluding Observations of the Human Rights Committee: Senegal, 1997. (CCPR/C/79/Add.).

144 Majority view in *J. B. and Ors v. Canada.* (118/82). A sizeable minority of the committee dissented, however.

145 HRC. Concluding Observations: Lebanon, 1997. (A/52/40 [vol. II]); ICCPR. Chile, 1999. (A/54/40 [vol. II]).

146 ICCPR. Germany, 1997. (A/52/40 [vol. II]).

- In contrast to Article 22(3) ICCPR, Article 8(1)(d) ICESCR contains an explicit guarantee of the right to strike which the CESCR has stated could be self-executing.¹⁴⁷
- “Consultation and co-operation are no substitute for the right to strike” under Article 8(1) of the ICESCR.¹⁴⁸
- The CESCR has condemned the refusal of some employers to recognize or deal with new, “alternative” unions and the fact that some employers take adverse action, including dismissal, against union activists.¹⁴⁹
- The apparent lack of measures to enable workers’ and employers’ organizations to participate in discussions about the determination of minimum wages for public sector employees has been criticized by the CESCR¹⁵⁰, as has been the failure to enact legislative measures to regulate the access of employers’ and workers’ organizations to the National Labour Council and other relevant organs.¹⁵¹

► **ILO Convention 87 on the Freedom of Association and Protection of the Right to Organise**¹⁵²

Article 2: *Workers and employers, without distinction whatsoever, shall have the right to establish and, subject only to the rules of the organisation concerned, to join organisations of their own choosing without previous authorisation.*

Article 3: *(1) Workers’ and employers’ organisations shall have the right to draw up their constitutions and rules, to elect their representatives in full freedom, to organise their administration and activities and to formulate their programmes. (2) The public authorities shall refrain from any interference which would restrict this right or impede the lawful exercise thereof.*

Article 4: *Workers’ and employers’ organisations shall not be liable to be dissolved or suspended by administrative authority.*

Article 5: *Workers’ and employers’ organisations shall have the right to establish and join federations and confederations and any such organisation, federation or confederation shall have the right to affiliate with international organisations of workers and employers.*

► **ILO Convention 98 on Right to Organize and Collective Bargaining**¹⁵³

Article 1: *(1) Workers shall enjoy adequate protection against acts of anti-union discrimination in respect of their employment. (2) Such protection shall apply*

147 ICES CR. Luxembourg, 1990. (E/1991/23). It is questioned whether the covenant, virtually alone among applicable international human rights treaties, is considered a non-self-executing in its totality. It was observed that, by contrast, the covenant contained a number of provisions that the great majority of observers would consider to be self-executing. These included, for example, provisions dealing with nondiscrimination, the right to strike, and the right to free primary education.

148 ICESCR. Rwanda, 1989. (E/1989/22). See also Peru, 1997. (E/1998/22). Convention expresses concern about the ineffectiveness of labor legislation to protect the rights of trade unions, including the right to strike.

149 ICESCR. Russian Federation, 1997. (E/1998/22).

150 ICESCR. Uruguay, 1994. (E/1995/22).

151 ICESCR. Belgium, 1994. (E/1995/22).

152 Table of ratifications at <http://www.ilo.org/ilolex/cgi-lex/ratifce.pl?C087>

153 Table of ratifications at <http://www.ilo.org/ilolex/cgi-lex/ratifce.pl?C098>

more particularly in respect of acts calculated to: (a) Make the employment of a worker subject to the condition that he shall not join a union or shall relinquish trade union membership; (b) Cause the dismissal of or otherwise prejudice a worker by reason of union membership or because of participation in union activities outside working hours or, with the consent of the employer, within working hours.

Article 2 (1): Workers' and employers' organisations shall enjoy adequate protection against any acts of interference by each other or each other's agents or members in their establishment, functioning or administration.

Article 6: This Convention does not deal with the position of public servants engaged in the administration of the State, nor shall it be construed as prejudicing their rights or status in any way.

- Although there is no explicit recognition of the right to strike in any ILO convention or recommendation, the ILO's Freedom of Association Committee frequently states that the right to strike is a fundamental right of workers and of their organizations¹⁵⁴ and defines the limits within which it may be exercised. In addition, in at least two resolutions of the International Labour Conference, which provide guidelines for ILO policy, have emphasized recognition of the right to strike in member states in at least two resolutions.¹⁵⁵
- Persons employed in public hospitals should enjoy the right to collective bargaining as guaranteed by ILO Convention No. 98.¹⁵⁶
- Recognition of the principle of freedom of association in the case of public servants does not necessarily imply the right to strike.¹⁵⁷
- The ILO Freedom of Association Committee has acknowledged that the right to strike can be restricted or even prohibited in the public service or in certain essential services when striking could cause serious hardship to the national community, provided that the limitations are accompanied by certain compensatory guarantees.¹⁵⁸
- The ILO Committee has expressly stated that the hospital sector is considered an essential service for the purposes of prohibiting work stoppages.¹⁵⁹ More

154 ILO. Digest of Decisions and Principles of the Freedom of Association Committee, 1952. Fourth (revised) edition. During its second meeting, in 1952, the Committee on Freedom of Association declared strike action to be a right and laid down the basic principle underlying this right, from which all others to some extent derive and which recognizes the right to strike to be one of the principal means by which workers and their associations may legitimately promote and defend their economic and social interests.

155 ILO. Resolution Concerning the Abolition of Anti-Trade Union Legislation in the States Members of the International Labour Organisation, 1957. Resolution called for the adoption of "laws ... ensuring the effective and unrestricted exercise of trade union rights, including the right to strike, by the workers. See also Resolution Concerning Trade Union Rights and Their Relation to Civil Liberties, 1970. Resolution invited the governing body to instruct the director-general to take action in a number of ways "with a view to considering further action to ensure full and universal respect for trade union rights in their broadest sense," with particular attention to be paid, inter alia, to the "right to strike."

156 ILO. 306th Report of the Freedom of Association Committee. Case No. 1882.

157 ILO. Digest, 2005; Digest, 1996; and 304th Report of the Freedom of Association Committee. Case No. 1719.

158 ILO. Digest of Decisions and Principles of the Freedom of Association Committee, 2005; Digest, 1996; 300th Report of the Freedom of Association Committee. Case No. 1791; 302nd Report. Case No. 1849; and 318th Report. Case No. 2020.

159 ILO. Digest, 2005; Digest, 1996; 300th Report of the Freedom of Association Committee. Case No. 1818; 306th Report. Case No. 1882; 308th Report. Case No. 1897; 324th Report. Case No. 2060 and Case No. 2077; 329th Report. Case No. 2174; 330th Report. Case No. 2166; and 338th Report. Case No. 2399.

broadly, to determine situations in which a strike could be prohibited in an essential service, there must be a clear and imminent threat to the life, personal safety or health of the whole or part of the population.¹⁶⁰ Within those services considered essential, however, certain categories of employees, such as hospital laborers and gardeners, should not be deprived of the right to strike.

160 ILO. Digest, 2005; Digest, 1996; 320th Report. Case No. 1989; 324th Report. Case No. 2060; 329th Report. Case No. 2195; 332nd Report. Case No. 2252; 336th Report. Case No. 2383; and 338th Report. Case No. 2326 and Case No. 2329.

RIGHT TO DUE PROCESS AND RELATED RIGHTS

This section outlines the relevant due process standards that health care providers enjoy when commencing or responding to civil proceedings, including disciplinary matters. It does not deal with the rights of the accused in criminal proceedings.¹⁶¹ As in previous sections, material that elaborates on the interpretation of standards in relation to health sector personnel has been highlighted. Relevant standards from the 1998 UN Human Rights Defenders Declaration underscore the fact that health care providers, in addition to enjoying the same core rights as patients, are defenders of rights in their daily work.

The first part of this section examines the right to a fair hearing. The second part focuses on the related right to an effective remedy. The interpretation of what is meant by a “suit at law” under Article 14(1) of the ICCPR continues to evolve, although regulation of the activities of a professional body and scrutiny of such regulations by the courts may fall within its scope.

This section also details those standards that protect the privacy rights of health care providers - in and outside the workplace - and their honor and reputations. In addition, there is a brief discussion of standards that address the right to free expression and the right to impart information. These liberties are particularly important as they might offer protection to whistleblowers who seek to place certain information in the public domain. This protection is important because public sector employees are often reluctant to disseminate information due to fear of adverse consequences.

Right to a Fair Hearing

EXAMPLES OF POTENTIAL VIOLATIONS

- A doctor facing disciplinary proceedings is unable to obtain access to all of the evidence presented against him in advance of the hearing
- A nurse facing a medical negligence suit has still not been given a hearing date five years after commencement of the proceedings

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 14(1) ICCPR

All persons shall be equal before the courts and tribunals. In the determination of any criminal charge against him, or of his rights and obligations in a suit at law, everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law.

¹⁶¹ The United Nations Human Rights Treaties. Rights of the accused in criminal proceedings. <http://www.bayefsky.com/bytheme.php/id/1041>.

- HRC General Comment 32:
- The concept of “suit at law” under Article 14(1) of the ICCPR is based on the nature of the right in question rather than on the status of one of the parties (whether state or nonstate). The particular forum that the legal systems employ to adjudicate individual claims does not determine the nature of the right (an especially important condition in the case of common law systems).¹⁶²
- The regulation of the activities of a professional body and the scrutiny of such regulations by the courts may raise issues under Article 14.¹⁶³
- Purely administrative proceedings will fall outside the scope as not amounting to a determination of civil rights and obligations.¹⁶⁴
- The notion of a “tribunal” in Article 14(1) refers to a body- regardless of denomination- that is a) established by law; b) independent of the executive and legislative branches of government; and c) in specific cases enjoys judicial independence in deciding legal matters in proceedings that are judicial in nature.¹⁶⁵
- Determination of public law rights falls within the scope of Article 14(1) if, within the relevant municipal legal system, it is conducted by a court of law or if the administrative determination is subject to judicial review.
- Article 14 does not, however, appear to guarantee a right of judicial review of public law determinations by administrators or administrative tribunals and does not guarantee that any such review entails evaluation of the merits.
- The right to a fair hearing in a civil suit encompasses:
 - » Equality before the courts;¹⁶⁶ This distinction is narrower than the right of equality before the law under Article 26 of the ICCPR as the latter applies to all organs involved in the administration of justice and not just to judicial power.¹⁶⁷
 - » Access to courts;¹⁶⁸ Access includes the provision of legal aid.¹⁶⁹ Article 14 ICCPR requires that states provide for particular causes of action “in certain circumstances” and for competent courts to determine those causes of action, although it is not clear what those circumstances are.¹⁷⁰
- Article 14, in guaranteeing procedural equality, cannot be interpreted as guaranteeing equality of results or absences of error on the part of the competent tribunal.¹⁷¹

162 HRC. General Comment 32 of the Human Rights Committee; *Y. L. v. Canada*. (112/81). Applying this interpretation, claim for disability pension did amount to a “suit at law.” See also *Casanovas v. France*. (441/90). Covers procedure concerning employment dismissal; *Jansen-Gielsen v. The Netherlands*. (846/99). Tribunal proceedings to determine the psychiatric ability of people to perform their jobs amounted to “suit at law.”

163 *J.L. v Australia*. (491/92).

164 *Kolanowski v. Poland*. (837/98). Challenge to the fact that denied promotion of police officer was not covered but dismissals from public service are (*Casanovas v. France* [441/90]). See also *Kazantzis v. Cyprus*. (972/01). Procedure for appointing public servants (in this case, judicial appointments) did not fall within scope of Article 14.

165 HRC. General Comment 32 of the Human Rights Committee, paras. 18 and 19.

166 *Ibid.*, paras. 3 and 7.

167 *Ibid.*, para. 65.

168 *Ibid.*, paras. 8, 9, and 12.

169 *Bahamonde v. Equatorial Guinea*. (468/91); *Avellanal v. Peru*. (202/86); and HRC GC 32, para. 10.

170 *Mahuika v. New Zealand*. (547/93).

171 HRC. GC 32, para. 26; *B. D. B v. The Netherlands*. (273/88).

- Elements of a fair hearing in a civil suit encompass equality of arms,¹⁷² respect for the principle of adversarial proceedings, preclusion of ex officio worsening of an earlier verdict, and an expeditious procedure.¹⁷³
 - Public hearings in civil suits have been explicitly recognized by the HRC subject only to limited public interest exceptions.¹⁷⁴
 - Placing the burden of proof on defendants in civil cases is permissible.¹⁷⁵
 - Examples of breaches of Article 14 include: refusing to allow a complainant to attend the proceedings and to have the opportunity to brief legal representatives properly,¹⁷⁶ failing to inform the author of his appeal date until after it has taken place,¹⁷⁷ refusal of an administrative tribunal to admit crucial evidence¹⁷⁸ and failure to permit one litigant to submit comments on the other side's submissions.¹⁷⁹
- **Article 26 ICCPR:** *All persons are equal before the law and are entitled without any discrimination to the equal protection of the law.*
- **Article 5(a) CERD:** *In compliance with the fundamental obligations laid down in article 2 of this Convention, States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of the following rights: The right to equal treatment before the tribunals and all other organs administering justice.*
- **Article 15(1) CEDAW:** *States Parties shall accord to women equality with men before the law.*

Right to an Effective Remedy¹⁸⁰

EXAMPLES OF POTENTIAL VIOLATIONS

- No damages are awarded to a doctor after his reputation has been damaged following the appearance of unsubstantiated and false accusations of medical negligence in the media
- A nurse is unable to appeal an employment tribunal decision to a court

172 HRC. GC 32, para. 13. See concurring individual opinion of Prafullachandra Natwarlal Bhagwati in *Pezoldova v. The Czech Republic*. (757/1997). "As a prerequisite to have a fair and meaningful hearing of a claim, a person should be afforded full and equal access to public sources of information. ..."

173 *Moraël v. France*. (207/86). See also *Fei v. Colombia*. (514/92); HRC. GC 32, para. 27 on delay.

174 HRC. GC 32, paras. 28 and 29. See also *van Meurs v. The Netherlands*. (215/1986).

175 HRC. GC 32, para. 9.4.

176 *Wolf v. Panama*. (289/88).

177 *Thomas v. Jamaica*. (272/88).

178 *Jansen-Gielen v. Netherlands*. (846/99). Proceedings to determine psychiatric ability to perform job.

179 *Aarela & Anor v. Finland*. (779/97).

180 UN. Human Rights Defenders Declaration. Article 9.

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 2(3) ICCPR

Each State Party to the present Covenant undertakes:

- (a) *To ensure that any person whose rights or freedoms as herein recognized are violated shall have an effective remedy, notwithstanding that the violation has been committed by persons acting in an official capacity;*
- (b) *To ensure that any person claiming such a remedy shall have his right thereto determined by competent judicial, administrative or legislative authorities, or by any other competent authority provided for by the legal system of the State, and to develop the possibilities of judicial remedy;*
- (c) *To ensure that the competent authorities shall enforce such remedies when granted.*

- There is a clear link between the right to an effective remedy and the right to a fair hearing and/or due process and in general; this provision needs to be respected whenever any guarantee of Article 14 has been violated.¹⁸¹
- Remedies must be accessible and effective. Although a remedy generally entails appropriate compensation, reparation can, where appropriate, involve restitution, rehabilitation, and measures of satisfaction, such as public apologies, public memorials, guarantees of nonrepetition and changes in relevant laws and practices, and actions to bring to justice the perpetrators of human rights violations.¹⁸²
- States are required, as part of the obligation under Article 2(3)(a) of the ICCPR, to ensure determination of the right to a remedy by a competent judicial, administrative, or legislative authority,¹⁸³ a guarantee that would be void if it were not available in cases in which a violation of the ICCPR had not been established. The State is not obliged to make such procedures available, however, regardless of how unmeritorious the claim might be.¹⁸⁴

► Article 2(1) ICESCR

- Each state party to the present covenant undertakes to take steps, individually and through international assistance and cooperation, especially in economic and technical matters, to the maximum extent allowed by its available resources, with a view to achieving progressively the full realization of the rights recognized in the present covenant by all appropriate means, including, particularly, the adoption of legislative measures.
- Administrative remedies will, in many cases, be adequate. Any such remedies should be accessible, affordable, timely and effective. The ultimate right of judicial appeal from administrative procedures is also often appropriate, how-

181 HRC. General Comment 32 of the Human Rights Committee, para. 58.

182 HRC. General Comment 31 of the Human Rights Committee, paras. 15 and 16.

183 *Ibid.*, para. 15.

184 *Kazantzis v Cyprus*. (972/01).

ever. There are some obligations, such as (but by no means limited to) those concerning nondiscrimination, for which the provision of some form of judicial remedy is indispensable.¹⁸⁵

► **Article 9 Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms (Human Rights Defenders Declaration) 1998**¹⁸⁶

- All human rights defenders have the right to an effective remedy and to protection in the event of the violation of their rights. This right includes the right to complain about the policies and actions of government bodies and officials. In turn the state should conduct a prompt and impartial investigation or ensure that an inquiry takes place whenever there is reasonable ground to believe that a violation has occurred in any territory under its jurisdiction.

Right to Protection of Privacy and Reputation

EXAMPLES OF POTENTIAL VIOLATIONS

- The phone of a hospital chief executive is bugged without any prior lawful authorisation
- A doctor involved in a civil suit against a hospital for unfair dismissal finds out that his correspondence has been routinely intercepted and read without his knowledge

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 17 ICCPR:** *(1) No one shall be subjected to arbitrary or unlawful interference with his privacy, family, or correspondence, nor to unlawful attacks on his honour and reputation. (2) Everyone has the right to the protection of the law against such interference or attacks.*

► **HRC General Comment 16 on the Right to Privacy**

- The term “home” is to be understood to indicate the place where a person resides or carries out his usual occupation.¹⁸⁷
- Even with regard to interferences that conform to the covenant, relevant legislation must specify in detail the precise circumstances in which such interferences may be permitted. Compliance with Article 17 requires that the integrity and confidentiality of correspondence should be guaranteed de jure and de

185 ICESCR, General Comment 9. (E/C.12/1998/24, CES CR). December 3, 1998.

186 UN General Assembly Resolution 53/144. December 9, 1998.

187 HRC. General Comment 16 of the Human Rights Committee. August 4, 1988.

facto. Surveillance, whether electronic or other; interceptions of telephonic, telegraphic and other forms of communication; wiretapping; and recording of conversations should be prohibited. Searches of a person's home should be restricted to a search for necessary evidence and should not be allowed to amount to harassment.¹⁸⁸

- The gathering and holding of personal information on computers, data banks, and other devices, whether by public authorities or private individuals or bodies, must be regulated by law.¹⁸⁹
- The state is obliged to provide protection under the law against any unauthorized interferences with correspondence¹⁹⁰ and to ensure strict and independent (ideally judicial) regulation of any such practices, including wiretapping.¹⁹¹
- Searches – both of a home (and workplace) and of a person - should also be subject to appropriate safeguards.¹⁹²
- The protection of honor and reputation under Article 17 is probably limited to unlawful rather than arbitrary attacks - in other words, attacks that fail to comply with an established legal procedure.¹⁹³ Given the HRC's interpretation of "lawful" in the context of another ICCPR provision (Article 9[4]), the term may extend beyond domestic law.¹⁹⁴
- Professional duties of confidence, such as those undertaken by the medical profession, are an important aspect of the right to privacy and any limitations on professional privilege must be specified in detail.¹⁹⁵

► **Article 19(3) ICCPR:** *The exercise of the rights provided for in paragraph 2 of this article carries with it special duties and responsibilities. It may therefore be subject to certain restrictions, but these shall only be such as are provided by law and are necessary: (a) For respect of the rights or reputations of others; (b) For the protection of national security or of public order (ordre public), or of public health or morals.*

Right to Free Expression and Information ¹⁹⁶

EXAMPLES OF POTENTIAL VIOLATIONS

- A senior health service manager is dismissed after revealing that a hospital has been purchasing unlicensed drugs
- State authorities intervene to prevent employees from learning that their hospital contains dangerously high levels of radiation

188 Ibid. para. 8.

189 Ibid. para. 10.

190 Ibid., para. 8; HRC. Concluding Observations of the Human Rights Committee: Zimbabwe, 1998. (CCPR/C/79/Add.89).

191 HRC. Concluding Observations: Poland, 1999. (CCPR/C/79/Add.10). See also Concluding Observations: Lesotho, 1999. (CCPR/C/79/Add. 106).

192 HRC. General Comment 16 of the Human Rights Committee, para. 8.

193 I. P. v. Finland. (450/91); Joseph, Schultz, and Castan. The ICCPR, 494.

194 Joseph, Schultz, and Castan. The ICCPR, 494.

195 HRC. Concluding Observations of the Human Rights Committee: Portugal, 2003. (CCPR/CO/78/PRT).

196 See also Human Rights Defenders Declaration 1998, Article 6.

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 19(2) ICCPR:** *Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice.*

- The right to free expression under Article 19 of the ICCPR includes the freedom to impart information, and any restrictions that do not accord with acceptable limitations contained in Article 19(3), such as public order or public health, could result in a breach.¹⁹⁷
- Therefore, in theory, whistleblowers within the medical profession could be protected from unlawful prosecution provided that the information they are seeking to put into the public domain cannot legitimately be restricted.
- Permissible limitations on public health grounds under Article 19 are unclear, although it has been suggested that prohibiting misinformation on health-threatening activities could be justified.¹⁹⁸
- Freedom of expression (including that of the media) can be lawfully restricted to protect the rights and reputation of others, through, for example, the use of reasonable civil defamation laws.¹⁹⁹

► **Article 5(d)(viii) CERD:** *In compliance with the fundamental obligations laid down in article 2 of this Convention, States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of the following rights: The right to freedom of opinion and expression. ...*

► **Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms (Human Rights Defenders Declaration) 1998**²⁰⁰

Article 6: Everyone has the right, individually and in association with others:

- (a) *To know, seek, obtain, receive and hold information about all human rights and fundamental freedoms, including having access to information as to how those rights and freedoms are given effect in domestic legislative, judicial or administrative systems;*
- (b) *As provided for in human rights and other applicable international instruments, freely to publish, impart or disseminate to others views, information and knowledge on all human rights and fundamental freedoms;*
- (c) *To study, discuss, form and hold opinions on the observance, both in law and in practice, of all human rights and fundamental freedoms and, through these and other appropriate means, to draw public attention to those matters.*

197 *Laptsevich v. Belarus*. (780/97).

198 Joseph, Schultz, and Castan. *The ICCPR*, 525.

199 *Ibid.*, 541.

200 UN General Assembly Resolution 53/144. December 9, 1998.

3

Regional framework for Human Rights in Patient Care

3.1 Introduction

This chapter elaborates on the main standards that safeguard human rights inpatient care within Europe (as defined geographically by the Council of Europe [COE]) and examines how they have been interpreted by supranational bodies, most notably the European Court of Human Rights (ECtHR) and the European Committee of Social Rights (ECSR). As in the preceding chapter on the international framework, this chapter is divided into two parts that describe key regional sources governing human rights in patient care and also examine patients' and providers' rights. Each part includes subsections that discuss the standards and relevant interpretations connected to a particular right (for example, the right to liberty and security of the person) and also provide some examples of potential violations. The standards addressed include binding treaties, such as the [European] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights [ECHR]), the European Social Charter (ESC), and other standards developed by the COE and civil society, such as the highly significant European Charter of Patients' Rights.

3.2 Key sources

COUNCIL OF EUROPE

► **Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997 (European Convention on Human Rights and Biomedicine)¹**

This convention sets out certain basic patient rights principles based on the premise that there is a “need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being.”² It is binding on ratifying states.

Key provisions include:

- Equitable access to health care (Article 3)
- Protection of consent (Chapter II, Articles 5-9)
- Private life and right to information (Chapter III, Article 10)

► **European Convention on Human Rights (ECHR)³**

The ECHR is the leading regional human rights instrument and it has been ratified by all Council of Europe member states. It is enforced by the ECtHR, which hands down binding decisions that frequently involve monetary compensation for victims.

Relevant provisions include:

- Article 2 (right to life)
- Article 3 (protection against torture and cruel, inhuman or degrading treatment)
- Article 5 (right to liberty and security of person)
- Article 6 (access to a fair hearing)
- Article 8 (right to privacy)
- Article 13 (right to effective remedies)
- Article 14 (prohibition of discrimination)

► **European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment**

Article 1 establishes the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, which monitors compliance with the treaty through regular monitoring visits to places of detention. The rest of the treaty sets out the membership and working methods of the committee.

1 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. <http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm>.

2 Subsequent additional protocols have been produced on prohibition of cloning (Treaty No. 168), transplantation of organs and tissues (Treaty No. 186), and biomedical research (Treaty No. 195).

3 European Convention on Human Rights. <http://www.hri.org/docs/ECHR50.html>.

► **European Social Charter 1961 and 1996 (ESC)⁴**

The ESC is the leading regional economic and social rights instrument. It is monitored by the ECSR through a system of periodic state reporting and collective complaints. Originally drafted in 1961, the ESC was significantly revised in 1996, although some states have not ratified the later version and have the option as to which provisions they accept.

Given the generality of many of the clauses and given the progressive/liberal approach of the ECSR, patients' rights can be advocated under a number of provisions even in the absence of acceptance of the specific health care guarantees.

Relevant provisions include:

- Article 11 (right to protection of health)
- Article 13 (right to social and medical assistance)
- Article 14 (right to benefit from social welfare services)
- Article 15 (right of persons with disabilities to independence, social integration and participation in the life of the community)
- Article 16 (right of the family to social, legal and economic protection)
- Article 17 (right of children and young persons to appropriate social, legal and economic protection)
- Article 19 (right of migrant workers and their families to protection and assistance)
- Article 23 (right of elderly persons to social protection)

The ECSR has stated that rights related to health in the ESC are inextricably linked to their counterpart guarantees in the ECHR because *“human dignity is the fundamental value and indeed the core of positive European human rights law – and health care is a prerequisite for the preservation of human dignity.”*⁵

► **Framework Convention for the Protection of National Minorities 1995⁶**

This binding treaty guarantees equal treatment for all ethnic and other minorities.

Relevant provisions include:

- Article 4(2) (adoption of adequate measures to promote, in all areas of economic, social, political and cultural life, full and effective equality for persons belonging to a national minority, taking due account of the specific conditions of the persons belonging to national minorities)

4 Council of Europe (COE). European Social Charter. http://www.coe.int/T/E/Human_Rights/Esc/.

5 International Federation of Human Rights Leagues (FIDH) v. France. (14/2003).

6 Framework Convention for the Protection of National Minorities. <http://conventions.coe.int/treaty/en/Treaties/Html/157.htm>.

► **Recommendation No. R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decisionmaking process affecting health care** ⁷

Although not binding, this recommendation possesses strong political and moral authority. It focuses on the need to ensure effective participation for all in increasingly diverse and multicultural societies where groups such as ethnic minorities are frequently marginalized.

EUROPEAN UNION

► **EU Charter of Fundamental Rights** ⁸

Signed in Nice, France on November 7, 2000, this charter sets out in a single text, for the first time in the history of the European Union (EU), the whole range of civil, political, economic, and social rights belonging to European citizens and all persons resident in the EU. This charter was incorporated as part two of the treaty establishing a constitution for Europe on June 18, 2004. After the rejection of the proposed EU constitution, an adapted version of this charter was retained and proclaimed in Strasbourg on December 12, 2007, before the signing of the Treaty of Lisbon, which makes it legally binding.

The charter's full implications for EU member states remain unclear, but it will be an important reference point even for countries outside of the EU, especially with respect to those in the process of accession.

Key provision:

Article 35 (right to health protection as the “*right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices*”, specifying that the EU must guarantee “a high level of protection of human health”)

Other relevant provisions include:

- Article 1 (the inviolability of human dignity)
- Article 2 (the right to life)
- Article 3 (the right to the integrity of the person)
- Article 6 (the right to security)
- Article 8 (the right to the protection of personal data)
- Article 21 (the right to nondiscrimination)
- Article 24 (the rights of the child)
- Article 25 (the rights of the elderly)
- Article 34 (the right to social security and social assistance)
- Article 37 (the right to environmental protection)
- Article 38 (the right to consumer protection)

⁷ COE. Recommendation Rec No. R (2000) 5. <https://wcd.coe.int/ViewDoc.jsp?id=340437&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75>.

⁸ Charter of Fundamental Rights of the European Union. http://www.europarl.europa.eu/charter/default_en.htm.

► Proposed EU Directive on Patients' Rights In Cross-Border Health Care ⁹

After repeated delays, the European Commission released this proposed directive, together with a communication on improving cooperation between member states in this area, on July 2, 2008. The aim of the directive is to create legal certainty on the issue, thereby avoiding potential court cases, as the EU treaty grants individuals the right to seek health care in other member states, a principle confirmed by several clear rulings by the European Court of Justice.

Under the treaty's major provisions:

- **Patients** have the right to seek health care abroad and to be reimbursed the same amount that they would have received if they had sought care in their home country. The directive will provide clarity as to how these rights can be exercised, including the limits that member states can place on cross-border health care and the level of financial coverage provided for it.
- **Member states** are responsible for health care provided on their territory. Patients should be confident that the quality and safety standards of the treatment they will receive in another member state are regularly monitored and based on sound medical practices.

In its press release, the commission stated that the directive “provides a solid basis to unlock the huge potential for European cooperation to help improve the efficiency and effectiveness of all EU health systems.” ¹⁰

The European Public Health Alliance (EPHA) has expressed some concerns about the draft directive, including in relation to patients' rights and whether it can really resolve the existing significant differences concerning access to and quality of health care between member states. The EPHA goes on to warn that the directive may merely lead to financial savings for the tiny minority who can already afford “health care tourism” as opposed to equal access for all.

NONTREATY INSTRUMENTS

► The European Charter of Patients' Rights ¹¹

“As European citizens, we do not accept that rights can be affirmed in theory, but then denied in practice, because of financial limits. Financial constraints, however justified, cannot legitimize denying or compromising patients' rights. We do

9 The draft directive, along with other key documents, communication from the commission, and press releases are available at http://ec.europa.eu/health/ph_overview/co_operation/healthcare/cross-border_healthcare_en.htm.

10 European Commission. “Commission Adopts Proposal for Directive on Patients' Rights in Cross-Border Healthcare.” July 2, 2008. (IP/08/1080).

11 European Charter of Patients' Rights. http://www.activecitizenship.net/health/european_charter.pdf.

not accept that these rights can be established by law, but then left not respected, asserted in electoral programmes, but then forgotten after the arrival of a new government.”¹²

Drawn up in 2002 by Active Citizenship Network, a European network of civic, consumer, and patient organizations, this charter provides a clear, comprehensive statement of patients’ rights. This statement was part of a grassroots movement across Europe that encouraged patients to play a more active role in shaping the delivery of health services and was also an attempt to convert regional documents concerning the right to health care into specific provisions.¹³

The charter identifies 14 concrete patients’ rights that are currently at risk: the right to preventive measures, access, information, consent, free choice, privacy and confidentiality, respect of patients’ time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain, personalized treatment, the filing of complaints and compensation.

Although the charter is not legally binding, a strong network of patients’ rights groups across Europe has successfully lobbied their national governments for recognition and adoption of the rights it addresses.¹⁴ The charter has also been used as a reference point to monitor and evaluate health care systems across Europe.

► **WHO Declaration on the Promotion of Patients’ Rights in Europe: European Consultation on the Rights of Patients, Amsterdam**¹⁵

“In its scope and focus, this document seeks to reflect and express people’s aspirations not only for improvements in their health care but also for fuller recognition of their rights as patients. In so doing, it keeps in mind the perspectives of health care providers as well as of patients. This implies the complementary nature of rights and responsibilities: patients have responsibilities both to themselves for their own self-care and to health care providers, and health care providers enjoy the same protection of their human rights as all other people. There is a basic assumption in the text that the articulation of patients’ rights will in turn make people more conscious of their responsibilities when seeking and receiving or providing health care, and that this will ensure that patient/provider relationships are marked by mutual support and respect.”¹⁶

This nonbinding declaration was issued by the WHO Regional Office for Europe in 1994 and has become a significant reference point. Taking as its conceptual

¹² Ibid., preamble.

¹³ The pharmaceutical company Merck & Co., Inc., also provided funding for this movement.

¹⁴ One of the activities of new EU member states during the process of preparation for accession in the EU was adjustment of health care legislation toward European legislation and standards. Many countries, such as Bulgaria, adopted new health law, whose structure and contents are strictly in line with the European Charter of Patients’ Rights.

¹⁵ World Health Organization (WHO). Declaration on the Promotion of Patients’ Rights in Europe. www.who.int/genomics/public/eu_declaration1994.pdf.

¹⁶ Ibid.

foundation the International Bill of Human Rights, the ECHR, and the ESC, the declaration focuses on rights to information, consent, confidentiality and privacy and care and treatment.

► **The WHO Ljubljana Charter on Reforming Health Care 1996**¹⁷

This charter contains a number of fundamental principles to ensure that “health care should first and foremost lead to better health and quality of life for people.”¹⁸ Specifically, it recommends that health care systems be people-centric and calls for patient participation in shaping improvements.

3.3 Patients’ rights

Just as in the preceding chapter on the international framework, this section is structured around nine critical patient rights: the rights to liberty and security of the person; privacy; information; bodily integrity; life; highest attainable standard of health; freedom from torture, cruel, inhuman, and degrading treatment; participation in public policy; and nondiscrimination and equality for patients.

The lack of an explicit provision guaranteeing the right to health in the ECHR has not prevented the ECtHR, the ECHR’s supervisory and enforcement body, from addressing some patients’ rights issues. Article 5, which guarantees the right to liberty and security of person, has been used by the ECtHR to protect the rights of those detained on mental health grounds. Article 3 has outlawed the use of torture and/or cruel, inhuman or degrading treatment against detainees including those detained on mental health grounds. Article 8, safeguarding the right to privacy, has been successfully argued in relation to unlawful disclosure of personal medical data. Beyond these examples, however, the ECtHR has been reluctant to indirectly recognize a positive right to health, although the door has been left open in relation to the right to life under Article 2 in cases in which preexisting obligations have not been fulfilled. This reluctance is in line with the ECtHR’s general desire not to make decisions that could have a significant economic and/or social impact on policy or resources.

On the other hand, in Article 11 of the ESC, the ESCR has specifically defined the right to protection of health, together with a number of related guarantees, such as the right to social and medical assistance under Article 13. Because the ESC cannot be used by individual victims, however, all of the ECSR’s analysis relates to country reports or to the collective complaints mechanism and, therefore, tends to be general in nature (stating, for example, that health care systems must be accessible to everyone or that there must be adequate staff and facilities). To date, under the collective complaints mechanism, the ECSR has only considered one right to health care

¹⁷ Ljubljana Charter on Reforming Health Care. <http://www.bmj.com/cgi/content/full/312/7047/1664>.

¹⁸ Ibid.

case, concerning denial of medical assistance to poor illegal immigrants. Therefore, there is great potential for development of the ECSR's case law further in this area.

Other significant sets of standards discussed in this chapter, such as the European Charter of Patients' Rights, also contain a number of specific relevant guarantees, but these standards lack any form of supervisory body. They, therefore, cannot be directly enforced by victims to gain redress. Nonetheless, that does not mean that they cannot be referred to when arguing claims under binding treaties, such as the ECHR and the ESC, in order to better interpret the treaties' own provisions. In turn, increased references to nonbinding documents such as the European Charter of Patients' Rights will help them gain further credibility and strength so that, over time, some of their provisions might attain customary international law status.¹⁹

EXAMPLES OF POTENTIAL VIOLATIONS

- A person is detained indefinitely on mental health grounds without efforts to seek any medical opinion
- Residents of an institution are not informed about their right to apply to a court or tribunal to challenge their involuntary admission
- A female drug user is detained in hospital after giving birth and is denied custody of her child

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 5(1)(e) ECHR

Everyone has the right to liberty and security of person. No one shall be deprived of his liberty save in the following cases and in accordance with a procedure prescribed by law... the lawful detention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drug addicts, or vagrants. ...

- The ECtHR has not defined the phrase “unsound mind” on the basis that its meaning is continually evolving.²⁰ It is established, however, that there must be objective expert medical evidence that the person at the relevant time is of unsound mind (other than in emergencies).²¹ Therefore, detention pursuant to the order of a prosecutor, without obtaining a medical opinion, will breach Article 5(1)(e), even if the purpose of the detention is to obtain such an opinion.²²

19 Article 38(1)(b) of the Statute of the International Court of Justice refers to “international custom” as a source of international law, specifically emphasizing the two requirements of state practice and acceptance of the practice as obligatory.

20 Litwa v. Poland. (33 EHRR 53). Providing definition of alcoholism for purposes of Article 5(1)(e).

21 Herz v. Germany. (44672/98); Rakevich v. Russia. (No 58973/00).

22 Varbanov v Bulgaria. (31365/96).

- The ECtHR has established a number of procedural guarantees in relation to the application of Article 5(1)(e):
 - ▶ Committing somebody to confinement must only occur according to a properly prescribed legal procedure and cannot be arbitrary. In relation to the condition of "unsound mind", this guarantee means that the person must have a recognized mental illness and require confinement for the purposes of treatment.²³
 - ▶ Any commitment must be subject to a speedy periodic legal review that incorporates the essential elements of due process.²⁴
 - ▶ Where such guarantees have not been adhered to, the ECtHR has been prepared to award damages for breaches of a person's liberty under Article 5(1)(e).²⁵
- Detention under Article 5(1)(e) can be justified both in the interests of the individual and on public safety grounds.²⁶ A relevant factor in determining the legality of detention is whether the detention occurs in a hospital, clinic, or other appropriate authorized institution.

The fact that detention may be in a suitable institution has no bearing on the appropriateness of the patient's treatment or conditions under which he or she is detained.²⁷ A violation of Article 5(1)(e) was found where a person was detained as a person infected with HIV - after having transmitted the virus to another man as a result of sexual activity - on the grounds that a fair balance had not been struck between the need to ensure that the virus did not spread and the individual's right to liberty.²⁸

Right to Privacy

EXAMPLES OF POTENTIAL VIOLATIONS

- A doctor discloses a patient's history of drug use or addiction without their consent
- Government requires disclosure of HIV status on certain forms

23 *Winterwerp v. The Netherlands*. (6301/73). See also *HL v. UK* (45508/99). System of detaining "informal patients" in psychiatric institutions did not incorporate sufficient procedural safeguards in order to prevent arbitrary deprivations of liberty.

24 *X v. United Kingdom*, 46 Eur. Ct. H.R. (ser. A) (1981)

25 *Gajcsi v. Hungary*. (34503/03). Patient unlawfully detained for three years in a Hungarian psychiatric hospital, where the commitment procedure was superficial and insufficient to show dangerous conduct.

26 *Litwa v. Poland*. (33 EHRR 53). See also *Hutchinson Reid v. UK*. (37 EHRR 9). Detention under Article 5(1)(e) of a person with psychopathic personality disorder justified both in the interests of the individual and on public safety grounds, even where his condition was not susceptible to medical treatment.

27 *Ashingdane v. UK*. (7 EHRR 528)

28 *Enhorn v. Sweden*. (56529/00).

- Health care workers require young people to obtain parental consent as a condition of receiving sexual health services
- Residents of an institution have no place to keep their personal possessions

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 8(1) ECHR

Everyone has the right to respect for his private and family life, his home and his correspondence.

- The ECtHR has held that *“the protection of personal data, not least medical data, is of fundamental importance to a person’s enjoyment of his or her right to respect for private and family life ... Respecting the confidentiality of health data is a vital principle in the legal systems of [State] Parties. ... It is crucial not only to respect the sense of privacy of the patient but also to preserve his or her confidence in the medical profession and in the health services in general.”*²⁹

The reasons for such protection are clear: without it, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community.³⁰

The ECtHR has gone on to note that the disclosure of health data *“may dramatically affect a person’s private and family life, as well as social and employment situation, by exposing him or her to opprobrium and the risk of ostracism.”*³¹ Disclosure is clearly particularly damaging in case of HIV infection. Therefore sufficient safeguards in domestic law must be in place. A person’s body concerns the most intimate aspect of one’s private life³² so there are clear links between the right to privacy and the right to bodily integrity.³³

► Article 10(1) European Convention on Human Rights and Biomedicine:

Everyone has the right to respect for private life in relation to information about his or her health.

► Article 13(1) COE Recommendation No. R (2004) 10:

All personal data relating to a person with mental disorder should be considered to be confidential. Such data may only be collected, processed and communi-

²⁹ M.S. v. Sweden. (27/08/1997); Z. v. Finland. (25 EHRR 371).

³⁰ Z. v. Finland. (25 EHRR 371).

³¹ Ibid.

³² Y v. Turkey. (24209/94). A forced gynecological exam conducted on woman in police custody breached Article 8 of the ECHR.

³³ Glass v. UK. (39 EHRR 15). The practice of administering diamorphine to a severely mentally and physically ill child against the clearly expressed wishes of the mother breached Article 8 of the ECHR.

cated according to the rules relating to professional confidentiality and personal data collection.

► **Article 6 European Charter of Patients' Rights:**

Every individual has the right to the confidentiality of personal information, including information regarding his or her state of health and potential diagnostic or therapeutic procedures, as well as the protection of his or her privacy during the performance of diagnostic exams, specialist visits, and medical/surgical treatments in general.

► **Article 4(1) and (8) Declaration on the Promotion of Patients' Rights in Europe:**

All information about a patient's health status . . . must be kept confidential, even after death. ... Patients admitted to health care establishments have the right to expect physical facilities which ensure privacy.

► **Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data:**³⁴ Provides additional safeguards to protect a person's privacy with respect to the automatic processing of personal data (i.e., data protection).

- **Article 5: Quality of data:** *Personal data undergoing automatic processing shall be: obtained and processed fairly and lawfully; stored for specified and legitimate purposes and not used in a way incompatible with those purposes; adequate, relevant and not excessive in relation to the purposes for which they are stored; accurate and, where necessary, kept up to date; preserved in a form which permits identification of the data subjects for no longer than is required for the purpose for which those data are stored.*
- **Article 6: Special categories of data:** *Personal data revealing racial origin, political opinions or religious or other beliefs, as well as personal data concerning health or sexual life, may not be processed automatically unless domestic law provides appropriate safeguards. The same shall apply to personal data relating to criminal convictions.*
- **Article 7: Data security:** *Appropriate security measures shall be taken for the protection of personal data stored in automated data files against accidental or unauthorised destruction or accidental loss as well as against unauthorised access, alteration or dissemination.*
- **Article 8: Additional safeguards for the data subject** *Any person shall be enabled: (a) to establish the existence of an automated personal data file, its main purposes, as well as the identity and habitual residence or principal place of business of the controller of the file; (b) to obtain at reasonable intervals and without excessive delay or expense confirmation of whether personal data relating to him are stored in the automated data file as well as communication to him of such data in an intelligible form; (c) to obtain, as the case may be, rectification or erasure of such data if these have been processed contrary to the provisions of domestic law giving effect to the basic principles set out in*

³⁴ Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. <http://conventions.coe.int/treaty/EN/Treaties/Html/108.htm>.

Articles 5 and 6 of this convention; (d) to have a remedy if a request for confirmation or, as the case may be, communication, rectification or erasure as referred to in paragraphs b and c of this article is not complied with.

Right to Information

EXAMPLES OF POTENTIAL VIOLATIONS

- Government bans publications about drug use or harm reduction, claiming they promote illegal activity
- Young people are deliberately denied information about STDs and the use of condoms
- Roma women do not have access to information about sexual and reproductive health

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 8(1) ECHR:** *Everyone has the right to respect for his private and family life, his home and his correspondence.*
 - The ECtHR has held that there is a positive obligation for the state to provide information to those whose right to respect for family and private life, under Article 8, is threatened by environmental pollution,³⁵ suggesting that any claim to the right to information in relation to health protection will have more prospects for success under Article 8 than Article 10.
- ▶ **Article 10(1) ECHR:** *Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.*
 - The ECtHR has narrowly interpreted Article 10 of the ECHR as only prohibiting authorities from restricting a person from receiving information that others wish to impart and not imposing a positive obligation on the state to collect and disseminate information on its own motion.³⁶
- ▶ **Article 3 European Charter of Patients' Rights:** *Every individual has the right to access to all kind of information regarding their state of health, the health*

³⁵ Ibid. See also *McGinley and Egan v. UK.* (27 EHRR 1). Positive obligation could arise under Article 8 in relation to provision of information about risks of exposure to radiation.

³⁶ *Guerra v. Italy.* (26 EHRR 357).

services and how to use them, and all that scientific research and technological innovation makes available.

- ▶ **COE Recommendation No. R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care**

II. Information

6. Information on health care and on the mechanisms of the decision-making process should be widely disseminated in order to facilitate participation. It should be easily accessible, timely, easy to understand and relevant.

7. Governments should improve and strengthen their communication and information strategies should be adapted to the population group they address.

8. Regular information campaigns and other methods such as information through telephone hotlines should be used to heighten the public's awareness of patients' rights. Adequate referral systems should be put in place for patients who would like additional information (with regard to their rights and existing enforcement mechanisms).

- ▶ **Article 10(2) European Convention on Human Rights and Biomedicine:** *Everyone is entitled to know any information collected about his or her health.*

- ▶ **Article 2(2) and (6) Declaration on the Promotion of Patients' Rights in Europe:** *Patients have the right to be fully informed about their health status, including the medical facts about their conditions; about the proposed medical procedures, together with potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis, and progress of treatment. [Moreover, patients] have the right to choose who, if any one, should be informed on their behalf.*

Right to Bodily Integrity

EXAMPLES OF POTENTIAL VIOLATIONS

- A Roma woman is sterilized against her will
- Doctors compel a drug-using pregnant woman to undergo an abortion
- Treatment is routinely given to residents of an institution without their consent as they are assumed to lack the capacity to make decisions about their treatment and care
- Patients at a psychiatric hospital are treated as part of a clinical medication trial without being informed that they are included in the research
- Patients are given ECT (electroconvulsive therapy) having been told that this

is “sleep therapy”

- HIV tests are routinely administered without informed consent

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 5 European Convention on Human Rights and Biomedicine:** *An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.*
- ▶ **Article 18 COE Recommendation No. R (2004)10:** *Council of Europe guidelines concerning the protection of the human rights and dignity of persons with mental disorder. A person should be subject to involuntary treatment for a mental disorder only if: the individual has a mental disorder which “represents a significant risk of serious harm to his or her health or to other persons;” less intrusive means of providing appropriate care are not available; and “the opinion of the person concerned has been taken into consideration.”*
- ▶ **Articles 4 and 5 European Charter of Patients’ Rights:** *A patient has the right to refuse a treatment or a medical intervention and to change his or her mind during the treatment, refusing its continuation ... [and] the right to freely choose from different treatment procedures and providers on the basis of adequate information.*
- ▶ **Article 3(1) and (2) Declaration on the Promotion of Patients’ Rights in Europe:** *[T]he informed consent of the patient is a prerequisite for any medical intervention [and] [a] patient has the right to refuse or halt a medical intervention.*
- ▶ **Article 3 EU Charter of Fundamental Rights:** *(1) Everyone has the right to respect for his or her physical and mental integrity. (2) In the fields of medicine and biology, the following must be respected in particular: (a) the free and informed consent of the person concerned, according to the procedures laid down by law; (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons; (c) the prohibition on making the human body and its parts as such a source of financial gain; (d) the prohibition of the reproductive cloning of human beings.*

Note: ECHR and the Right to Bodily Integrity

The right to bodily integrity is not specifically recognized under the ECHR, but it has been interpreted to be part of the right to security of the person (ECHR 5), the right to freedom from torture and cruel, inhuman, and degrading treatment (ECHR 3), the right to privacy (ECHR 8), and the right to the highest attainable standard of health (ESC 11).

- The ECtHR has found in relation to Article 8 of the ECHR that a person’s body concerns the most intimate aspect of one’s private life.³⁷ It has gone on to hold that a breach of physical and moral integrity occurred when dimorphine was

administered to a son against his mother's wishes and a DNR (Do Not Resuscitate) order was placed in his records without his mother's knowledge.³⁸

- English courts have considered whether the compulsory treatment of a mentally competent patient has the potential to breach Articles 8 and 3 of the ECHR (even if the proposed treatment complies with the legislative requirements). Relevant factors include the consequences of the patient's not receiving the proposed treatment, the treatment's possible side effects, and the potential for less invasive options.³⁹

► **European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment**

- The European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment has stated that every competent patient should be given the opportunity to refuse treatment or any other medical intervention. Any derogation from this fundamental principle should be based upon law and should only relate to clearly and strictly defined exceptional circumstances.

Right to Life

EXAMPLES OF POTENTIAL VIOLATIONS

- No one calls 911 in the case of a drug overdose due to fear of arrest, and the person subsequently dies
- Drugs users die in locked hospital wards
- Government places unjustified legal restrictions on access to lifesaving HIV prevention or treatment
- The mortality rate of an institution is particularly high during the winter months due to the poor condition of the building, inadequate sanitation and heating, and poor quality of care
- A patient of a psychiatric hospital known to be at risk of suicide is not monitored adequately and subsequently takes her own life

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- **Article 2(1) ECHR:** *Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.*

³⁷ Y.F. v. Turkey. (24209/94).

³⁸ Glass v. United Kingdom. (61827/00).

³⁹ R (on the application of PS) v. (1) Responsible Medical Officer (Dr. G) and (2) Second Opinion Appointed Doctor (Dr. W). (EWHC 2335 [Admin.]).

- Given the recognizable problems that arise in determining the allocation of limited resources for health care and the general reluctance of the ECtHR to sanction states for the impact of their economic decisions, it is likely that a breach of Article 2 for denial of health care will only be found in exceptional cases: ⁴⁰

“[I]t cannot be excluded that the acts and omissions of the authorities in the field of health care policy may in certain circumstances engage their responsibility under the positive limb of Article 2. However, where a Contracting State has made adequate provision for securing high professional standards among health professionals and the protection of the lives of patients, it cannot accept that matters such as error of judgment on the part of a health professional or negligent co-ordination among health professionals in the treatment of a particular patient are sufficient of themselves to call a Contracting State to account from the standpoint of its positive obligations under Article 2 of the Convention to protect life.” ⁴¹

The ECtHR has held that an issue may arise under Article 2 “where it is shown that the authorities ... put an individual’s life at risk through the denial of health care which they had undertaken to make available to the population generally”⁴² - in other words, where there are preexisting obligations these must not be applied in a discriminatory manner.

- The ECtHR has held that the right to life can impose a duty to protect those in custody, including in cases in which the risk derives from self-harm. ⁴³ The ECtHR will consider whether the authorities knew or ought to have known that the person “posed a real and immediate risk of suicide and, if so, whether they did all that could have been reasonably expected of them to prevent that risk.”⁴⁴
- In relation to medically caused deaths, states are required under Article 2 to create regulations compelling public and private hospitals: 1) to adopt measures for the protection of patients’ lives, and 2) to ensure that the cause of death, if in the case of the medical profession, can be determined by an “effective, independent judicial system” so that anyone responsible can be made accountable. Civil law proceedings may be sufficient in cases of medical negligence provided they are capable of both establishing liability and providing appropriate redress, such as damages.⁴⁵

40 In *Nitecki v. Poland* (65653/01), no breach of Article 2 was found where the authorities only paid 70 percent of the cost of lifesaving drugs prescribed to a patient, with the latter expected to pay the remainder.

41 *Powell v. UK*. (No 45305/99). Claim by parents that circumstances surrounding the alleged falsification of their son’s medical records and the authorities’ failure to investigate this matter properly gave rise to a breach of Article 2 (1) was declared inadmissible.

42 *Cyprus v. Turkey*. (EHRR 731).

43 *Keenan v. United Kingdom*. (33 EHRR 913)

44 *Ibid.*

45 *Calvelli and Ciglio v. Italy*. (32967/96). The dissenting judgments favored the use of criminal proceedings. On the facts, by accepting compensation through the settling of civil proceedings with respect to the death of their baby, plaintiffs denied themselves access to the best means of determining the extent of responsibility of the doctor concerned.

- To date, there has been no substantive decision on euthanasia, apart from the determination by the ECtHR that the right to life does not mean the right to die.⁴⁶
- The ECtHR has also left open the possibility that Article 2 could be engaged in a situation in which sending a terminally ill person back to their country of origin could seriously shorten their life span or could amount to cruel and inhuman treatment due to inadequate medical facilities.⁴⁷

Right to the Highest Attainable Standard of Health

EXAMPLES OF POTENTIAL VIOLATIONS

- State fails to take progressive steps to ensure access to antiretroviral drugs to prevent mother-to-child HIV transmission
- Doctors and health facilities are not located in close proximity to certain poor neighborhoods
- State fails to provide any training in palliative care for its medical personnel
- A child in a social care home becomes bedridden due to malnutrition
- A hospital is unable to provide the appropriate specialist pediatric services for children who instead have to be treated with adult patients
- Women with mental disabilities are denied reproductive health services

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 11 ESC:** *With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in co operation with public or private organisations, to take appropriate measures designed inter alia: (1) to remove as far as possible the causes of ill health; (2) to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; (3) to prevent as far as possible epidemic, endemic and other diseases, as well as accidents.*

- The ECSR has stated that Article 11 includes physical and mental well-being in accordance with the definition of health in the WHO Constitution.⁴⁸
- States must ensure the best possible state of health for the population according to existing knowledge, and health systems must respond appropriately to avoidable health risks, i.e. those controlled by human action.⁴⁹

46 Pretty v. UK. (35 EHRR 1).

47 D v. UK. (24 EHRR 423). Issues under Article 2 were indistinguishable from those raised under Article 3

48 COE. Conclusions of the European Committee of Social Rights. (XVII -2); Conclusions 2005. Statement of interpretation of Article 11.

49 COE. Conclusions: Denmark. (XV-2).

- The health care system must be accessible to everyone (see the section on right to nondiscrimination and equality). Arrangements for access must not lead to unnecessary delays in provision. Access to treatment must be based on transparent criteria, agreed upon at national level, taking into account the risk of deterioration in either clinical condition or quality of life.⁵⁰
- There must be adequate staffing and facilities with a very low density of hospital beds, combined with waiting lists, amounting to potential obstacles to access for the largest number of people.⁵¹

In relation to advisory and educational facilities the ECSR has identified two key obligations: 1) developing a sense of individual responsibility through awareness campaigns and 2) providing free and regular health screening especially for serious diseases.⁵²

► **Articles 8-10 The European Charter of Patients' Rights:** The charter refers to the right to “**the observance of quality standards**”, “**safety**” and “**innovation.**”

► **Article 5(3) WHO Declaration on the Promotion of Patients' Rights in Europe:** *Patients have the right to a quality of care which is marked both by high technical standards and by a humane relationship between the patient and health care provider.*

► **Article 35 EU Charter on Fundamental Rights:** *Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.*

Note: ECHR and Detainees' Right to Health

The ECtHR has ruled that states have a duty to protect the health of detainees and that lack of treatment may amount to a violation of Article 3, which prohibits torture and cruel, inhuman, and degrading treatment or punishment.⁵³

50 COE. Conclusions: United Kingdom. (XV-2).

51 COE. Conclusions: Denmark. (XV-2).

52 COE. The Right to Health and the European Social Charter. http://www.coe.int/t/dghl/monitoring/socialcharter/Presentation/FactsheetHealth_en.pdf.

53 *Hurtado v. Switzerland.* (280-A); *Ilhan v. Turkey.* (34 EHRR 36).

Right to Freedom from Torture and Cruel, Inhuman, and Degrading Treatment

EXAMPLES OF POTENTIAL VIOLATIONS

- Fearing prosecution by the state, a doctor refuses to prescribe morphine to relieve a patient's pain
- A prisoner suffering from cancer is denied treatment
- A drug user is denied mental health treatment while in detention
- Residents of an institution are not allowed to keep their own clothes as all clothes are communal
- Female residents of an institution are required to have showers together, supervised by male staff

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 3 ECHR: No one shall be subjected to torture or to inhuman or degrading treatment or punishment.**

- The former European Commission on Human Rights has stated that it “did not exclude that the lack of medical care in a case where someone is suffering from a serious illness could in certain circumstances amount to treatment contrary to Article 3.”⁵⁴
- However, the medical cases that the ECtHR has examined in relation to Article 3 have tended to involve those who are confined either (a) under the criminal law or (b) on mental health grounds. With respect to both forms of detention, failure to provide adequate medical treatment to persons deprived of their liberty may violate Article 3 in certain circumstances.⁵⁵ Breaches will tend to amount to inhuman and degrading treatment rather than torture.
- Article 3 cannot be construed as laying down a general obligation to release detainees on health grounds, however. Instead the ECtHR has reiterated the “right of all prisoners to conditions of detention which are compatible with human dignity, so as to ensure that the manner and method of execution of the measures imposed do not subject them to distress or hardship of an intensity exceeding the unavoidable level of suffering inherent in detention”.⁵⁶
- In relation to prisoners' health and well-being, this condition includes the provision of requisite medical assistance.⁵⁷ Where the lack of this assistance gives

⁵⁴ *Tanko v. Finland*. (23634/94).

⁵⁵ *Hurtado v. Switzerland*. (280-A); *Ilhan v. Turkey*. (34 EHRR 36).

⁵⁶ *Mouisel v. France*. (38 EHRR).

⁵⁷ *Kudla v. Poland*. (30210/96).

rise to a medical emergency or otherwise exposes the victim to “severe or prolonged pain”, the breach of Article 3 may amount to inhuman treatment.⁵⁸ However, even when these results do not occur, a finding of degrading treatment may still be made if the humiliation caused to the victim by the stress and anxiety that he suffers due to the lack of assistance is severe enough.⁵⁹ For example, this finding was made in a case in which lack of medical treatment for the applicant’s various illnesses, including TB contracted in prison, caused him considerable mental suffering, thereby diminishing his human dignity.⁶⁰

- Should a prisoner’s state of health require adequate medical assistance and treatment beyond that available in prison, he should be released subject to appropriate restrictions in the public interest.⁶¹
- Where detainees have preexisting conditions, it may not be possible to ascertain to what extent symptoms at the relevant time resulted from the conditions of the imposed detention. However, this uncertainty is not determinative as to whether the authorities have failed to fulfill their obligations under Article 3. Therefore, proof of the actual effects of the conditions of detention may not be a major factor.⁶²
- Examples of breaches of Article 3 include: the continued detention of a cancer sufferer, causing “particularly acute hardship”;⁶³ significant defects in the medical care provided to a mentally ill prisoner known to be suicide risk;⁶⁴ and systematic failings in relation to the death of a heroin addict in prison.⁶⁵
- In a recent case against Ukraine, the ECtHR found a breach of Article 3 both in terms of the conditions of detention in a pre-trial detention centre (overcrowding, sleep deprivation, and lack of natural light and air) and the failure to provide timely and appropriate medical assistance to the applicant for his HIV and tuberculosis infections.⁶⁶
- If an individual suffers from multiple illnesses, the risks associated with any illness he suffers during his detention may increase and his fear of those risks may also intensify. In these circumstances the absence of qualified and timely medical assistance, coupled with the authorities’ refusal to allow an indepen-

58 *McGlinchey v. UK.* (37 EHRR 821).

59 *Sarban v. Moldova.* (3456/05).

60 *Hummatov v. Azerbaijan.* (9852/03) and (13413/04).

61 *Wedler v. Poland.* (44115/98). See also *Mousiel v. France.* (38 EHRR 34).

62 *Keenan v. UK.* (33 EHRR 48). The treatment of a mentally ill person may be incompatible with the standards imposed by Article 3 with regard to the protection of fundamental human dignity, even though the person may not be able to point to any specific ill effects.

63 *Moussel v. France.* (38 EHRR 34). Finding the detention amounted to inhuman and degrading treatment.

64 *Keenan v. UK.* (33 EHRR 48). Finding failure to refer to psychiatrist and lack of medical notes.

65 *McGlinchey and Ors v. UK.* (37 EHRR 821). Finding inadequate facilities to record weight loss, gaps in monitoring, failure to take further steps including admission to hospital.

66 *Yakovenko v. Ukraine.* (15825/06). See also *Hurtado v. Switzerland (A 280-A)*. An X-ray, which revealed a fractured rib, was only ordered after a delay of six days.

dent medical examination of the applicant's state of health, leads to the person's strong feeling of insecurity, which, combined with physical suffering, can amount to degrading treatment.⁶⁷

- Generally, compulsory medical intervention in the interests of the person's health, where it is of "therapeutic necessity from the point of view of established principles of medicine", will not breach Article 3.⁶⁸ In such cases, however, the necessity must be "convincingly shown" and appropriate procedural guarantees must be in place. Furthermore, the level of force used must not exceed the minimum level of suffering/humiliation that would amount to a breach of Article 3, including torture.⁶⁹
- The combined and cumulative impact on a detainee of both the conditions of detention and a lack of adequate medical assistance may result in a breach of Article 3.⁷⁰
- The mere fact that a doctor saw the detainee and prescribed a certain form of treatment cannot automatically lead to the conclusion that the medical assistance was adequate.⁷¹
- The authorities must also ensure that there is a comprehensive record concerning the detainee's state of health and the treatment he underwent while in detention⁷² and that the diagnoses and care are prompt and accurate.⁷³ The medical record should contain sufficient information, specifying the kind of treatment the patient was prescribed, the treatment he actually received, who administered the treatment and when, how the applicant's state of health was monitored, etc. In the absence of such information, the court may draw inappropriate inferences.⁷⁴ Contradictions in medical records have been held to amount to a breach of Article 3.⁷⁵
- Experimental medical treatment may amount to inhuman treatment in the absence of consent.⁷⁶ During the drafting of the convention, compulsory sterilization was considered to amount to a breach.⁷⁷

67 Khudobin v. Russia. (59696/00).

68 Jalloh v. Germany. (44 EHRR 667).

69 Nevermerzhitsky v. Ukraine. (43 EHRR 32). Finding that force feeding of prisoner on hunger strike was unacceptable and amounted to torture. See also *Herczegfalvy v. Austria*. (15 EHRR 437). Finding that forcible administration of drugs and food to violent prisoner on hunger strike complied with established medical practice.

70 Popov v Russia. (26853/04); Lind v. Russia. (25664/05); Kalashnikov v. Russia. (47095/99) and (ECHR 2002-VI).

71 Hummatov v. Azerbaijan. (9852/03) and (13413/04); Malenko v. Ukraine. (18660/03).

72 Khudobin v. Russia. (59696/00).

73 Aleksanyan v. Russia. (46468/06).

74 Hummatov v. Azerbaijan. (9852/03) and (13413/04); Melnik v. Ukraine. (72286/01). See also *Holomiov v. Moldova*. (30649/05).

75 Radu v. Romania. (34022/05).

76 X v. Denmark. (32 DR 282).

77 COE. Travaux préparatoires of the European Convention on Human Rights. Volume 1.

- Medical negligence that does not cause a level of suffering/stress/anxiety in excess of the minimal level of humiliation, as defined by the ECtHR, will not involve a breach of Article 3.

► **European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment**

The convention's monitoring mechanism, the European Committee for the Prevention of Torture (CPT), monitors compliance with Article 3 of the European Convention on Human Rights through regular visits to places of detention and institutions. Its mandate includes prisons, juvenile detention centers, psychiatric hospitals, police holding centers, and immigration detention centers. The CPT has established detailed standards for implementing human rights-based policies in prisons and has also set monitoring benchmarks.⁷⁸

The CPT has emphasized the impact of overcrowding on prisoners' health.⁷⁹ It has also highlighted the frequent absence of sufficient natural light and fresh air in pretrial detention facilities and the impact of these conditions on detainees' health.⁸⁰

- **Article 11 European Charter of Patients' Rights:** *Each individual has the right to avoid as much suffering and pain as possible, in each phase of his or her illness. The health services must commit themselves to taking all measures useful to this end, like providing palliative care treatment and simplifying patients' access to them.*

- **Articles 5(10) and (11) Declaration on the Promotion of Patients' Rights in Europe:** *Patients have the right to relief of their suffering according to the current state of knowledge. ... Patients have the right to humane terminal care and to die in dignity.*

- The ECSR has stated in relation to Article 11 of the ESC that conditions of stay in hospital, including psychiatric hospitals, must be satisfactory and compatible with human dignity.⁸¹

78 COE. European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment. The CPT Standards. (CPT/Inf/E [2002, rev. 2006]).

79 Ibid.

80 Ibid.

81 COE. Conclusions of the European Committee of Social Rights. (XVII -2); Conclusions 2005. Statement of interpretation of Article 11; Conclusions 2005: Romania.

Right to Participate in Public Policy

EXAMPLES OF POTENTIAL VIOLATIONS

- An indigenous group is denied any meaningful participation in decisions regarding the design of appropriate systems to meet their health care needs
- LGBT groups are deliberately excluded from developing policies on addressing HIV/AIDS
- Civil society organizations are excluded from government deliberations to prepare applications for funds from the Global Fund to Fight AIDS, Tuberculosis and Malaria
- The government negotiates a large-scale clinical trial without consulting or requiring researchers to consult affected communities

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 5.3 Fundamental Principles of the Ljubljana Charter on Reforming Health Care:** *Health care reforms must address citizens' needs, taking into account their expectations about health and health care. They should ensure that the citizen's voice and choice decisively influence the way in which health services are designed and operate. Citizens must also share responsibility for their own health.*
- ▶ **Part III European Charter of Patients' Rights: Section on the Rights of Active Citizenship:** *Citizens have the "right to participate in the definition, implementation and evaluation of public policies relating to the protection of health care rights."*
- ▶ **COE Recommendation No. R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care⁸²**

Recommends that the governments of member states:

- *ensure that citizens' participation should apply to all aspects of health care systems, at national, regional and local levels and should be observed by all health care system operators, including professionals, insurers and the authorities;*
- *take steps to reflect in their law the guidelines contained in the appendix to this recommendation;*

⁸² COE. Recommendation No. R (2000) 5. <https://wcd.coe.int/ViewDoc.jsp?id=340437&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383>.

- *create legal structures and policies that support the promotion of citizens' participation and patients' rights, if these do not already exist;*
- *adopt policies that create a supportive environment for the growth, in membership, orientation and tasks, of civic organisations of health care "users", if these do not already exist;*
- *support the widest possible dissemination of the recommendation and its explanatory memorandum, paying special attention to all individuals and organisations aiming at involvement in decision-making in health care.*

The guidelines in this recommendation cover: citizen and patient participation as a democratic process; information; supportive policies for active participation; and appropriate mechanisms.

► **Committee of Ministers Recommendation No. R (2006) 18 to member states on health services in a multicultural society⁸³**

5.1. Patient training programmes should be developed and implemented to increase their participation in the decision-making process regarding treatment and to improve outcomes of care in multicultural populations.

5.2. Culturally appropriate health promotion and disease prevention programmes have to be developed and implemented as they are indispensable to improve health literacy in ethnic minority groups in terms of health care.

5.3. Ethnic minority groups should be encouraged to participate actively in the planning of health care services (assessment of ethnic minorities' health needs, programme development), their implementation and evaluation.

Right to Nondiscrimination and Equality

EXAMPLES OF POTENTIAL VIOLATIONS

- **Asylum seekers are denied access to all health care apart from emergency treatment**
- **Hospitals routinely place Roma women in separate maternity wards**
- **Drug users are underrepresented in HIV-treatment programs despite the fact that they account for a majority of people living with HIV**
- **A woman with a diagnosis of schizophrenia is told by nursing staff that her**

83 COE. Committee of Ministers Recommendation No. R (2006) 18. <https://wcd.coe.int/ViewDoc.jsp?id=1062769&BackColorInternet=9999CC&BackColorIntranet>.

abdominal pains are “all in your mind” and is later diagnosed as having ovarian cancer

- A person with intellectual disabilities is not provided with the appropriate community care support to effectively socially integrate in the community

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 14 ECHR: Prohibition of Discrimination:** *The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, color, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.*

- Article 14 is not a stand-alone provision – in other words, it must be argued in conjunction with one of the substantive provisions of the ECHR.⁸⁴ For this reason, the court has not always examined Article 14 claims in cases in which it has already found a violation of the main provision.
- To date, there have been no significant Article 14 decisions in relation to health care. Because Article 14 case law has increased during the last decade in areas such as racial discrimination and sexual orientation, it is likely that this circumstance will change in the future.
- The main principles for considering an Article 14 claim are: evidence that there has been a difference of treatment on one of the nonpermitted categories (although this condition is not exhaustive); and, if so, the existence of an objective and reasonable justification for such difference.⁸⁵
- The court has also recently accepted the use of statistics to prove indirect discrimination,⁸⁶ a practice that in itself may not amount to impermissible discrimination but that disproportionately affects members of a particular group.

► **Article 11 ESC (taken together with Article E of the charter guaranteeing non-discrimination)**

With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organizations, to take appropriate measures designed inter alia: (1) to remove as far as possible the causes of ill-health; (2) to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; (3) to prevent as far as possible epidemic, endemic and other diseases, as well as accidents.

⁸⁴ A stand-alone provision on nondiscrimination in the form of Protocol 12 to the convention entered into force in 2005 but has not been widely ratified. <http://www.humanrights.coe.int/Prot12/Protocol%2012%20and%20Exp%20Rep.htm>

⁸⁵ Rasmussen v. Denmark. (7 EHRR 371).

⁸⁶ D.H. v. Czech Republic. (57325/00).

► **Article 15 ESC: Rights of persons with disabilities to vocational training, rehabilitation and social resettlement**

With a view to ensuring to persons with disabilities, irrespective of age and the nature and origin of their disabilities, the effective exercise of the right to independence, social integration and participation in the life of the community, the Parties undertake, in particular: (1) to take the necessary measures to provide persons with disabilities with guidance, education and vocational training in the framework of general schemes wherever possible or, where this is not possible, through specialised bodies, public or private; (2) to promote their access to employment through all measures tending to encourage employers to hire and keep in employment persons with disabilities in the ordinary working environment and to adjust the working conditions to the needs of the disabled or, where this is not possible by reason of the disability, by arranging for or creating sheltered employment according to the level of disability. In certain cases, such measures may require recourse to specialised placement and support services; (3) to promote their full social integration and participation in the life of the community in particular through measures, including technical aids, aiming to overcome barriers to communication and mobility and enabling access to transport, housing, cultural activities and leisure.

- The ECSR has stated that the health care system must be accessible to everyone and that restrictions on the application of Article 11 ESC must not be interpreted in such a way as to impede disadvantaged groups' exercise of their right to health.⁸⁷

Specifically, the right of access to care requires that care must not represent an excessively heavy cost for the individual, and steps must be taken to reduce the financial burden on patients from the most disadvantaged sections of the community.⁸⁸

The ECSR, in considering a claim brought against France that it had violated (a) the right to medical assistance of poor illegal immigrants on very low incomes under Article 13⁸⁹ of the Revised European Social Charter⁹⁰ by ending their

87 COE. Conclusions of the European Committee of Social Rights. (XVII -2); Conclusions 2005. Statement of interpretation of Article 11.

88 COE. Conclusions: Portugal. (XVII -2).

89 Article 13: With a view to ensuring the effective exercise of the right to social and medical assistance, the Parties undertake: (1) to ensure that any person who is without adequate resources and who is unable to secure such resources either by his own efforts or from other sources, in particular by benefits under a social security scheme, be granted adequate assistance, and, in case of sickness, the care necessitated by his condition; (2) to ensure that persons receiving such assistance shall not, for that reason, suffer from a diminution of their political or social rights; (3) to provide that everyone may receive by appropriate public or private services such advice and personal help as may be required to prevent, to remove, or to alleviate personal or family want; (4) to apply the provisions referred to in paragraphs 1, 2 and 3 of this article on an equal footing with their nationals to nationals of other Parties lawfully within their territories, in accordance with their obligations under the European Convention on Social and Medical Assistance, signed at Paris on 11 December 1953.

90 The Revised Social Charter of 1996 (ETS No. 163) embodies in one instrument all the rights guaranteed by the original charter of 1961 (ETS No. 035), its additional protocol of 1988 (ETS No. 128) and adds new rights and amendments adopted by the parties. is the revised charter gradually replacing the initial, 1961 treaty.

exemption from charges for medical and hospital treatment⁹¹ and (b) the rights of children of immigrants to protection under Article 17 of the revised charter⁹² by a 2002 legislative reform that restricted their access to medical services for children, upheld the claim of the children but not of the adults.

With regard to Article 13, the ECSR did find, based on a purposive interpretation of the ESC consistent with the principle of individual human dignity, that medical assistance protection should extend to illegal and to lawful foreign migrants (although this condition did not apply to all ESC rights). This finding is highly significant in relation to the protection afforded to such marginalized groups within Europe. On the facts, however, by a majority of nine to four, the ES CR found no violation of Article 13 as illegal immigrants could access some forms of medical assistance after three months of residence, and all foreign nationals could, at any time, obtain treatment for “emergencies and life threatening conditions”.

By contrast, the ECSR found a violation of Article 17 (right of children to protection), even though the affected children had similar access to health care as adults, because Article 17 was considered more expansive than the right to medical assistance. In response to the decision, the government of France changed its policy in relation to migrant children.⁹³

► **Article 3 European Convention on Human Rights and Biomedicine:**⁹⁴
Equitable access to health care

► **Article 23 Convention Relating to the Status of Stateless Persons**

The contracting states shall accord to stateless persons lawfully staying in their territory the same treatment with respect to public relief and assistance as is accorded to their nationals.

► **Article 4 Framework Convention for the Protection of National Minorities**

The Parties undertake to guarantee to persons belonging to national minorities the right of equality before the law and of equal protection of the law. In this respect, any discrimination based on belonging to a national minority shall be prohibited.

91 International Federation of Human Rights Leagues (FIDH) v. France. (13/2003).

92 Article 17: With a view to ensuring the effective exercise of the right of children and young persons to grow up in an environment which encourages the full development of their personality and of their physical and mental capacities, the Parties undertake, either directly or in co-operation with public and private organisations, to take all appropriate and necessary measures designed: (1) (a) to ensure that children and young persons, taking account of the rights and duties of their parents, have the care, the assistance, the education and the training they need, in particular by providing for the establishment or maintenance of institutions and services sufficient and adequate for this purpose; (b) to protect children and young persons against negligence, violence or exploitation; (c) to provide protection and special aid from the state for children and young persons temporarily or definitively deprived of their family's support; (2) to provide to children and young persons a free primary and secondary education as well as to encourage regular attendance at schools.

93 The government issued a circular on March 16, 2005, which provided that “all care and treatment dispensed to minors resident in France who are not effectively beneficiaries under the State medical assistance scheme is designed to meet the urgency requirement.” (CIRCULAR DHOS/DSS/DGAS).

94 Convention on Human Rights and Biomedicine. <http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc>

The Parties undertake to adopt, where necessary, adequate measures in order to promote, in all areas of economic, social, political and cultural life, full and effective equality between persons belonging to a national minority and those belonging to the majority. In this respect, they shall take due account of the specific conditions of the persons belonging to national minorities.

The measures adopted in accordance with paragraph 2 shall not be considered to be an act of discrimination.

► **Committee of Ministers Recommendation No. R (2006) 18 to member states on health services in a multicultural society**

This recommendation includes a number of strategies for promoting health and health care for multicultural populations, including: nondiscrimination and respect for patient rights; equal access to health care; overcoming language barriers; sensitivity to health and socioeconomic needs of minorities; empowerment; and greater participation and development of appropriate knowledge base of the health needs of multicultural populations.

► **Paragraph 4 COE Parliamentary Assembly Recommendation 1626 (2003) on the Reform of Health Care Systems in Europe: Reconciling equity, equality and efficiency:**⁹⁵ *Member states should take as their main criterion for judging the success of health system reforms the existence of effective access to health care for all, without discrimination, as a basic human right.*

► **Article 2 European Charter of Patients Rights: Right of Access**

Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.

⁹⁵ COE. Parliamentary Assembly Recommendation 1626 (2003). <http://assembly.coe.int/Documents/AdoptedText/TA03/EREC1626.htm>

3.4 Providers' rights

This section presents relevant European regional standards as they appear in the European Convention on Human Rights and the European Social Charter. It also explains how these standards have been interpreted in relation to three key rights for health care and service providers: (i) work-related rights, including the right to work and to equal opportunity based on sex; (ii) freedom of association, including the right to form trade unions and the right to strike; and (iii) due process and related rights such as fair hearing, effective remedy, protection of privacy and reputation, and freedom of expression and information.

The chapter is divided into three major sections. Part I discusses the right to work in decent conditions; Part II discusses freedom of association; and Part III discusses due process and related rights. Each section outlines the significance of the right for health providers and gives examples of potential violations. The relevant standards from the Council of Europe treaties are then presented. Finally, key interpretative guidelines based on case law and concluding observations of state reports issued by the monitoring bodies are summarized.

RIGHT TO WORK IN DECENT CONDITIONS

The right to work and rights in work are governed by the European Social Charter (ESC). Although they are not the focus of this section, relevant ECHR standards may include Article 2 (right to life) and Article 3 (prohibition of torture and subjection to inhuman or degrading treatment or punishment) insofar as they provide safeguards against ill treatment in the workplace.

The European Committee of Social Rights (ECSR) has provided extensive interpretation of the right to work in decent conditions in the ESC, particularly in the following four areas: the right to work (article 1[2]) and to equal opportunity based on sex (article 20); the right to reasonable daily and weekly working hours (article 2[1]); the right to safe and healthy working conditions (article 3); and the right to a fair remuneration.⁹⁶ Each of these is discussed in turn in this section. Although there is little or no direct reference to health sector personnel, they enjoy the same level of protection as other workers.

⁹⁶ A digest of the case law of the ECSR is regularly updated and available at http://www.coe.int/t/dghl/monitoring/socialcharter/Digest/DigestIndex_en.asp

The Right to Work and to Equal Opportunity Based on Sex

EXAMPLES OF POTENTIAL VIOLATIONS

- A female doctor is constantly passed over for promotion despite having more relevant experience and better qualifications than male colleagues
- All nationals from a country are banned from taking jobs in the health sector following a territorial dispute subsequently referred to the International Court of Justice
- Female employees are subject to frequent sexual harassment by other members of staff, and no action taken to stop harassment

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 1(2) ESC: The right to work

With a view to ensuring the effective exercise of the right to work, the Parties undertake to protect effectively the right of the worker to earn his living in an occupation freely entered upon.

- Article 1(2) of the ESC, ensuring the effective exercise of the right to work, is further divided into three separate issues:
 - a) the prohibition of all forms of discrimination in employment (which overlaps with the right to equal opportunity based on sex);
 - b) the prohibition of any practice that might interfere with a workers' right to earn a living in an occupation freely entered upon;⁹⁷
 - c) the prohibition of forced or compulsory labor.

The first two of these issues are discussed below, with an emphasis on the definition and scope of discrimination. Acceptable domestic policies to combat discriminatory practices that limit enjoyment of the right to work, as set forth in Article 1, are also outlined.

Prohibition of all forms of discrimination in employment

- The ESC defines discrimination as the different treatment of persons in comparable situations where such treatment does not pursue a legitimate aim, is not based on objective and reasonable grounds or is not proportionate to the aim pursued.⁹⁸ The assessment of whether a difference in treatment pursues a legitimate aim and is proportionate is assessed taking into account Article G,⁹⁹ the limitation provision of the ESC.¹⁰⁰

97 COE. Conclusions of the European Committee of Social Rights. Conclusions (II and XVI-1). Statements of interpretation of Article 1§2.

98 *Syndicat national des Professions du Tourisme v. France*. (6/1999). Decision on the merits of October 10, 2000.

99 Article G: *The rights and principles set forth in Part I when effectively realised, and their effective exercise as provided for in Part II, shall not be subject to any restrictions or limitations not specified in those parts, except such as are prescribed by law and are necessary in a democratic society for the protection of the rights and freedoms of*

- Under Article 1(2), legislation should prohibit any discrimination in employment on grounds of inter alia sex, race, ethnic origin, religion, disability, age, sexual orientation, and political opinion.¹⁰¹ This provision is inherently linked to other provisions of the ESC, in particular to Article 20 (the right to equal opportunities and equal treatment in matters of employment and occupation without discrimination on grounds of sex) and Article 15(2) (the right of persons with disabilities to employment).
- Legislation should prohibit both direct and indirect discrimination.¹⁰²
- Indirect discrimination arises when a measure or practice that is identical for everyone, without a legitimate aim disproportionately affects persons having a particular religion or belief, disability, age, sexual orientation, political opinion, ethnic origin, etc.¹⁰³
- Discrimination may also result from the failing to take positive account of all relevant differences or failing to take adequate steps to ensure that the rights and collective advantages that are open to all are genuinely accessible to and by all.¹⁰⁴
- The discriminatory acts and provisions prohibited by this provision are ones that may occur in connection with recruitment or with employment conditions in general. Remuneration, training, promotion, transfer and dismissal or other detrimental action are especially important.¹⁰⁵
- In order to make the prohibition of discrimination effective, domestic law must at least provide for:
 - ▶ the power to set aside, rescind, abrogate, or amend any provision contrary to the principle of equal treatment, which appears in collective labor agreements, in employment contracts or in firms' own regulations;¹⁰⁶
 - ▶ protection against dismissal or other retaliatory action by the employer against an employee who has lodged a complaint or taken legal action;¹⁰⁷

others or for the protection of public interest, national security, public health, or morals. The restrictions permitted under this Charter to the rights and obligations set forth herein shall not be applied for any purpose other than that for which they have been prescribed.

100 COE. Conclusions: Greece. (XVI-1).

101 COE. Conclusions: Iceland. (XVIII -1); Conclusions 2006 (Albania).

102 COE. Conclusions: Austria. (XVIII -1).

103 David Harris et al. Law of the European Convention on Human Rights. (Oxford: Oxford University Press, 2009), 607.

104 Association Internationale Autisme-Europe (AIAE) v. France. (13/2002). Decision on the merits of November 4, 2003.

105 COE. Conclusions: Austria. (XVI-1).

106 COE. Conclusions: Iceland. (XVI-1).

107 COE. Conclusions: Iceland. (XVI-1).

appropriate and effective remedies that are adequate and proportionate and available to victims in the event of an allegation of discrimination. The imposition of predefined upper limits to compensation that may be awarded are not in conformity with Article 1(2).¹⁰⁸

- Domestic law should also provide for an alleviation of the burden of proof that rests with the plaintiff in discrimination cases.¹⁰⁹
- The following measures also contribute to combating discrimination in accordance with Article 1(2) of the ESC:
 - ▶ Recognizing the right of trade unions to take action in cases of employment discrimination, including action on behalf of individuals¹¹⁰
 - ▶ The right to challenge discriminatory practices that violate the right to take collective action
 - ▶ Establishing a special, independent body to promote equal treatment, particularly by providing discrimination victims with the support they need to take proceedings
- States parties to the ESC may make foreign nationals' access to employment while in their territories subject to possession of a work permit. They cannot, however, in general, ban nationals of other states from occupying jobs for reasons other than those set out in Article G. The only jobs from which foreigners may be banned are those that are inherently connected with the protection of the public interest or national security and involve the exercise of public authority.¹¹¹
- Exclusion of individuals from functions on grounds of previous political activities, either in the form of refusal to recruit or dismissal, is prohibited unless the job relates to law and order and national security or to functions involving such responsibilities.¹¹²
- The ECSR has offered limited interpretation of the following standard: "Prohibition of any practice that might interfere with workers' right to earn their living in an occupation freely entered upon." Practices that could violate this standard include:
 - ▶ the lack of adequate legal safeguards against discrimination in respect to part-time work. In particular, there must be rules to prevent non-declared

108 COE. Conclusions 2006: Albania.

109 COE. Conclusions 2002: France; *Syndicat Sud Travail et Affaires Sociales v. France*. (24/2004). Decision on the merits of November 16, 2005.

110 COE. Conclusions: Iceland. (XVI-1).

111 COE. Conclusions 2006: Albania.

112 COE. Conclusions 2006: Lithuania.

work through overtime, and equal pay, in all its aspects, between part-time and full-time employees;¹¹³

- ▶ undue interference in employees' private or personal lives associated with or arising from their employment situation, in particular through electronic communication and data collection techniques.¹¹⁴

▶ Article 20 ESC: Equal opportunity based on sex

All workers have the right to equal opportunities and equal treatment in matters of employment and occupation without discrimination on the grounds of sex.

With a view to ensuring the effective exercise of the right to equal opportunities and equal treatment in matters of employment and occupation without discrimination on the grounds of sex, the Parties undertake to recognize that right and to take appropriate measures to ensure or promote its application in the following fields: (a) access to employment, protection against dismissal and occupational reintegration; (b) vocational guidance, training, retraining and rehabilitation; (c) terms of employment and working conditions, including remuneration; (d) career development, including promotion.

Right to Reasonable Daily and Weekly Working Hours

EXAMPLES OF POTENTIAL VIOLATIONS

- A doctor regularly works 100 hour weeks including, on occasion, 18-hour shifts
- A nurse is forced to work overtime without prior agreement

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

- ▶ **Article 2(1) ESC: Reasonable working hours to ensure the right to just conditions of work:** *With a view to ensuring the effective exercise of the right to just conditions of work, the Parties undertake to provide for reasonable daily and weekly working hours, the working week to be progressively reduced to the extent that the increase of productivity and other relevant factors permit.*

¹¹³ COE. Conclusions: Austria. (XVI-1).

¹¹⁴ COE. Conclusions 2006. Statement of Interpretation on Article 1§2.

- Article 2(1) ESC guarantees workers the right to reasonable limits on daily and weekly working hours, including overtime. This right must be guaranteed through legislation, regulations, collective agreements or any other binding means. In order to ensure that the limits are respected in practice, an appropriate authority must supervise whether the limits are being respected.¹¹⁵
- The ESC does not expressly define what constitutes reasonable working hours, assesses situations on a case-by-case basis: extremely long working hours (more than 16 hours in one day)¹¹⁶ or, under certain conditions, more than 60 hours in one week¹¹⁷ are unreasonable and therefore contrary to the ESC.
- Overtime work must not simply be left to the discretion of the employer or the employee. The reasons for overtime work and its duration must be subject to regulation.¹¹⁸
- Article 2(1) also provides for the progressive reduction of weekly working hours, to the extent permitted by productivity increases and other relevant factors. These “relevant factors” may include the nature of the work to be performed and the safety and health risks to which workers are exposed.¹¹⁹
- Periods of “on call” duty, during which the employee has not been required to perform work for the employer do constitute effective working time and cannot be regarded as a rest periods, in the meaning of Article 2 of the ESC, except in the framework of certain occupations or particular circumstances and pursuant to appropriate procedures. The absence of effective work cannot constitute an adequate criterion for regarding such a period as a period of rest.¹²⁰

Right to Safe and Healthy Working Conditions

EXAMPLES OF POTENTIAL VIOLATIONS

- Medical staff in the X-ray department are frequently exposed to dangerously high levels of radiation due to faulty equipment that has not been checked or replaced
- A nurse is infected with HIV after medical equipment is not properly sterilized
- A staff canteen remains open despite repeatedly failing basic hygiene standards

115 COE. Conclusions I. Statement of Interpretation on Article 2§1.

116 COE. Conclusions: Norway. (XIV-2).

117 COE. Conclusions: The Netherlands. (XIV-2).

118 COE. Conclusions. (XIV-2). Statement of Interpretation on Article 2(1).

119 Ibid.

120 Confédération Française de l'Encadrement CFE-CGC v. France. (16/2003). Decision on the merits of October 12, 2004

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 3 ESC: The right to safe and healthy working conditions

With a view to ensuring the effective exercise of the right to safe and healthy working conditions, the Parties undertake, in consultation with employers' and workers' organisations: To formulate, implement and periodically review a coherent national policy on occupational safety, occupational health and the working environment. The primary aim of this policy shall be to improve occupational safety and health and to prevent accidents and injury to health arising out of, linked with or occurring in the course of work, particularly by minimising the causes of hazards inherent in the working environment; (1) to issue safety and health regulations; (2) to provide for the enforcement of such regulations by measures of supervision; (3) to promote the progressive development of occupational health services for all workers with essentially preventive and advisory functions.

- The right of every worker to a safe and healthy working environment is a “widely recognised principle, stemming directly from the right to personal integrity, one of the fundamental principles of human rights”.¹²¹
- The purpose of Article 3 ESC is thus directly related to that of Article 2 of the European Convention on Human Rights, which recognises the right to life.¹²²
- Article 3 ESC applies to both the public and private sectors.¹²³
- Occupational risk prevention must be a priority. It must be incorporated into the public authorities' activities at all levels and form part of other public policies (on employment, persons with disabilities, equal opportunities, etc.).¹²⁴ The policy and strategies adopted must be assessed and reviewed regularly, particularly in light of changing risks.
- At the employer level, in addition to compliance with protective rules, there must be regular assessment of work-related risks and the adoption of preventive measures geared to the nature of risks in addition to information and training for workers. Employers are also required to provide appropriate information, training, and medical supervision for temporary workers and employees on fixed-term contracts (for example, taking account of employees' accumulated periods of exposure to dangerous substances while working for different employers).¹²⁵

121 COE. Conclusions I. Statement of Interpretation on Article 3.

122 COE. Conclusions. (XIV-2). Statement of Interpretation on Article 3.

123 COE. Conclusions II . Statement of Interpretation on Article 3.

124 COE. Conclusions 2005: Lithuania.

125 COE. Conclusions 2003: Bulgaria.

- The ESC does not actually define the risks to be regulated. Supervision takes an indirect form, referring to international technical occupational health and safety standards, such as the ILO conventions and European Community Directives on health and safety at work.
- Domestic law must include framework legislation (often the Labour Code) that sets out employers' responsibilities, workers' rights and duties, and specific regulations. The risks that the ECSR currently highlights include:
 - ▶ establishment, alteration, and upkeep of workplaces (equipment, hygiene);
 - ▶ hazardous agents and substances;
 - ▶ risks connected with certain sectors (the health sector is not expressly mentioned)
- Most of the risks listed above have to be covered by a specific regulation, i.e., they must set out rules in sufficient detail for them to be applied properly and efficiently.¹²⁶ Accordingly, the ECSR does not consider that states are required to introduce specific insurance for occupational diseases and accidents to comply with Article 3(2).¹²⁷
- All workers, all workplaces, and all sectors of activity must be covered by occupational health and safety regulations.¹²⁸
- There is a need for regular inspections and effective penalties for breaches.

Right to a Fair Remuneration

EXAMPLES OF POTENTIAL VIOLATIONS

- Some health staff are only paid the equivalent of 40 percent of the national average wage, and ancillary staff are paid less than the national minimum wage
- A nurse working overtime receives the same wage that she is normally paid

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

▶ Article 4 ESC: The right to a fair remuneration

With a view to ensuring the effective exercise of the right to a fair remuneration, the Parties undertake: (1) to recognise the right of workers to a remuneration

¹²⁶ COE. Conclusions: Norway. (XIV-2).

¹²⁷ Marangopoulos Foundation for Human Rights (MFHR) v. Greece. (30/2005). Decision on the merits of December 6, 2006.

¹²⁸ COE. Conclusions 2005: Estonia.

such as will give them and their families a decent standard of living; (2) to recognise the right of workers to an increased rate of remuneration for overtime work, subject to exceptions in particular cases; (3) to recognise the right of men and women workers to equal pay for work of equal value; (4) to recognise the right of all workers to a reasonable period of notice for termination of employment; (5) to permit deductions from wages only under conditions and to the extent prescribed by national laws or regulations or fixed by collective agreements or arbitration awards. The exercise of these rights shall be achieved by freely concluded collective agreements, by statutory wage-fixing machinery, or by other means appropriate to national conditions.

- To be considered fair within the meaning of Article 4(1) of the ESC, wages must be above the poverty line in a given country - in other words, 50 percent of the national average wage. In addition, a wage must not fall too far short of the national average wage. The threshold adopted by the ECSR is 60 percent.¹²⁹
- Employees who work overtime must be paid at a higher rate than the normal wage rate.¹³⁰ Article 4(2) permits granting an employee leave to compensate for overtime, provided that the leave is longer than the overtime worked. It is not sufficient, therefore, to offer employees leave of equal length to the number of overtime hours worked.¹³¹
- Exceptions to Article 4(2) may be authorized in certain specific cases. These “special cases” have been defined by the ECSR as “state employees, management executives, etc.”¹³² With respect to state employees, confining exceptions to “senior officials” is compatible with Article 4(2).¹³³ Exceptions to receipt of a higher rate of overtime pay cannot, however, be applied to all state employees or public officials, irrespective of their level of responsibility.¹³⁴ Exceptions may be applied to all senior managers. The ECSR has ruled that certain limits must apply, however, particularly on the number of hours of overtime not paid at a higher rate.¹³⁵
- Women and men are entitled to “equal pay for work of equal value” and this right must be expressly provided for in legislation.¹³⁶ The equal pay principle should apply to all jobs performed by both women and men. The principle of

129 COE. Conclusions. (XIV-2). Statement of Interpretation on Article 4§1. The committee’s calculations are based on net amounts, (after deduction of taxes and social security contributions). Social transfers (for example, social security allowances or benefits) are taken into account only when they have a direct link to the wage.

130 COE. Conclusions I. Statement of Interpretation on Article 4§2.

131 COE. Conclusions: Belgium. (XIV-2).

132 COE. Conclusions: Ireland. (IX-2).

133 COE. Conclusions: Ireland. (X-2).

134 COE: Conclusions: Poland. (XV-2).

135 Confédération Française de l’Encadrement CFE-CGC v. France. (9/2000). Decision on the merits of 16 November 2001.

136 COE. Conclusions: Slovak Republic. (XV-2, addendum).

equality should cover all the elements of pay, including minimum wages or salary plus all other benefits paid directly or indirectly in cash or in kind by the employer to the worker.¹³⁷ It must also apply to full-time and part-time employees, covering the calculation of hourly wages, pay increases and the components of pay.¹³⁸

- Domestic law must provide for appropriate and effective remedies in the event of alleged wage discrimination.¹³⁹ Employees who claim that they have suffered discrimination must be able to take their cases to court.
- Domestic law should provide for an alleviation of the burden of proof in favor of the plaintiff in discrimination cases. Anyone who suffers wage discrimination on grounds of sex must be entitled to adequate compensation, sufficient to make good the damage suffered by the victim and act as a deterrent to the offender.¹⁴⁰ In cases of unequal pay, any compensation must, at minimum, cover the difference in pay.¹⁴¹

RIGHT TO FREEDOM OF ASSOCIATION

Freedom of association is recognized under Article 11 of the ECHR. Although the European Court of Human Rights has only examined this right in a limited number of cases, it has confirmed that it includes the freedom to abstain from joining an association. In addition, the ECtHR has determined that official regulatory body members do not fall within the scope of the guarantee. This finding is particularly important for medical professionals as these bodies are established by law and have the authority to discipline their members.¹⁴²

The most comprehensive analysis of the right to strike has been made under the ESC. The ECtHR has engaged in a more limited exploration of trade unions, which includes upholding workers' right to strike.

This section covers two aspects of freedom of association: the freedom of association and assembly, found in Article 11 of the ECHR, and the right to form trade unions and to strike, addressed by Articles 5, 6, 21 and 22 of the ESC.

137 COE. Conclusions I. Statement of Interpretation on Article 4§3.

138 COE. Conclusions: Portugal. (XVI-2).

139 COE. Conclusions I. Statement of Interpretation on Article 4§3.

140 COE. Conclusions. (XIII -5). Statement of Interpretation on Article 1 of the Additional Protocol.

141 COE. Conclusions: Malta. (XVI-2).

142 See also International Centre for the Protection of Legal Rights. INTERIGHTS Manual for Lawyers. Article 11 of the European Convention of Human Rights: Freedom of Assembly and Association. <http://www.interights.org/view-document/index.htm?id=520>.

Provides information on how the ECtHR has interpreted Article 11 of the ECHR.

Right to Freedom of Association and Assembly

EXAMPLES OF POTENTIAL VIOLATIONS

- A professional medical association is not approved by the Ministry of Health because its president is a leading member of an opposition political party
- Without any justification, authorities prevent a rally for improved pay and conditions for health workers from taking place

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 11 ECHR:** *(1) Everyone has the right to freedom of peaceful assembly and to freedom of association with others, including the right to form and to join trade unions for the protection of his interests. (2) No restrictions shall be placed on the exercise of these rights other than such as are prescribed by law and are necessary in a democratic society in the interests of national security or public safety, for the prevention of disorder or crime, for the protection of health or morals or for the protection of the rights and freedoms of others. This article shall not prevent the imposition of lawful restrictions on the exercise of these rights by members of the armed forces, of the police or of the administration of the State.*

- Under Article 11, "association" is an autonomous concept not dependent on the classification adopted under domestic law. This factor is relevant but not decisive.¹⁴³

The right to freedom of association under Article 11 applies to private law bodies only. Public law bodies (i.e. those established under legislation) are not considered to be 'associations' within the meaning of Article 11. This limited scope of the right may be particularly relevant for health professionals and their compulsory membership of national professional bodies.¹⁴⁴

- The right also includes the freedom not to join an association or trade union.¹⁴⁵

143 Chassagnou and Ors v. France. (29 EHRR 615). Hunters' associations in France are held to be "associations" for purposes of Article 11 even though government argued that they were public law institutions.

144 *Le Compte v. Belgium*. (4 EHRR 1). After being suspended by the regulatory body for their profession, doctors unsuccessfully complained about their compulsory membership in it and their subjection to the jurisdiction of its disciplinary organs. Given the regulatory body's public law status—it was integrated with the structure of the state, and judges were appointed to most of its organs by the state—its functions of regulating medical practice and maintaining the register of practitioners, and its administrative, rule making, and disciplinary powers, the court held that it was also relevant that there were no restrictions on practitioners establishing or joining their own professional associations. See also the subsequent cases of *Albert and Le Compte v. Belgium* (7299/75, etc.) as regards medical doctors; *Revert and Legallais v. France* (14331/88 and 14332/88) as regards architects; *A. and others v. Spain* (13750/88) as regards bar associations; and *Barthold v. Germany* (8734/79) as regards veterinary surgeons. See also *O. VR. v. Russia* (44139/98) and *A v. Spain* (6 DR 188).

145 *Young and Ors v. UK*. (4 EHRR 38). "Closed shop," compulsory membership of the rail trade union breached Article 11. See also *Sigurjonsson v. Iceland*. (A264).

- Article 11(2) permits ‘lawful restrictions’ to be placed on certain public officials (e.g. the armed forces and the police) including members of the ‘administration of the state’.¹⁴⁶ However, the latter term should be narrowly interpreted, the ECtHR having left open whether it should apply to teachers.¹⁴⁷

Trade Unions and the Right to Strike

EXAMPLES OF POTENTIAL VIOLATIONS

- A nurse is refused a promotion on the grounds that she has been “causing problems” for the management through her trade union activities
- A collective agreement between a trade union and health authority management ensures that 30 percent of the vacant posts will be reserved for the union’s members
- There is a blanket ban on all health sector workers, prohibiting them from taking any form of industrial action

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 5 ESC: The right to organize

With a view to ensuring or promoting the freedom of workers and employers to form local, national or international organisations for the protection of their economic and social interests and to join those organisations, the Parties undertake that national law shall not be such as to impair, nor shall it be so applied as to impair, this freedom. The extent to which the guarantees provided for in this article shall apply to the police shall be determined by national laws or regulations. The principle governing the application to the members of the armed forces of these guarantees and the extent to which they shall apply to persons in this category shall equally be determined by national laws or regulations.

- Article 5 of the ESC applies both to the public and to the private sector.¹⁴⁸ Domestic law must guarantee the right of workers to join a trade union and include effective punishments and remedies when this right is not respected.
- Under Article 5, workers must be free to join and free not to join a trade union.¹⁴⁹ Any form of compulsory trade union membership imposed by law is incompatible with Article 5.¹⁵⁰

146 This approach has been endorsed by ES CR experts but not by the ILO Freedom of Association Committee, although Article 9(1) of ILO Convention No. 87 limiting public servants’ rights does not refer to “administration of the state.”

147 *Vogt v. Germany*. (21 EHRR 205). The court has left open whether teachers are members of the “administration of the state,” but the commission decided that they are not.

148 COE. Conclusions I. Statement of Interpretation on Article 5.

149 COE. Conclusions I. Statement of Interpretation on Article 5.

150 COE. Conclusions III . Statement of Interpretation on Article 5.

- Domestic law must clearly prohibit all preentry or postentry “closed shop” clauses and all union security clauses (automatic deductions from wages).¹⁵¹ Consequently, clauses in collective agreements or legally authorized arrangements whereby jobs are reserved in practice for members of a specific trade union are a breach of Article 5.¹⁵²
- Trade union members must be protected from any harmful consequence that their trade union membership or activities may have on their employment, particularly any form of reprisal or discrimination in the areas of recruitment, dismissal, or promotion. Where such discrimination occurs, domestic law must make provision for compensation that is adequate and proportionate to the harm suffered by the victim.¹⁵³
- Trade unions and employers’ organizations must be independent from excessive state interference in relation to their infrastructure or effective functioning.¹⁵⁴ For example, trade unions are entitled to choose their own members and representatives, and there should be not excessive limits on the reasons for which a trade union may take disciplinary action against a member.¹⁵⁵ Further, trade union officials must have access to the workplace, and union members must be able to hold meetings at work, subject to the requirements of the employer.¹⁵⁶
- Trade unions and employers’ organizations must be free to organize without prior authorization, and initial formalities, such as declaration and registration, must be simple and easy to apply. If fees are charged for the registration or establishment of an organization, they must be reasonable and designed only to cover strictly necessary administrative costs.¹⁵⁷
- Registration requirements as to the minimum number of members comply with Article 5 if the number is reasonable and presents no obstacle to the founding of organizations.¹⁵⁸
- Domestic law may restrict participation in various consultation and collective bargaining procedures to certain representative trade unions, subject to certain criteria being met.¹⁵⁹
- The right to strike may be restricted, provided that any restriction satisfies the conditions laid down in Article G, which outlines the circumstances that can justify limitation of rights guaranteed by the charter. Any limitation must serve a legitimate purpose and be necessary in a democratic society for the protec-

151 COE. Conclusions VIII . Statement of Interpretation on Article 5.

152 COE. Conclusions: Denmark. (XV-1).

153 COE. Conclusions 2004: Bulgaria.

154 COE. Conclusions: Germany. (XII -2).

155 COE. Conclusions: United Kingdom. (XVII).

156 COE. Conclusions: France. (XV-1).

157 COE. Conclusions: United Kingdom. (XV-1).

158 COE. Conclusions: Portugal. (XIII -5).

159 COE. Conclusions: Belgium. (XV-1); Conclusions: France. (XV-1).

tion of the rights and freedoms of others or for the protection of public interest, national security, public health, or morals.¹⁶⁰

- Prohibiting strikes in sectors that are essential to the community is deemed to serve a legitimate purpose, as strikes in these sectors could pose a threat to public interest, national security, and/or public health. Simply banning strikes, however, even in essential sectors—particularly when they are extensively defined, for example, as “energy” or “health”—is not deemed proportionate to the specific requirements of each sector. At most, the introduction of a minimum service requirement in these sectors might be considered in conformity with Article 6(4).¹⁶¹

► **Article 19(4) ESC: The right of migrant workers and their families to protection and assistance**

With a view to ensuring the effective exercise of the right of migrant workers and their families to protection and assistance in the territory of any other Party, the Parties undertake: ... (4) to secure for such workers lawfully within their territories, insofar as much matters are regulated by law or regulations or are subject to the control of administrative authorities, treatment not less favorable than that of their own nationals in respect of the following matters: ... (b) membership of trade unions and enjoyment of the benefits of collective bargaining.

► **Article 6 ESC: The right to bargain collectively**

With a view to ensuring the effective exercise of the right to bargain collectively, the Parties undertake: (1) to promote joint consultation between workers and employers; (2) to promote, where necessary and appropriate, machinery for voluntary negotiations between employers or employers’ organisations and workers’ organisations, with a view to the regulation of terms and conditions of employment by means of collective agreements; (3) to promote the establishment and use of appropriate machinery for conciliation and voluntary arbitration for the settlement of labour disputes; and recognise: (4) the right of workers and employers to collective action in cases of conflicts of interest, including the right to strike, subject to obligations that might arise out of collective agreements previously entered into.

- Public officials enjoy the right to strike under Article 6(4). Prohibiting all such officials from exercising the right to strike is not permissible. The right of certain categories of public officials to strike may be restricted, however. Under Article G, these restrictions should be limited to public officials whose duties and functions, given their nature or level of responsibility, are directly related to national security or to the general public interest.¹⁶²

160 COE. Conclusions: Norway. (X-1). Regarding Article 31 of the charter.

161 COE. Conclusions I. Statement of Interpretation on Article 6§4; Confederation of Independent Trade Unions in Bulgaria, Confederation of Labour “Podkrepa” and European Trade Union Confederation v. Bulgaria. (32/2005). Decision on the merits of October 16, 2006.

162 Ibid.

- A strike should not be considered a violation of the contractual obligations of the striking employees, constituting a breach of their employment contract; participation should be accompanied by a prohibition of dismissal. If strikers are fully reinstated when the strike has ended and their previously acquired entitlements (for example, pensions, holidays and seniority) are not affected, then formal termination of the employment contract does not violate Article 6(4).¹⁶³ Any deduction from strikers' wages should not exceed the proportion of their wage that would be attributable to the duration of their strike participation.¹⁶⁴ Workers who are not members of the striking trade union but participate in the strike are entitled to the same protection as the trade union members.¹⁶⁵

► **Article 21 ESC: The right to information and consultation**

With a view to ensuring the effective exercise of the right of workers to be informed and consulted within the undertaking, the Parties undertake to adopt or encourage measures enabling workers or their representatives, in accordance with national legislation and practice: (a) to be informed regularly or at the appropriate time and in a comprehensible way about the economic and financial situation of the undertaking employing them, on the understanding that the disclosure of certain information which could be prejudicial to the undertaking may be refused or subject to confidentiality; and (b) to be consulted in good time on proposed decisions which could substantially affect the interests of workers, particularly on those decisions which could have an important impact on the employment situation in the undertaking.

► **Article 22 ESC: The right to take part in the determination and improvement of the working conditions and working environment**

With a view to ensuring the effective exercise of the right of workers to take part in the determination and improvement of the working conditions and working environment in the undertaking, the Parties undertake to adopt or encourage measures enabling workers or their representatives, in accordance with national legislation and practice, to contribute: (a) to the determination and the improvement of the working conditions, work organisation and working environment; (b) to the protection of health and safety within the undertaking; (c) to the organisation of social and socio-cultural services and facilities within the undertaking; (d) to the supervision of the observance of regulations on these matters.

163 COE. Conclusions I. Statement of Interpretation on Article 6§4.

164 COE. Conclusions: France. (XIII -1); Confédération Française de l'Encadrement (CFE CGC) v. France. (16/2003). Decision on the merits of 12 October 2004.

165 COE. Conclusions: Denmark. (XVIII -1).

► Article 11 ECHR: Freedom of assembly and association

(1) *Everyone has the right to freedom of peaceful assembly and to freedom of association with others, including the right to form and to join trade unions for the protection of his interests.*

- The right to form and join trade unions is a subdivision of freedom of association and is not a special and independent right under Article 11.¹⁶⁶
- Article 11 does not explicitly guarantee any particular treatment of trade unions, such as the right to be consulted by the government or to strike.¹⁶⁷ Trade unions, however, should be heard and be permitted to take action to protect the occupational interests of their members.¹⁶⁸
- This protection can include the right to strike which may only be limited under certain circumstances.¹⁶⁹

RIGHT TO DUE PROCESS AND RELATED RIGHTS

Health providers have rights to due process when complaints about their conduct are lodged against them. The ECtHR has provided extensive interpretation of the right to a fair hearing, which is protected in Article 6 of the ECHR. It is clear that this right covers matters such as licensing and medical negligence suits against a hospital.

Administrative proceedings do not necessarily need to comply with Article 6, provided that, at some point, there is an opportunity to appeal at some point to a judicial process that does adhere to Article 6 standards. Similarly, legal proceedings do not need to meet fair trial standards at each stage of the process. Rather, courts will assess whether the proceedings, taken together as a whole, constitute a fair trial.

This section discusses four aspects of due process and related rights: the interpretation of the right to a fair hearing in Article 6(1) of the ECHR; the guarantee of effective remedy articulated in Article 13 of the ECHR; the protection of privacy and reputation in Article 8 of the ECHR; and the protection of freedom of expression and information in Article 10 of the ECHR.

It should be noted that there is no explicit right to information under the ECHR, and Article 10 (freedom of expression) offers only very limited protection in relation to information. There is no right to impart information and the right to receive has been narrowly interpreted.

Freedom of expression can be restricted legitimately, through application of Article 8, to protect the rights and reputation of others. For example, the media does not have an absolute right to publish unwarranted attacks on public officials.

166 *National Union of Belgian Police v. Belgium*. (1 EHRR 578).

167 *Schmidt and Dahlstrom v. Sweden*. (1 EHRR 632).

168 *National Union of Belgian Police v. Belgium*. (1 EHRR 578).

169 *Wilson and Ors v. UK*. (35 EHRR 20). Court found violation of Article 11 where law permitted an employer to derecognize trade unions for collective bargaining purposes and to offer inducements to employees to relinquish some of their union rights.

Right to a Fair Hearing

EXAMPLES OF POTENTIAL VIOLATIONS

- A doctor facing a disciplinary hearing is denied the opportunity to contest the allegations made against him
- A disciplinary body decides, without explanation, that all of its hearings should take place in private
- A nurse's disciplinary hearing takes more than three years to complete, during which time she is suspended

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 6(1) ECHR: Right to a fair hearing

In the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law. Judgment shall be pronounced publicly but the press and public may be excluded from all or part of the trial in the interests of morals, public order or national security in a democratic society, where the interests of juveniles or the protection of the private life of the parties so require, or to the extent strictly necessary in the opinion of the court in special circumstances where publicity would prejudice the interests of justice.

- Article 6(1) of the ECHR applies to the determination of civil rights or criminal charges. It also covers all related proceedings between the state and the individual or between private parties, the result of which is “decisive” for civil rights and obligations.¹⁷⁰
- *In König v. Federal Republic of Germany*, the court found: “Whether or not a right is to be regarded as civil ... must be determined by reference to the substantive contents and effects of the right—and not its legal classification—under the domestic law of the State concerned.”¹⁷¹
- A merely investigative procedure will not engage Article 6(1),¹⁷² even though pretrial proceedings may be determinative of civil rights and obligations under certain circumstances.¹⁷³

170 Ringeisen v. Austria. (1 EHRR 466).

171 König v. Federal Republic of Germany. (2 EHRR 170).

172 Fayed v. UK. (18 EHRR 393).

173 Brennan v. UK. (34 EHRR 50).

- The ECtHR has confirmed that civil rights and obligations are implicated in disciplinary proceedings that determine the right to practice a profession. The ECtHR was ruling on claims brought by medical professionals in these cases.¹⁷⁴ Licensing decisions are also covered.¹⁷⁵
- Article 6(1) will usually apply where an individual claims compensation from a public authority for an unlawful act provided there is a right to such compensation. Medical negligence proceedings against a hospital have been held to be covered.¹⁷⁶
- Disputes relating to private law relations between private employers and employees do fall within the scope of Article 6(1).¹⁷⁷ As a general rule, however, disputes relating to the employment of public servants fall outside of it.¹⁷⁸
- In civil proceedings a litigant has the right to:
 - real and effective access to a court;
 - notice of the time and place of the proceedings;¹⁷⁹
 - a real opportunity to present his/her case;
 - a reasoned decision.
- There is no express requirement for legal aid in civil cases. In order to give effect to the right of access and the need for fairness, however, some assistance may be required in certain cases.¹⁸⁰
- Entitlement to present one's case effectively is not as strong in the civil context as it is in the criminal context. There is no automatic requirement to be present and to have an oral hearing. The principle of the "equality of arms" does apply, however,¹⁸¹ and can be violated by mere procedural inequality.¹⁸²
- The same principle applies to the submissions of nonparties to the proceedings.¹⁸³
- Both parties have a right to be informed of the other's submissions, other written material and to have a right to reply.¹⁸⁴ Disclosure is crucial for a fair hearing.¹⁸⁵

174 *Konig v. Germany*. (2 EHRR 170). Concerning the revocation of the applicant's permission to practice as a doctor in proceedings before the Tribunal for the Medical Profession; *Wickramsinghe v. UK*. (31503/96).

175 *Konig v. Germany*. (2 EHRR 170). Disciplinary proceedings led to the withdrawal of the applicant's licence to run a medical clinic.

176 *H v. France*. (12 EHRR 74).

177 *Obermeier v. Austria*. (13 EHRR 290).

178 *Lombardo v. Italy*. (21 EHRR 188).

179 *De La Pradelle v. France*. (A 253-B).

180 *Airey v. Ireland*. (2 EHRR 305); *P and Ors v. UK*. (35 EHRR 31).

181 *Ruiz-Martin v. Spain*. (16 EHRR 505).

182 *Fischer v. Austria*. (ECHR 33382/96).

183 *Van Orshoven v. Belgium*. (26 EHRR 55). Breach of Article 6(1), where applicant, who had been struck off the medical register following disciplinary proceedings, was given no prior notice of submission by the advocate-general intended to advise the court.

184 *Dombo Beheer B. V. v. The Netherlands*. (18 EHRR 213).

185 *Ruiz Torija v. Spain*. (19 EHRR 55).

- Although there is no obligation on a court to obtain an expert report merely because one party seeks it,¹⁸⁶ where an expert is appointed, there must be compliance with the equality of arms principle.¹⁸⁷
- In order to comply with the obligation to give a reasoned decision, the court or tribunal does not need to provide a detailed answer to every argument, but needs to address the essential issues in the case.¹⁸⁸
- A decision-making disciplinary or administrative process does not need to comply with Article 6 at all stages, provided it is subject to appeal and/or judicial review.¹⁸⁹
- Similarly, even where an adjudicatory body is not impartial and independent, it will not breach Article 6(1) if its deliberations are subject to control by a body that has the power to quash its decision.¹⁹⁰
- The right to a public hearing includes disciplinary hearings of professionals.¹⁹¹
- Determining whether a hearing has been held within a reasonable time will depend upon a number of relevant factors, including the complexity of the case, the applicant's conduct, and the importance of what is at stake for the applicant.¹⁹² The time period begins at the moment when proceedings are instituted¹⁹³ and does not end until all matters – including appeals and determination of costs – have been completed.¹⁹⁴

Right to an Effective Remedy

EXAMPLES OF POTENTIAL VIOLATIONS

- No damages are awarded to a doctor after his reputation is damaged by unsubstantiated and false accusations of medical negligence that appear in the media
- A nurse is unable to appeal an employment tribunal decision to a court

186 *H v. France*. (12 EHRR 74).

187 *Mantovanelli v. France*. (24 EHRR 370). Claimants in medical negligence case had not been given an opportunity to give instruction to court-appointed expert.

188 *Helle v. Finland*. (26 EHRR 159).

189 *Le Compte v. Belgium*. (5 EHRR 533). The Court of Cassation's review of a medical disciplinary body was insufficient for Article 6(1) as the court did not "take cognisance" of the merits of the case, as many aspects fell outside of its jurisdiction.

190 *Kingsley v. UK*. (35 EHRR 10).

191 *Diennet v. France*. (21 EHRR 554). Concluding that misconduct hearing of a general practitioner should have been in public, except in the event that a confidential private or professional matter arose in the proceedings.

192 *Gast and Popp v. Germany*. (33 EHRR 37).

193 *Scopelliti v. Italy*. (17 EHRR 493); *Darnell v. UK* (18 EHRR 205). The total period of nine years—for the determination of the dismissal of the applicant from a health authority following several judicial review applications, an industrial tribunal hearing, and an Employment Appeal Tribunal hearing—was considered unreasonable.

194 *Somjee v. UK*. (36 EHRR 16).

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 13 ECHR: Right to an effective remedy

Everyone whose rights and freedoms as set forth in this Convention are violated shall have an effective remedy before a national authority notwithstanding that the violation has been committed by persons acting in an official capacity.

- According to the terms of Article 13, the availability of a remedy must include the determination of the claim and the possibility of redress.¹⁹⁵ All procedures, including judicial and nonjudicial, will be examined.¹⁹⁶
- Formal remedies that prevent examination of the merits of the claim, including, judicial review, may not comply with Article 13.¹⁹⁷
- The nature of the remedy required to satisfy the obligation under Article 13 will depend upon the nature of the alleged violation. In most cases, compensation will suffice. In all cases the remedy must be “effective” in both practice and law, meaning that there must not be undue interference by state authorities.¹⁹⁸
- The authority with the ability to provide the remedy must be independent of the body alleged to have committed the breach.¹⁹⁹

Right to Protection of Privacy and Reputation

EXAMPLES OF POTENTIAL VIOLATIONS

- The phone of a hospital’s chief executive is bugged without any prior lawful authorization
- A doctor involved in a civil suit against a hospital for unfair dismissal finds out that his correspondence has been routinely intercepted and read without his knowledge

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► Article 8 ECHR: Privacy and reputation

(1) Everyone has the right to respect for his private and family life, his home and his correspondence. (2) There shall be no interference by a public authority with

¹⁹⁵ Klass v. Germany. (2 EHRR 214).

¹⁹⁶ Silver v. UK. (5 EHRR 347).

¹⁹⁷ Peck v. UK. (36 EHRR 41).

¹⁹⁸ Aksoy v. Turkey. (23 EHRR 553).

¹⁹⁹ Khan v. UK. (31 EHRR 45); Taylor-Sabori v. UK. (36 EHRR 17).

the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

- The term “private life”, within the context of Article 8 of the ECHR can extend to an individual’s office, offering protection, for example, against the unlawful bugging of telephone calls.²⁰⁰ Protection can extend to certain behavior and activity that takes place in public, depending on whether the individual had a “reasonable expectation of privacy” and whether that expectation was voluntarily waived.²⁰¹ It had been held, however, that private life is not engaged by “real time” closed-circuit television if no images are recorded, although once a systematic record is made or the image is processed in some way it will be engaged.²⁰²

► **Article 10(2) ECHR: Limiting free expression to protect rights and reputation of others**

The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.

Right to Freedom of Expression and Information

EXAMPLES OF POTENTIAL VIOLATIONS

- A senior health service manager is dismissed after revealing that a hospital has been purchasing unlicensed drugs
- State authorities intervene to prevent employees from receiving information that their hospital contains dangerously high levels of radiation

HUMAN RIGHTS STANDARDS AND RELEVANT INTERPRETATIONS

► **Article 10(1) ECHR: Freedom of expression including information**

Everyone has the right to freedom of expression. This right shall include free-

200 Halford v. UK. (20605/92). Concluding that bugging of private telephone calls made to an office telephone could constitute a breach of Article 8.

201 Von Hannover v. Germany. (43 EHRR 7).

202 Peck v. UK. (36 EHRR 41).

dom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.

- There is no right to impart information under Article 10 of the ECHR. The right to receive information has been narrowly interpreted as prohibiting the authorities from restricting a person from receiving information that others may wish to impart. The state has no positive obligation to collect and disseminate information on its own motion.²⁰³
- Civil servants, insofar as they should enjoy public confidence, can be protected from “offensive and abusive verbal attacks”. Even in such cases, however, civil servants have a duty to exercise their powers by reference to professional considerations only, without being unduly influenced by personal feelings.²⁰⁴

203 Guerra and Ors v. Italy. (26 EHRR 357).

204 Yankov v. Bulgaria. (39084/97).

4

International and Regional Procedures

4.1 Treaties and enforcement mechanisms

International and regional human rights mechanisms play an important role in the implementation of rights. These mechanisms were established to enforce governments' compliance with the international and regional human rights treaties they have ratified. These treaties make up the so-called "hard law" of international human rights, and the interpretations of the treaty mechanisms make up "soft law" that is not directly binding on governments. There are two main types of enforcement mechanisms:

- ▶ **courts, which act in a judicial capacity and issue rulings that are binding on governments in the traditional sense; and**
- ▶ **committees, which examine reports submitted by governments on their compliance with human rights treaties and, in some cases, examine individual complaints of human rights violations.**

4.2 The international system

Human Rights Committee

MANDATE

The Human Rights Committee (HRC) oversees government compliance with the International Covenant on Civil and Political Rights (ICCPR). The HRC has two mandates: to monitor country progress on the ICCPR by examining periodic reports submitted by governments and to examine individual complaints of human rights violations under the Optional Protocol to the ICCPR.

CIVIL SOCIETY PARTICIPATION

NGOs can submit “shadow reports” to the HRC on any aspect of a government’s compliance with the ICCPR. Shadow reports should be submitted through the HRC Secretariat based at the Office of the High Commissioner for Human Rights (OHCHR) in Geneva, which also keeps a calendar of when governments come before the committee. The HRC meets three times a year. Individuals and NGOs can also submit complaints to the HRC under the Optional Protocol.

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Committee on Economic, Social, and Cultural Rights

MANDATE

The Committee on Economic, Social, and Cultural Rights (CESCR) oversees government compliance with the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The CESCR monitors country progress on the ICESCR by examining periodic reports submitted by governments.

CIVIL SOCIETY PARTICIPATION

NGOs can submit “shadow reports” to the CESCR on any aspect of a government’s compliance with the ICESCR. Shadow reports should be submitted through the CESCR Secretariat based at the Office of the High Commissioner for Human Rights (OHCHR) in Geneva, which also keeps a calendar of when governments come before the committee. The CESCR meets twice a year.

CONTACT

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Committee on the Elimination of Racial Discrimination

MANDATE

The Committee on the Elimination of Racial Discrimination (CERD) is the body of independent experts that monitors implementation of the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) by states. It monitors country progress on ICERD by examining periodic reports submitted by governments. The committee then addresses its concerns and recommendations to the country in the form of “concluding observations”. Besides commenting on country reports, CERD monitors state compliance through an early-warning procedure and through the examination of interstate and individual complaints.

CIVIL SOCIETY PARTICIPATION

NGOs can submit “shadow reports” to the CERD on any aspect of a government’s compliance with the ICERD. Shadow reports should be submitted through the CERD Secretariat based at the Office of the High Commissioner for Human Rights (OHCHR) in Geneva, which also keeps a calendar of when governments come before the committee. CERD meets twice a year.

CONTACT

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Fax: +41.22.917.90.22
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Web:

International Labour Organization

MANDATE

The International Labour Organization (ILO), located within the United Nations, is primarily concerned with respect for human rights in the field of labor. In 1989, they adopted the Convention concerning Indigenous and Tribal Peoples in Independent Countries. States must provide periodic reports on their compliance with the convention to the ILO and to national employers’ and workers’ associations. National employers’ and workers’ associations may submit comments on these reports to the ILO. The ILO Committee of Experts (CE) evaluates the reports and may send “Direct

Requests” to governments for additional information. The CE then publishes its “observations” in a report, which is presented at the International Labour Conference. On the basis of this report, the Conference Committee on the Application of Standards may decide to more carefully analyze certain individual cases and publishes its conclusions.

Additionally, an association of workers or employers may submit a representation to the ILO alleging that a member state has failed to comply with the convention, and a member state may file a complaint against another member state.

CIVIL SOCIETY PARTICIPATION

The convention encourages governments to consult indigenous peoples in preparing their reports. Indigenous peoples may also affiliate with a workers’ association or form their own workers’ association in order to more directly communicate with the ILO. The CE meets in November and December of each year, and the International Labour Conference is held in June.

CONTACT

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Web: www.ilo.org/public/english/index.htm

Committee on the Elimination of All Forms of Discrimination Against Women

MANDATE

The Committee on the Elimination of All Forms of Discrimination Against Women oversees government compliance with the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW). The committee has three mandates: to monitor country progress on CEDAW by examining periodic reports submitted by governments; to examine individual complaints of violations of women’s rights under the Optional Protocol to CEDAW; and to conduct missions to state parties in the context of concerns about systematic or grave violations of treaty rights.

CIVIL SOCIETY PARTICIPATION

NGOs can submit “shadow reports” to the committee on any aspect of a government’s compliance with CEDAW. Shadow reports should be submitted through the Division for the Advancement of Women in New York, which also keeps a calendar of when governments come before the committee. The committee meets twice a year. Individuals and NGOs can also submit complaints to the committee under the Optional Protocol, or they can encourage the committee to undertake country missions as part of its inquiry procedure.

CONTACT

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Email: changt@un.org
Web: <http://www.un.org/womenwatch/daw/cedaw/cedaw38/NGOnote.pdf>

Committee on the Rights of the Child

MANDATE

The Committee on the Rights of the Child oversees government compliance with the Convention on the Rights of the Child (CRC). It monitors country progress on the CRC by examining periodic reports submitted by governments.

CIVIL SOCIETY PARTICIPATION

NGOs can submit “shadow reports” to the committee on any aspect of a government’s compliance with the convention. Shadow reports should be submitted through the CRC Secretariat based at the Office of the High Commissioner for Human Rights (OHCHR) in Geneva, which also keeps a calendar of when governments come before the committee. The committee meets three times a year.

CONTACT

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UN Charter bodies

In addition to the treaty bodies listed above, there are a number of bodies created for the protection and promotion of human rights under the Charter of the United Nations.

The principal charter body is the Human Rights Council (HRC), which replaced the Commission on Human Rights (CHR) in 2006. The HRC is a subsidiary organ of the United Nations General Assembly with a mandate “to address situations of violations of human rights, including gross and systematic violations.”

The responsibilities of the HRC include: the Universal Periodic Review (UPR); the Special Procedures; the Human Rights Council Advisory Committee (formerly the Sub-

Commission on the Promotion and Protection of Human Rights); and the Complaints Procedure. These responsibilities are summarized at: <http://www2.ohchr.org/english/bodies/hrcouncil/>

UNIVERSAL PERIODIC REVIEW (UPR)

Beginning in 2008, the HRC will periodically review the human rights obligations and commitments of all countries. All UN member states will be reviewed for the first time within four years. A working group will meet for two weeks, three times per year, to carry out the review. The review will take into account a report from the state concerned, as well as recommendations from the Special Procedures and Treaty Bodies, and information from nongovernmental organizations and national human rights institutions.

SPECIAL PROCEDURES

“Special Procedures” is the general term given to individuals (known as Special Rapporteurs, Special Representatives, or Independent Experts) or groups (known as Working Groups) that are mandated by the HRC to address specific country situations or thematic issues throughout the world. The HRC currently includes 28 thematic and 10 country Special Procedures.

Special Procedures activities include responding to individual complaints, conducting studies, providing advice on technical cooperation at the country level, and engaging in general promotional activities. The Special Procedures are considered “the most effective, flexible, and responsive mechanisms within the UN system.”

Special Procedures cited in this guide include:

- Working Group on Arbitrary Detention
- Special Rapporteur on Extrajudicial, Summary, or Arbitrary Executions
- Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health
- Special Rapporteur on Violence against Women, its Causes and Consequences
-

For more information about the Special Procedures, see: <http://www.ohchr.org/english/bodies/chr/special/index.htm>

HUMAN RIGHTS COUNCIL ADVISORY COMMITTEE

The Human Rights Council Advisory Committee functions like a think tank, providing expertise and advice and conducting substantive research and studies on issues of thematic interest to the HRC at its request. The committee is made up of 18 experts who serve in their personal capacity for a period of three years.

COMPLAINTS PROCEDURE

This confidential complaints procedure allows individuals or organizations to bring complaints about “gross and reliably attested violations of human rights” to the attention of the HRC. The procedure is intended to be “victims oriented” and is expected to conduct investigations in a timely manner. Complaints are reviewed by two working groups that meet for five days at least twice a year.

ECONOMIC AND SOCIAL COUNCIL

The UN Economic and Social Council (ECOSOC) coordinates the work of 14 specialized UN agencies, functional commissions, and regional commissions working on various international economic, social, cultural, educational, and health matters. The ECOSOC holds several short sessions per year and an annual substantive session for four weeks every July.

The ECOSOC consults regularly with civil society, and nearly 3,000 NGOs enjoy consultative status. ECOSOC-accredited NGOs are permitted to participate, present written contributions, and make statements to the council and its subsidiary bodies. Information about NGOs with consultative status can be found at:

<http://www.un.org/esa/coordination/ngo/>.

ECOSOC agencies and commissions that may be cited in or may be relevant to this guide include the following:

- Commission on the Status of Women
- Commission on Narcotic Drugs
- Commission on Crime Prevention and Criminal Justice
- Committee on Economic, Social and Cultural Rights
- International Narcotics Control Board

4.3 The European system

European Court of Human Rights

MANDATE

The European Court of Human Rights (ECtHR), a body of the Council of Europe (COE), enforces the provisions of the European Convention on Human Rights (ECHR). The ECtHR adjudicates both disputes between states and complaints of individual human rights violations. The Committee of Ministers of the Council of Europe is responsible for monitoring the implementation of judgments made by the ECtHR. (See note on Committee of Ministers below.)

CIVIL SOCIETY PARTICIPATION

Any individual or government can lodge a complaint directly with the ECtHR alleging a violation of one of the rights guaranteed under the convention, provided they have exercised all other options available to them domestically. An application form may be obtained from the ECtHR website (www.echr.coe.int/echr/).

The COE has established a legal aid scheme for complainants who cannot afford legal representation. NGOs can file briefs on particular cases either at the invitation of the president of the court, or as *amici curiae* (“friends of the court”) if they can show that they have an interest in the case or special knowledge of the subject matter and can also show that their intervention would serve the administration of justice. The hearings of the ECtHR are generally public.

CONTACT

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Web: www.echr.coe.int

European Committee of Social Rights

MANDATE

The European Committee of Social Rights (ECSR), also a body of the COE, conducts regular legal assessments of government compliance with provisions of the European Social Charter (ESC). These assessments are based on reports submitted by governments at regular two-to four-year intervals known as supervision cycles. The governmental committee and the Committee of Ministers of the Council of Europe also evaluate government reports under the ECSR. (See note on Committee of Ministers below.)

CIVIL SOCIETY PARTICIPATION

Reports submitted by governments under the ESC are public and may be comment-

ed upon by individuals or NGOs. International NGOs with consultative status with the COE and national NGOs authorized by their government, may also submit collective complaints to the COE alleging violations of the charter.

CONTACT

Web: www.humanrights.coe.int/cseweb/GB/index.htm

Committee of Ministers

The Committee of Ministers (www.coe.int/cm) is the decision-making body of the COE. It is composed of the foreign ministers of all COE member states (or their permanent representatives).

In addition to supervising judgments of the ECtHR and evaluating reports under the ECSR, the Committee of Ministers also makes separate recommendations to member states on matters for which the committee has agreed to a “common policy”—including matters related to health and human rights.

Some of these recommendations are provided by the Parliamentary Assembly of the Council of Europe (assembly.coe.int), which is a consultative body composed of representatives of the parliaments of member states.

Advisory Committee

MANDATE

The Advisory Committee (AC) assists the Committee of Ministers in monitoring compliance with the Framework Convention for the Protection of National Minorities (FCNM). It monitors country progress on the FCNM by examining periodic reports submitted by governments. Besides examining these reports, the AC may hold meetings with governments and request additional information from other sources. The AC then prepares an opinion, which is submitted to the Committee of Ministers. Based on this opinion, the Committee of Ministers issues conclusions concerning the adequacy of measures taken by each state party. The AC may be involved by the Committee of Ministers in the monitoring of the follow-up to the conclusions and recommendations.

CONTACT

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 Fax: +33/(0)3.90.21.49.18
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 Web: www.coe.int/minorities

CIVIL SOCIETY PARTICIPATION

NGOs can submit “shadow reports” to the AC on any aspect of a government’s compliance with the FCNM. Shadow reports should be submitted through the FCNM Secretariat. (http://www.coe.int/t/dghl/monitoring/minorities/2_Monitoring/NGO_Intro_en.asp)

4.4 Complaint Procedure: European Convention on Human Rights

This section excerpts and updates information from the publication *Reported Killings Human Rights Violations* by Kate Thompson and Camille Giffard (published by the Human Rights Centre, University of Essex).

TABLE: BASIC FACTS ON THE EUROPEAN COURT OF HUMAN RIGHTS

Origin:	How was it created?	By the 1950 European Convention on Human Rights, revised by Protocol 11 to that convention, 1994
	When did it become operational?	In 1998, under the revised system
Composition:	How many persons is it composed of?	As many judges as there are states parties to the convention
	are these persons independent experts or state representatives?	Independent experts
Purpose:	General objective	To examine complaints of violation of the eCHR
	Functions	Interstate complaints (compulsory) (article 33, eCHR)
		Individual complaints (compulsory) (article 34, eCHR)
		Fact finding (in the context of individual complaints only and an optional step in the procedure)

WHAT ARE THE ADMISSIBILITY REQUIREMENTS?

A communication will be declared inadmissible if:

- the communication is anonymous;
- the communication has not been submitted within six months of the date of the domestic authorities' final decision in the case;
- the communication is manifestly ill founded or an abuse of the right of petition;
- the communication is incompatible with the provisions of the Convention

- the application is substantially the same as one that has already been considered by the court or as another procedure of international investigation and contains no new and relevant information;
- domestic remedies have not been exhausted, except where the remedies are ineffective or unreasonably prolonged.

As of June 1, 2010, in accordance with Protocol 14 to the eCHR (Council of Europe treaty series no. 194), a new admissibility requirement allows the court to declare inadmissible applications where the applicant has not suffered a significant disadvantage, unless respect for human rights requires an examination of the application on the merits and provided that no case may be rejected on this ground that has not been duly considered by a domestic tribunal (article 12 of Protocol 14, amending article 35 of the eCHR). In order to avoid rejection of cases warranting an examination on the merits, single-judge formations and committees will not be able to apply this new criterion for the first two years after the entry into force of Protocol 14 (article 20 of the protocol).

WHAT SHOULD YOUR APPLICATION CONTAIN?

Your initial letter should contain:

- a brief summary of your complaints;
- an indication of which convention rights you think have been violated;
- an indication of the remedies you have used;
- a list of the official decisions in your case, including the date of each decision, who it was made by, and an indication of what it said (attach a copy of each of these decisions).
- if you later receive an application form, you should follow the instructions on that form and in the accompanying letter.

TABLE: BASIC CHRONOLOGY OF INDIVIDUAL COMPLAINT PROCEDURE TO THE ECHR

Your initial letter, containing brief summary information, is sent to the court

•

You may be asked for further information; if it appears that there may be a case, you will be sent an application form

•

Upon receipt, your completed application is registered and brought to the attention of the court

•

The allegations are communicated to the government, which is asked to submit its observations on the admissibility of the application

•

You reply to the government's observations

•

The court decides if the application is admissible

(Sometimes, the court may hold an admissibility hearing)

•

Possibility of friendly settlement

•

Parties are asked to submit any further observations on the merits or additional evidence

•

The court considers the merits and adopts a judgment, possibly after an oral hearing

•

The court usually decides the question of just satisfaction when it makes its judgment, but could choose to do so at a later date instead

•

The state party must execute the judgment under the supervision of the Committee of ministers of the Council of Europe

TABLE: PRACTICALITIES OF USE OF INDIVIDUAL COMPLAINT PROCEDURE TO THE ECHR

Who can bring a case under this procedure?	Individuals, NGOs, and groups of individuals claiming to be victim of a human rights violation; a case can be brought by a close relative of the victim where the victim cannot do so in person, for example, if he or she has disappeared or died
Is there a time limit for bringing an application?	Six months from the date of the final decision taken in the case by the state authorities
Can you bring a case under this procedure if you have already brought one under another procedure concerning the same set of facts?	No
Do you need legal representation?	Legal representation is not necessary at the time of the application, but is required for proceedings after the case has been declared admissible, unless the president of the court gives exceptional permission for the applicant to present his or her own case
Is financial assistance available?	Yes, but only if the application is communicated to the government; the applicant will need to fill out a statement of means, signed by a domestic legal aid board, as legal aid is only granted where there is a financial need
Are amicus curia briefs accepted?	Yes, with permission (Rule 61 of the Rules of Court)
Who will know about the communication?	In principle, the proceedings are public unless the President of the Chamber decides otherwise. In exceptional cases, where an applicant does not wish his or her identity to be made public and submits a statement explaining the reasons for this, anonymity may be authorized by the president.
How long does the procedure take?	Several years
What measures, if any, can the mechanism take to assist the court in reaching a decision?	Fact-finding hearings, expert evidence, written pleadings, and oral hearings
Are provisional or urgent measures available?	Yes, but they are practices that have been developed by the court and have no basis in the convention and are applied only in very specific cases, mainly immigration/ deportation cases, where there is a "real risk" to a person (Rule 39 of the Rules of Court)

HELPFUL GUIDELINES

- Under the original procedure, which was replaced in 1998, the initial stages of the case took place before the European Commission on Human Rights. If you are researching a particular topic under the convention case law, remember to search for reports by the commission and also for court judgments.
- If the six-month period within which an application must be submitted is about to expire, and there is no time to prepare a full application, you can send a “stop the clock” application with a short summary of your complaint, which should be followed by the complete application as soon as possible.
- For the purpose of respecting the deadlines set by the court, keep in mind that the court considers the date of posting—not the date of receipt—as determinative. It is advisable, however, to notify the court on the day of the deadline that the submission has been posted, either via email or telephone or by faxing a copy of the application cover letter.
- The court may, on its own initiative or at the request of one of the parties, obtain any evidence it considers useful to the case, including by holding fact-finding hearings. Where such measures are requested by one of the parties, that party will normally be expected to bear the resulting costs, although the chamber may decide otherwise. If you do not wish to bear such costs, it is advisable to word your letter carefully—for example, suggest to the court that it might wish to exercise its discretion to take measures to obtain evidence.
- The court carries out most of its regular work in chambers of seven judges. Where a case is considered to raise a serious issue or might involve a change in the views of the court in relation to a particular subject, it can be referred to a grand chamber of 17 judges. Where a case has been considered by a chamber and a judgment delivered, it is possible, in exceptional cases, to request within three months of the judgment that the case be referred to the grand chamber for reconsideration (Rule 73 of the Rules of Court).
- As of June 1, 2010, in accordance with Protocol 14 to the eCHR (article 6), the court will carry out its regular work in the following structures: (1) a single-judge formation, assisted by a nonjudicial rapporteur from the registry, will be able to declare inadmissible or strike out an individual application in clear-cut cases, where the inadmissibility of the application is manifest from the outset (article 7 of Protocol 14 of the eCHR, which will become article 27); (2) Three-judge committees will rule, in a simplified procedure, on both the admissibility and the merits of an application in cases where the underlying question falls under the already well-established case law of the court, that is, those cases consistently applied by a chamber (article 8 of Protocol 14, which will become article 28 of the eCHR); (3) Seven-judge chambers will rule, through joint decisions, on both the admissibility and merits of individual applications that have not been considered under articles 27 or 28 (article 9 of the

Protocol 14, amending current article 29 of the eCHR); (4) a seventeen-judge grand chamber will rule on cases referred by one chamber and raising a serious question about the interpretation of the convention or its protocols, or where the resolution of a question before the chamber might have a result inconsistent with a judgment previously delivered by the court (articles 30 and 31 of the eCHR).

- In accordance with Protocol 14 to the eCHR, the Council of Europe Commissioner for Human Rights may submit written comments and take part in hearings in all cases before a chamber or the grand chamber (article 13, amending article 31 of the eCHR). This factor becomes significant in cases where the commissioner's experience may help the court by highlighting structural or systemic weaknesses in the respondent or other high-contracting parties (article 13 of the protocol).
- It is possible to request the interpretation of a judgment within one year of its delivery (Rule 79 of the Rules of Court). It is also possible to request, within six months of the discovery, the revision of a judgment if important new facts are discovered that would have influenced the court's findings (Rule 80 of the Rules of Court).

5

Country-Specific Notes

5.1 Status of International and Regional Law

Republic of Macedonia has signed and ratified a number of international and regional documents, one part of which is already transposed into the national legislation. In the table on the next page, there is a list of some of these documents that are related to healthcare, especially related to patients' rights and responsibilities, as well as providers' rights and responsibilities.

5.2 Specifics of the National Legal System

Adoption of the Constitution of the Republic of Macedonia resulted in establishing the Republic of Macedonia as an independent and sovereign state. Like most European democracies, Republic of Macedonia has opted for constitutionalism. The provisions pertaining to individual rights and freedoms in the Constitution of the Republic of Macedonia¹ are very similar to those in the Constitutions of other European countries. The Constitutional provisions in this segment have been inspired by the international and regional human rights instruments. Rights and freedoms proclaimed in the Constitution have been rightfully considered as maybe its greatest quality and an evidence of the degree of democratization achieved in the Republic of Macedonia. Promotion, enhancement and protection of basic human rights and freedoms are among the highest political commitments of the Republic of Macedonia. On a national level, this commitment entails consistency in the implementation of policies accepted regionally and globally, which have been transposed into international human rights instruments.

1 Official Gazette of the Republic of Macedonia No. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

Article 8 of the Constitution of the Republic of Macedonia includes, among the fundamental values of the Constitutional order, the basic freedoms and rights of the individual and citizen, recognized in international law and determined with the Constitution, as well as the respect of the generally accepted international legal norms. Rights and freedoms guaranteed by the Constitution of the Republic of Macedonia and by the ratified international acts have been incorporated into the domestic legislation and are enjoyed by all persons under the jurisdiction of the Republic of Macedonia. Their exercise is conducted directly, on the basis of the Constitution and conditions and manners of their exercise may be prescribed by a law only if explicit constitutional authority exists thereto and only within such authority.

In Chapter II governing the Basic Rights and Freedoms, the Constitution of the Republic of Macedonia includes civil and political rights, as well as economic, social and cultural rights. In the system and the substance of fundamental freedoms and rights, the Constitution corresponds fully with the solutions incorporated into the ratified international human rights conventions.

In the segment of **civil and political rights**, the Constitution, among other, guarantees the right to life, right to liberty and security of the person, respect of private and family life, and guarantees the freedom of conviction, conscience, thought and public expression of thought, speech, public address and public information, equality of citizens before the law, and irrevocability of the physical and moral integrity of a person through prohibition of torture, inhuman or degrading treatment or punishment, slavery or forced labor.

In the segment of **economic, social and cultural rights**, the Constitution, among other, guarantees the right to work, as well as the rights deriving from employment, occupational safety and the right to health insurance.

An integral part of the legal reform has been the analysis of the harmonization of the domestic legislation with international standards. In that respect, ratification of the conventions for the Republic of Macedonia has been not only a formal obligation and a goal for itself, but also an initiation of a continuous process of implementation of international standards at a national level.

Regarding the protection of the existing rights protected by the Constitution, there are a number of mechanisms illustrated in Chapter 8 of this Guide. Briefly, besides the regular courts, citizens may also exercise direct protection of freedom and rights before the Constitutional Court of the Republic of Macedonia. Namely, pursuant to Article 110, paragraph 1, subparagraph 3 of the Constitution of the Republic of Macedonia, the Constitutional Court protects the freedoms and rights of the individual and citizen relating to the freedom of conviction; conscience; thought and public expression of thought; political association and activity; and the prohibition of discrimination of citizens on the grounds of gender, race, religious, ethnic, social or political affiliation.

In the legal system of the Republic of Macedonia, the relation between the domestic

and the international law is a constitutional issue and has been regulated in line with the monistic theory. Pursuant to Article 118 of the Constitution, international treaties ratified in accordance with the Constitution are a part of the domestic legal order and may not be changed by law. Consequently, within the hierarchical structure of legal norms, international treaties stand above the domestic legislation.

Most of the international instruments, Republic of Macedonia inherited by succession from the former federation (SFRY).

The Government has played an important role in the implementation and the monitoring of the obligations under international acts. However, bearing in mind the direct application of international acts in the domestic legal system, the judiciary has been awarded key role. The constitutional concept of the rule of law, therefore, insists on the independent position of courts before which, by applying ordinary procedural and legal means in a fair procedure, the protection of basic rights and freedoms has been exercised as well as control over political authorities through law. The unbreakable link has been emphasized between the remedies for protection of a right and the right itself. Apart from the regular courts, an important role in the protection of human rights has been awarded to the Constitutional Court of the Republic of Macedonia, the Ombudsman and the Standing Inquiry Committee for Protection of Civil Freedoms and Rights within the Assembly of the Republic of Macedonia.

Organization of state power: The state power in the Republic of Macedonia functions on the basis of its separation into legislative (the Assembly of the Republic of Macedonia), executive (the President of the Republic of Macedonia and the Government of the Republic of Macedonia) and judicial power.

Judicial power is exercised by the courts. The courts are autonomous and independent state organs and judge on the basis of the Constitution, the laws and the international acts ratified in accordance with the Constitution. There is a single form of organization for the judiciary and extraordinary courts are prohibited.

The organizational structure, working and jurisdiction of the courts, besides the Constitution, is regulated with number of laws of which most important are the Law on Courts², Law on the Judicial Budget³, the Law on the Judicial Council of the Republic of Macedonia⁴ etc.

Characteristic of the judicial system in Republic of Macedonia is that it has accepted the Continental Model, instead of the Common Law or the Case Law Model. The delivery of the court's ruling is awarded to the independence and the competence

2 Official Gazette of the Republic of Macedonia No. 58/06, 62/06, 35/08

3 Official Gazette of the Republic of Macedonia No. 60/03, 37/06, 103/08

4 Official Gazette of the Republic of Macedonia No. 60/06, 69/06

of a single judge or judicial council, instead to the jury that decides for someone's guilt in the common law system. As a admixture from the common law, in Republic of Macedonia in certain cases it's regulated that rulings are delivered by a council of professional judges and jury-judges, where jury-judges are not professional judges. It's Courts responsibility to lead the process and deliver rulings on the basis of provisions of law that were applicable when the concerned legal matter took place. Protection of the rights is conducted based on the Constitution, law or ratified international acts. In application of the law, a judge is not bound by a superior court's legal opinion or a previous ruling. A judge renders unbiased rulings on the basis of his/her free judgment of evidence and application of law. Rulings of the court are not legally binding for judges (or the judicial council) for the equivalent of making such decisions in the same cases. Thus, in each separate proceeding the court examines the evidence and does not make reference to previous rulings of the court.

Because of this in Republic of Macedonia there is no case study as it is known in the common law.

6

National Patients' Rights and Responsibilities

6.1 Patients' Rights

1. Right to Preventive Measures

a. Right as stated in the European Charter of Patients' Rights (ECPR)¹

Every individual has the right to a proper service in order to prevent illness. The health services have the duty to pursue this end by raising people's awareness, guaranteeing health procedures at regular intervals free of charge for various groups of the population at risk, and making the results of scientific research and technological innovation available to all.

b. Right as stated in national laws/legislation

The Constitution of the Republic of Macedonia² is explicit in guaranteeing the right to healthcare (defined in the Law on Healthcare) to every citizen (Article 39).

According to Article 32 of the Law on Healthcare,³ all Macedonian citizens shall be provided with general preventive measures that enable a healthy environment, and with physical examinations and other measures and activities (e.g.: immunization) for the prevention of illnesses (e.g.: brucellosis, tuberculosis, AIDS, infectious diseases).

1 European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

2 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

3 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

The provision of general preventive measures is possible through special programs drafted each year by government, and through financing from the state budget.

In accordance with the **Law on Health Insurance**,⁴ persons with health insurance have the right to access basic services under certain conditions defined by the law (Article 8). Basic healthcare services include the provision of preventive measures (Article 9, Para. 1, Point 6).

c. Specific supporting laws and regulations

According to the **Law on the Protection of Patients' Rights**,⁵ the protection of patients' rights "provides quality and continuous healthcare" (Article 2). The Law on Healthcare regulates the principles of healthcare.

The right to access to healthcare is based on the "continuity of healthcare, including cooperation among all healthcare providers, health associates and/or healthcare facilities which can be included in the entire process of treating certain condition or illness of the patient" (the principle of availability, as written in Article 3, Para. 3, Line 2).

"Medical intervention" means any medical check-up, treatment, or other activity with a **preventive**, diagnostic, therapeutic purpose or for the purpose of rehabilitation undertaken by authorized healthcare provider (Article 4, Para. 1, Point 2, written in accordance with Article 14, which establishes the right to accept or deny medical intervention).

According to the **Law on Mental Health**⁶, the treatment of persons suffering from mental disabilities shall be based on best practices, treatment, and rehabilitation in accordance with the latest developments in the field and within the framework of available resources that are adequate to the specific needs of the individual. The protection measures may not include any form of psychological or physical abuse, and they shall be administered with complete respect to the dignity of the person. Furthermore, such measures must be in the best interest of the mentally disabled individual (Article 3).

The **Law on Population Protection against Diseases**⁷ outlines measures for the prevention, early detection, containment, and eradication of infectious diseases (Article 1).

The **Law on Drugs and Medical Devices**⁸ establishes rigorous registration systems and tight controls for the issuance of both prescription and non-prescription drugs in order to be able to control and prevent adverse reactions to drugs.

4 Official Gazette of the Republic of Macedonia, no. 25/00, 34/00, 96/00, 50/01, 11/02, 31/03, 84/05, 37/06, 18/07, 36/07, 82/08, 98/08, 6/09, 67/09

5 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

6 Official Gazette of the Republic of Macedonia, no. 71/06

7 Official Gazette of the Republic of Macedonia, no. 66/04, 139/08, 99/09

8 Official Gazette of the Republic of Macedonia, no. 106/07

The **Law on Food Safety and Safety of Products and Materials in Contact with Food**⁹ protects people's health (Article 1) through the establishment of food safety regulations and sanitary standards for products and materials in contact with food during its production and distribution. The law also outlines the rights and responsibilities of legal and physical entities involved in food production and distribution.

The **Law on Cosmetic Products Safety**¹⁰ enumerates **health safety** standards for the production and distribution of cosmetic products (Article 1).

The **Law on Safety and Health of Work**¹¹ establishes occupational health and safety standards and defines employers' and employees' rights and responsibilities in this area. The law also sets forth **preventive measures to minimize professional risks and eliminate risk factors** through informing, consulting, training employees and their representatives and involving these parties in the planning and introduction of measures on occupational health safety (Article 1).

The **Law on Blood Safety**¹² stipulates that blood and blood components must meet rigorous quality and safety standards **in order not to endanger the life and health of blood and blood product recipients** (Article 20, Point 1).

The **Law on Biomedically Assisted Reproduction**¹³ establishes the right to biomedical assistance in reproduction; sets conditions for exercising one's right to biomedical assistance in reproduction; creates **safety standards** for the donation, supply, testing, processing, storage, distribution, and application of cells used in biomedically assisted reproduction; defines the rights and responsibilities of patients, health-care professionals, and healthcare facilities in biomedically assisted reproduction; and establishes requirements for conducting and supervising biomedically assisted reproduction (Article 1).

Biomedically assisted reproduction (BAR) must be conducted in a manner that preserves the human rights, dignity, and privacy of donors and recipients of germinative cells and sperm cells (Article 2, Para. 1).

The **Law on Safety of Products**¹⁴ requires the safety of all commercially available products **prior to their distribution and following their purchase**. The law protects consumers and other users of the products, the public interest, **the health and safety of the population**, and property, animals, plants, and the environment (Article 2).

The **Anti-Smoking Law**¹⁵ aims to protect citizens and the environment from the harmful effects of tobacco and tobacco products by prohibiting smoking in certain public facilities and banning the advertisement of cigarettes (Article 1).

9 Official Gazette of the Republic of Macedonia, no. 54/02 and 84/07

10 Official Gazette of the Republic of Macedonia, no. 55/07

11 Official Gazette of the Republic of Macedonia, no. 92/07

12 Official Gazette of the Republic of Macedonia, no. 110/07

13 Official Gazette of the Republic of Macedonia, no. 37/08

14 Official Gazette of the Republic of Macedonia, no. 33/06, 63/07

15 Official Gazette of the Republic of Macedonia, no. 36/95, 70/03, 29/04, 37/05, 103/08, 140/08

The **Law on Ionizing Radiation Protection and Safety**¹⁶ establishes a **control system for all radiation sources and contains measures for the protection of the population and environment from a real or potential ionizing radiation exposure** (Article 1).

The **Law on Preventing Harmful Noise**¹⁷ is designed to promote **healthy living and environmental conditions by reducing harmful noise** (Article 2, Para. 1, Line 1).

d. Relevant international/regional regulations

Human rights include civil, cultural, economic, political and social rights. These rights have been established under conventional international law and are imbedded in the principles of the Universal Declaration of Human Rights (UDHR)¹⁸.

Human rights are determined by two legally binding international covenants: the International Covenant on Economic, Social, and Cultural Rights (ICESCR)¹⁹ and the International Covenant on Civil and Political Rights (ICCPR).²⁰ These documents enumerate several rights related to health, including the right to health.

Other international documents and regulations codify the rights of women, children, religious and ethnic minorities, and persons with illnesses (e.g.: HIV/AIDS) and mental or physical disabilities. According to the World Health Organization (WHO), “[h]ealth is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.”²¹ In the absence of this definition, **the other rights make little sense.**²² The good health of the population and the prevention of illness and disease in that context are essential elements of human rights. Health is human right, and protecting the right to health is one of society’s main responsibilities. Realization of the right to health enables the exercise of other fundamental rights, and the protection of human rights allows for the opportunity to lead a safer and healthier life; therefore it may be assumed that human rights and public health are interconnected and are in continuous interplay. This point of view encapsulates the human rights-centered approach to public health, which places equal emphasis on processes (i.e.: the way human rights are incorporated into the healthcare system) and outcomes (i.e.: the extent to which a population’s health has improved). The synergy of health and human rights means that people can ensure their own well-being only through systematic efforts to protect and promote other relevant human rights within the framework of the healthcare system and their right to health.

16 Official Gazette of the Republic of Macedonia, no. 48/02, 135/07

17 Official Gazette of the Republic of Macedonia, no. 79/07

18 Universal Declaration of Human Rights, December 10, 1948 the General Assembly of the United Nations

19 International Covenant on Economic, Social, and Cultural Rights (ICESCR), December 19, 1966

20 International Covenant on Civil and Political Rights (ICCPR), December 19, 1966

21 Preamble to the Constitution of the World Health Organization, as adopted by the International Health Conference, New York on June 19-22, 1946; signed on July 22, 1946 by the representatives of 61 states (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on April 7, 1948.

22 Steven D. Jamar. The International Human Right to Health. Southern University Law Review 22 (Fall 1994): 1-68, citing UN Doc. A/CONF. 32/8.

The right to health is embedded in numerous international instruments. Article 25.1 of the Universal Declaration of Human Rights states: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services...." Article 12.1 of the International Covenant on Economic, Social, and Cultural Rights²³ is thorough in this regard, as it obliges signatory states to "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." Specific obligations to promote the health of certain social groups (e.g.: women, children) are set forth in other international agreements and declarations. The Committee on Economic, Social, and Cultural Rights (CESCR) notes in its General Comment 14 (which interprets Article 12 from the aforementioned Covenant) that the right to health is closely connected to exercising other human rights.²⁴ These rights include "the right to food, shelter, work, education, dignity of the human person, life, non-discrimination, equality, freedom from torture, privacy, access to information, and right to association and movement." Nevertheless, when governments ban or violate certain human rights (which are not absolute) in order to promote and protect public health, then their actions must be in accordance with the Syracuse Principles, which hold that any acts restricting basic freedoms (e.g.: the freedom of movement) must be made in accordance with the law. Furthermore, such actions must be proven as a legitimate method to protect the public interest, and they may not interfere with the functions of a democratic society.²⁵ According to the principles, government-imposed limitations must be as unrestrictive as possible in order to accomplish the desired goal, and they cannot be discriminatory in nature or imposed arbitrarily. (UNECOSOC 1985).

e. Relevant provisions of healthcare providers' codes of ethics

According to Article 107 of the **Code of Ethics of the Macedonian Chamber of Medicine**,²⁶ a doctor must act in accordance with international humanitarian doctrine when providing prevention, treatment, or rehabilitation services.

The **Code of Ethics of the Macedonian Chamber of Medicine** also obliges doctors and other healthcare professionals to promote healthcare education by helping people achieve a higher quality of life (Article 38) and educating the population about first aid techniques for use in the event of an emergency (Article 39, Para. 1).

The **Code of Professional Ethics of the Macedonian Pharmacists' Obligations and Rights**²⁷ states that "the pharmacist has to contribute to the healthcare education and increase healthcare awareness of the people. He has to help prevent all that endangers person's health..." (Article 6).

23 International Covenant on Economic, Social and Cultural Rights (ICESCR), December 19, 1966

24 General Comment No. 14 (2000), The right to the highest attainable standard of health 11/08/2000. E/C.12/2000/4. (General Comments)

25 United Nations, Economic and Social Council, Syracuse Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, U.N. Doc. E/CN.4/1985/4, Annex (1985).

26 Available at: <http://http://www.lkm.org.mk/akti/kodeks.htm>

27 Available at: http://http://www.farmaceutskakomora.com/index.php?option=com_content&task=view&id=19&Itemid=34

In its code of ethics,²⁸ the Dental Chamber of Macedonia defines the code of dental ethics and dentology as the system of ethical norms which acts as a baseline for the mutual obligations of the dental profession and society. The code of ethics is intended to protect and improve people's health; it demands rigorous professionalism during the treatment of patients and the holds every dental worker to high standards of integrity (Article 1, Para. 2).

g. Examples and case studies

1) Examples of compliance

Example 1.1

A healthcare professional regularly conducts preventive examinations in facilities that undergo mandatory inspections in accordance with the Law on Protection of Population against Communicable Diseases.²⁹

Example 1.2

A patient attends regular (annual) examinations for the early detection of breast cancer under the Program for Early Detection, Diagnosis, and Treatment of Breast Cancer in the Republic of Macedonia, a free preventive program administered by the Ministry of Health,

Example 1.3

Regular physical examinations of students under the Physical Examination Program for Pupils and Students in the Republic of Macedonia, a mandatory and free preventive program administered by the Ministry of Health.

2) Examples of violations

The most striking examples of violations in the field of preventive care are in the area of infectious disease prevention.

Example 1.4

A parent refuses to vaccinate his child against an infectious disease for which immunization is required by law. The child becomes ill and experiences further complications (e.g.: an unvaccinated, pregnant female who contacts rubella in the early terms of her pregnancy may give birth to a child with congenital malformations). An unvaccinated child can also spread disease to other persons, as in the case of a parotitis epidemic in Macedonia in 2008.

Example 1.5

A pharmaceutical producer distributes a medication without the necessary registration. A patient uses the medication and experiences harmful effects to her/his health.

²⁸ Available at: <http://stomatoloskakomora.org/?strana=statut>

²⁹ Official Gazette of the Republic of Macedonia, no. 66/04, 139/08, 99/09

3) Actual cases

Case study 1.1

Due to a lack of immunization or the poor quality of available vaccines, an epidemic of parotitis occurred in Macedonia in 2008 among persons born in the years 1988 and 1989. The epidemic struck five large cities. Additional immunizations were given to children and young persons in 2009.

(Source: Ministry of Health of the Republic of Macedonia).

Case study 1.2

Thirty residents of a Macedonian city suffered methanol poisoning after ingesting contaminated homemade alcohol. The alcohol was withdrawn and according to regulation, there is basis for criminal investigation.

(Source: Ministry of Health of the Republic of Macedonia).

Case study 1.3

Due to improper health and sanitary control measures and the negligence of an employee in the food-processing industry, 20 people were poisoned after eating contaminated food.

(Source: Ministry of Health of the Republic of Macedonia).

In such cases, both the employer and employee are held responsible for violating regulations for the prevention of communicable diseases.

Case study 1.4

In accordance with legislation and preventive programs administered by the Ministry of Health and financed directly from the state budget, every child has the right to comprehensive immunization, regardless of his or her health insurance status. However, in some Roma communities, children have never received any kind of immunization; this is due to the fact that most Roma children are not enrolled in the Macedonian education system. In addition, the births of some Roma children were never registered in the state record. Despite the efforts of preventive healthcare and immunization teams, not all Roma children can be immunized. As such, their right to preventive measures has been violated, and they are at risk of spreading vaccine-preventable diseases.

(Source: HCAR Mesecina)

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to preventive measures.

Under the administrative procedure, subjects seeking to exercise their rights or whose rights have been violated file a case with the responsible administrative body or with the body which has the public authority. The actual steps that must be undertaken are described first in the specific law regulating the legal issue, whereas the

Law on General Administrative Procedure³⁰ is used in cases dealing with legal situations that are not regulated by separate specific laws (Article 3, Para. 2).

Chapter 8 of this guide describes the administrative procedure in more detail. While an administrative procedure is pending review by state government bodies or other bodies and organizations with public authority, patients may request that the Ombudsman protect their rights. Such requests may be submitted in response to a protracted administrative procedure or when one's rights are violated through the actions or neglect of the aforementioned bodies. In case a court procedure has been initiated, the Ombudsman does not act according to complaint. For more information, see the section titled "Alternative mechanisms for protection/exercising of rights and obligations" in Chapter 8 of this guide.

A misdemeanor charge may be filed by the responsible government body,³¹ either as part of a regular investigation, upon the claim of an authorized civil servant, or upon the claim of an authorized civil servant in conjunction with the aggrieved party. This kind of procedure may be initiated when misdemeanor responsibility is enumerated in a specific law, for physical person, legal person and the individual of the legal person, responsible for violation of the right regulated and guaranteed under the specific law in question. Misdemeanor bodies are the courts, and public institutions and other institutions authorized for public responsibilities, authorized for pronouncement of misdemeanor sanctions, and which authority is regulated in separate law.

If a misdemeanor violation of one's rights contains elements of a criminal case, the responsibility is considered criminal. The elements that must be present in order to open a criminal case are enumerated either in the specific law regulating the issue or in the Criminal Code of the Republic of Macedonia.³² For the procedure determining the criminal responsibility, see details in Chapter 8.

If a misdemeanor violation of one's rights has caused material or non-material damage, then responsibility for such damage is determined under civil procedure. This procedure is described in Chapter 8.

31 The responsible body, in terms of the Law on Misdemeanors (Official Gazette of the Republic of Macedonia, no. 62/06 and 69/06), are the Public Prosecutor, the bodies of the state administration and local government, and other bodies that perform a public duty and are authorized to execute or supervise of execution of misdemeanor law. The responsible bodies are responsible for making a request to open a misdemeanor case every time there is reasonable doubt that misdemeanor has been committed.

32 Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

2. Right to Access

a. Right as stated in the ECPR³³

Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services. An individual requiring treatment, but unable to sustain the costs, has the right to be served free of charge.

Each individual has the right to adequate services, independently of whether he or she has been admitted to a small or large hospital or clinic.

Each individual, even without a required residence permit, has the right to urgent or essential outpatient and inpatient care.

An individual suffering from a rare disease has the same right to the necessary treatments and medication as someone with a more common disease.

b. Right as stated in national laws/legislation

According to Article 3, Point 3 of the **Law on the Protection of Patients' Rights**,³⁴ the principle of availability is based on the following:

- 1) "healthcare services constantly **available and accessible to all patients on equal basis and without discrimination**;
- 2) continuity of healthcare, including cooperation among all healthcare providers, health associates and/or healthcare facilities that can be included in the entire process of treating certain condition or illness of the patient;
- 3) just and fair procedure for choosing/selecting the treatment, under conditions when there is a possibility for healthcare facilities to choose potential patients for special treatment available in limited scope, whereby the selection has to be based on medical criteria, without discrimination;
- 4) choosing and changing the healthcare provider and healthcare facility within the healthcare system;
- 5) **availability of home treatment services**, i.e. services in the community where the patient lives and
- 6) **equal possibility for protection of the rights** for all patients on the territory of the Republic of Macedonia."

According to Article 5, Point 2 of the **Law on the Protection of Patients' Rights**, "the patient shall have the right to exercise the rights stipulated by this law **without any discrimination** based on gender, race, skin color, language, religion, political or any other affiliation, national or social background, national minority background, material status, status by birth, sexual orientation or any other status."

³³ European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

³⁴ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

c. Specific supporting laws and regulations

The **Law on Healthcare**³⁵ stipulates citizens' right to healthcare and outlines the healthcare management system. According to Article 3 of the law, "every person has the **right to protection of health.**" Equal access to healthcare is guaranteed by the additional implementation of 15 state-financed preventive and curative programs that are adopted annually by the government and are based on the Law on Healthcare. These programs are separate from regular healthcare programs financed through the health insurance system.

The **Law on Health Insurance**³⁶ determines the meaning of "health insurance for the citizens, the rights and responsibilities arising from the health insurance, the way in which health insurance is provided" (Article 1). Health insurance is required for all Macedonian citizens with a determined healthcare services package; and may be acquired voluntarily to cover healthcare services that are not included in the healthcare services package (Article 2). According to the law, health insurance must cover a number of aspects (Article 5) in order to provide mandatory health insurance to all citizens, without regard to their financial means, place of living, type of illness, or the time needed to access healthcare services. For cases in which a person does not have health insurance due to justifiable reasons, the state provides the necessary healthcare services through a program for persons without health insurance.

According to the Law on Health Insurance, coverage of basic healthcare services provided by primary care physicians and specialists, during medical consultations, or in hospital settings (short-term and long-term) also includes certain medications that are selected by the Health Insurance Fund under a general regulation approved by the Minister of Health. The Fund also determines "...supporting materials describing the application of medications, sanitary, and other material needed for treatments" (Article 9, Points A-8 and C-2).

Within the framework of basic healthcare services, the section regarding specialist-consultative healthcare grants beneficiaries the right to "prosthetic, orthopedic and other devices, supporting and sanitary equipment and materials, dental devices. The equipment and materials covered under the law are defined in the Fund's general act, which is approved by the Minister of Health" (Article 9, Para. 1, Point B-3).

Other relevant information:

One may exercise his right to orthopedic equipment by seeking confirmation of a device's medical necessity from a physician specializing in the relevant field. The stamped confirmation is submitted in the regional offices of the Health Insurance Fund.

35 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

36 Official Gazette of the Republic of Macedonia, no. 25/00, 34/00, 96/00, 50/01, 11/02, 31/03, 84/05, 37/06, 18/07, 36/07, 82/08, 98/08, 6/09, 67/09

Based on the stamped confirmation of the need for an orthopedic device, a person with health insurance acquires the device from a company that produces and sells orthopedic equipment.

If a person with health insurance wishes to acquire a non-standard orthopedic device, he must sign a statement requesting such non-standard orthopedic device. The patient must also cover the difference in cost between the standard and non-standard device.

A patient may use ambulance services in non-emergency situations if he is injured, immobile, or has limited mobility, and therefore cannot use public transport. The need for ambulance services is determined by one's chosen physician or by an attending physician at the appropriate healthcare.

A patient may use ambulance services in cases when he exercise the right to receiving healthcare abroad as suggested by Consiliar committee for directing patients to be treated abroad or as suggested by the attending physician in the healthcare facility.

According to the **Law on Mental Health**,³⁷ “a person with mental illness seeking treatment or rehabilitation has the right to receive care at a level that is equal to the standard of care given for the treatment and rehabilitation of other types of illness” (Article 8).

In accordance with the **Law on the Protection of Patients' Rights**,³⁸ genetic intervention “directed towards alteration of the human genome may be undertaken only for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants” (Article 21, Para. 1). Genetic screening and predisposition testing may be performed only for medical purposes or for scientific research linked to medical purposes, or to provide the subject with appropriate genetic counseling (Article 21, Para. 2).

The Law on the Termination of Pregnancy,³⁹ **the Law on Biomedically Assisted Reproduction**,⁴⁰ **the Law on Conditions of Extraction, Exchange, Transportation and Transplantation of Parts of Human Body for Treatment Purposes**,⁴¹ **and the Law on Blood Safety**⁴² also aim to establish safety conditions that enable equal access to adequate healthcare services (abortion, biomedically assisted reproduction, organ transplantation, blood safety).

d. Relevant international/regional provisions

See the section titled “Right to Preventive Measures: Relevant international/regional provisions.”

37 Official Gazette of the Republic of Macedonia, no. 71/06

38 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

39 Official Gazette of the Republic of Macedonia, no. 19/77, 15/95

40 Official Gazette of the Republic of Macedonia, no. 37/08

41 Official Gazette of the Republic of Macedonia, no. 30/95, 139/08

42 Official Gazette of the Republic of Macedonia, no. 110/07

e. Relevant provisions of healthcare providers' codes of ethics

According to the **Code of Ethics of the Macedonian Chamber of Medicine**,⁴³ “doctors are responsible for providing emergency medical aid in accordance with their level of proficiency and for taking further care of persons in distress” (Article 6). “A doctor is involved in patients’ admission, treatment, rehabilitation, and discharge, and must take into consideration each patient’s disabilities at birth or acquired disabilities” (Article 14).

Article 7 of the **Code of Ethics of the Dental Chamber of Macedonia**⁴⁴ states that “the dentist is responsible for providing appropriate dental service and must respect the patient’s human dignity in the process.”

Articles 14 through 19 of **Code of Professional Ethics of Macedonian Pharmacists’ Obligations and Rights**⁴⁵ require pharmacists to provide professional care and attention to all citizens, to counsel and communicate appropriately with patients, and to enable citizens’ easy access to quality pharmaceutical care.

Other relevant sources:

Other regulations from healthcare legislation guarantee patients’ right of access to healthcare and require non-discrimination in the provision of healthcare. These regulations may be viewed as applications of the right to access healthcare services, as guaranteed by the Constitution.

See also: “Right to Preventive Measures: Supporting specific laws and regulations”

Non-discrimination is a crucial issue in the realization of patients’ rights. Although no administrative, civil, or criminal suits have been filed yet on charges of discrimination, the issue should be taken into consideration, and discrimination must be viewed as violation of human rights. Specific to the field of healthcare, discrimination should be viewed a violation of the general right to access healthcare services without regard to one’s age, gender, ethnicity, type of illness or infirmity, geographic location, or financial status, among other identifiers. Therefore, it is important to emphasize that Macedonian law includes non-discriminatory clauses in order to prevent discrimination. However, not all clauses are consistent with each other, and some are rather general; these clauses continue to be violated in practice.

Non-discrimination clauses pertaining to healthcare legislation can be found in the following documents:

- **the Constitution of the Republic of Macedonia**,⁴⁶ which states that “every person has the right to healthcare protection” (Article 39, Para. 1);

43 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

44 Available at: <http://www.stomatoloskakomora.org/?strana=statut>

45 Available at: http://www.farmaceutskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

46 Official Gazette of the Republic of Macedonia no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

- **the Law on Healthcare**,⁴⁷ which states that “every person has the right to healthcare” (Article 3, Para. 1);

- **the Law on Mental Health**,⁴⁸ which states that “discrimination is any kind of isolation, exclusion, separation or other treatment, which will have an effect of harming or violating the equality of exercising the rights, except in cases determined by law” (Article 4) and that “the person suffering from mental illness has the right to protection from any kind of molestation, degradation, and abuse and the person must not be discriminated on grounds of his mental health” (Article 7);

- **the Law on Occupational Safety and Health**,⁴⁹ which holds that “all regulations arising from it are applied in all practices in the public and private sector for all persons with insurance covering workplace-related accidents or professional illnesses, according to regulations on pension, disability, and health insurance, and for all other persons included in work processes” (Article 2, Point 1);

- **the Law on Biomedically Assisted Reproduction (BAR)**,⁵⁰ which states that “the right to use the BAR procedure is available to all adult, work-capable men and women, which apart from the reasons of using the BAR procedure, Article 3 from this law, are married or in a out-of-wedlock partnership and are capable, according to their age and general health, of providing parental care.” The law also states that “marriage or out-of-wedlock partnership in Article 3, Paragraph 1 must be valid at the moment of conducting the BAR procedure. Adult, work-capable women that are not in a marriage or in out-of-wedlock partnership have the right to use the BAR procedure...” (Article 9).

Apart from these clauses, relevant non-discrimination clauses exist in criminal law and in the social sphere, as the areas also involve patients' rights (e.g.: equality in the realization of patients' rights in social protection programs and in court procedures).

The Law on Equal Opportunities of Women and Men⁵¹ is also important in the appropriate realization of the patients' rights. The law states: “Any form of discrimination against a person on grounds of gender in public and private sector in the area of employment and labor, education, social security, culture and sport is prohibited in accordance with this or other law” (Article 2).

f. Examples and case studies

1) Examples of compliance

Usually, healthcare providers give appropriate healthcare to patients, in accordance with the regulations and codes of ethics governing the work of the healthcare providers.

47 Official Gazette of the Republic of Macedonia no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

48 Official Gazette of the Republic of Macedonia no. 71/06

49 Official Gazette of the Republic of Macedonia, no. 92/07

50 Official Gazette of the Republic of Macedonia, no. 37/08

51 Official Gazette of the Republic of Macedonia, no. 66/06, 117/08

Example 2.1

A patient calls his primary care physician to report a certain health condition. The chosen physician conducts or orders appropriate diagnostic procedures, and accordingly the patient continues his medical treatment in an out-patient care or is admitted to a hospital.

For example, a patient visits his personal (chosen) physician with a complaint of pain on the left side of the chest and in the left arm. The physician conducts an ECG of the patient and orders laboratory testing of a blood sample.

Another example could involve a patient who visits his chosen physician and reports problems in the lower back; the physician refers the patient to a laboratory for blood and urine testing and performs an x-ray of the lower spinal area.

Example 2.2

In case of a need for urgent medical assistance, a healthcare provider in a hospital provides the necessary healthcare services to the patient. Acting in accordance with the patient's wishes, the healthcare provider communicates with his parents, spouse, adult children, guardian, or representative regarding payment for healthcare services based on the patient's insurance status.

For example, a patient suffering from acute appendicitis is admitted to a hospital and surgery is performed. After surgery (i.e. removing the causes for the acute condition), it is determined that the patient does not have health insurance. The healthcare facility advises the patient to apply for financing of his treatment under the Program for Persons Without Health Insurance Coverage and Foreigners, which is financed from the state budget and implemented by the Ministry of Health.

Example 2.3

A good practice involving patients' right to select or change healthcare providers or facilities within the healthcare system is the fact that almost all patients in Macedonia choose their own general practitioner. Patients have the right to change their chosen physician if they are not satisfied with the level of treatment provided by the doctor.

2) Examples of violations

Example 2.4

A physician working with a Roma partner directs all Roma patients to his colleague. No justifiable grounds exist for the doctor to direct Roma patients to his colleague. In this respect, the physician violates patients' right to choose their own physician, and he discriminates against patients on the grounds of their ethnicity.

Example 2.5

A dentist refuses to provide service to an HIV-positive patient.

Example 2.6

A hospital refuses to provide emergency care to a patient who lacks health insurance documents.

Example 2.7

Another example of a violation of the right to access healthcare services is the use of waiting lists, which contradicts the principles of the Law on the Protection of Patients' Rights. Namely, when there is unfair procedure regarding the choice of treatment, when there is a possibility for the healthcare facilities to choose potential patients for special treatment for a limited number of patients, where the choice is not based on medical criteria without discrimination. This is especially emphasized as a deviation of the possibility for health providers' secondary activity, based on the Law on Healthcare⁵².

Example 2.8

Patients suffering from mental illnesses still do not receive treatment entirely within the community in which they live; this is due to number of complex factors, including recent reforms in the mental healthcare system. The majority of mental health patients are directed to special psychiatric hospitals, even when there is no reason to do so. Furthermore, some patients remain in psychiatric hospitals on a long-term basis, despite a lack of medical indications; they are not transferred to community mental health centers.

3) Actual cases

Case study 2.1

A patient requested mediation in a dispute with a dentist acting as a service provider. The dentist charged the patient 1800 euros for providing the patient with a set of false teeth. The dentist refused to give the patient a receipt for payment, explaining that he had his own internal payment system. When she was being fitted for the prosthesis, the patient realized that the device was made improperly and was causing her pain. The dentist then destroyed the device. The patient requested that the doctor return her payment within one week. Initially, the dentist agreed to the request, but on the date that the money to be returned, he expelled the patient from his office and physically assaulted the patient's spouse. The patient then asked the Consumer Organization of Macedonia (COM) to assist her in reclaiming the payment and requested that the Dental Chamber initiate disciplinary procedures against the dentist.

The Dental Chamber refused COM's mediation offer and asked the patient to contact the chamber personally. The patient decided to seek justice through the court system.
(Source: COM)

Case study 2.2

A patient was dissatisfied with a dentist's quality of care and level of proficiency when providing prosthetics services. Following an intervention, the patient experienced complications and went to the Maxillofacial Surgery Clinic, which found that the fillings were poorly made. The patient has requested that the dentist return 750 euros and 4,900 denars for dental cavity fillings.

(Source: COM)

52 Official Gazette of the Republic of Macedonia no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

In such cases, one can file a criminal complaint against a dental care provider for the unprofessional treatment of patients (Article 207 of the Criminal Code⁵³). A patient may also seek compensation for damages through the court system if a settlement is not reached with the dentist.

Case study 2.3

A specialist physician working in a Skopje hospital directed a patient to purchase medical electrodes from a medical supply company. The electrodes were not used in the patient's treatment, but the patient's attempt to return the electrodes to the company was unsuccessful. The patient then asked for reimbursement from the Health Insurance Fund but was told that he could not be reimbursed for materials that were not used for the treatment of a medical condition.

The State Market Inspectorate intervened, and the company eventually reimbursed the patient. The patient is dissatisfied with the suffering caused by this procedure. (Source: COM)

Case study 2.4

A patient submitted a complaint protesting the refusal of a regional office of the Health Insurance Fund to reimburse the cost of medications required for an in vitro procedure. The office explained that the medication was not on the Positive List of Medications for patients over 40 years old (according to existing rules, in vitro medications are on the Positive List of Medications only for women under the age of 40). The patient filed a motion before the Constitutional Court of the Republic of Macedonia, challenging the lawfulness of the Positive List of Medications covered by the Health Insurance Fund (2007) and alleging discrimination on the grounds of age. As a result, the Constitutional Court outlawed the Positive List of Medications.

(Source: COM)

Case study 2.5

A doctor directed members of a patient's family to purchase a medicine at a particular pharmacy at a certain time. The patient had recently undergone a heart operation, and according to the doctor, the medicine in question was necessary to stabilize the patient's condition. The price of the medicine was 12,000 denars (approx. 200 euros), and it could be purchased only at that particular pharmacy. The patient's family asked the doctor whether he could prescribe an alternative medication that was less costly or that could be covered under an insurance plan. The doctor adamantly refused, saying that "financial aspects are not important when it is a matter of life or death." The family purchased the medicine but received no official receipt. The medication lacked a label, and the patient information sheet was written in Greek with no Macedonian translation.

53 Official Gazette of the Republic of Macedonia no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

The family filed a motion before the Drug Bureau, asking whether it was possible to substitute the medication with one that was less costly or could be covered by insurance. The Bureau answered that “the contents of the purchased medication is like any other antiinflammatory drug, acetylsalicylic acid.”

(Source: COM)

Case study 2.6

A patient was using a medication necessary to sustain his life. He had a prescription for the medication, and even though it was on the Positive List of Medications, he could not find the medication for sale under reimbursement conditions in any pharmacy. The patient purchased the medication from abroad, which further complicated the reimbursement procedure; the Health Insurance Fund covered only 50% of the cost.

(Source: COM)

The Ombudsman has intervened in a few instances to reconcile differences in a medication's reference price, which is determined and recognized by the Health Insurance Fund, and the actual price paid by the patient. The interventions are intended to protect certain classes of patients from paying high prices for medications; this is especially true for patients undergoing constant and long-term therapy (they are exempt from paying for drugs due to the character of their illness). The problem has not yet been resolved, although certain measures have been undertaken to remedy the situation.

Case study 2.7

A patient required a continuous supply of cytostatics. The medication was on the Positive List of Medications but was rarely found in pharmacies. The patient purchased the medication independently, but the Health Insurance Fund covered only 2,329 denars worth of the total 6,565-denar bill (approx. 110 euro).

(Source: COM)

Case study 2.8

A patient suffering from breast cancer underwent medical treatment and rehabilitation. A specialist physician then directed the patient to purchase a silicone prosthesis from an orthopedic company. The patient had health insurance, and according to healthcare legislation, she only had to pay for 10% of the total cost of the orthopedic device. In this case, the total cost was of the prosthetic device was 3,070 denars (approx. 50 euro), meaning that the patient should have paid only 307 denars; however, she was charged 1,000 denars. The Health Insurance Fund explained that the patient requested a non-standard device. In general, when a patient wants to obtain a non-standard device, he must sign a statement/consent. In this case, however, the Health Insurance Fund did not inform the patient of the protocol and did not inform her of the need to sign a statement/consent.

(Source: COM)

Case study 2.9

A patient was immobilized after suffering spinal injuries from a traffic accident and

was transported from a healthcare facility in Skopje to healthcare facility in Ohrid. The Emergency Healthcare Service transported the patient to the new facility and charged him 6,200 denars. The patient had health insurance, and he requested reimbursement from the Health Insurance Fund. However, the Health Insurance Fund answered that it can reimburse only 500 denars of the total cost.

Following the intervention of COM and the Ombudsman, the healthcare facility that is home to the Emergency Healthcare Service reimbursed all of the patient's transportation costs.

(Source: COM)

Case study 2.10

A patient was charged 350 denars for a panoramic x-ray of his teeth, even though he had health insurance. The patient argued that no price-list of services was visible in the dental clinic. The Ombudsman stated that citizens should be informed of the variety and cost of services available at the healthcare facilities.

(Source: COM)

Case study 2.11

As an example of a good practice, a patient-driven initiative that was carried out in collaboration with COM resulted in the widening of the official list of illnesses whose treatment do not require copayment from a patient. For example, Sclerodermia systematica progresiva was added to the list.

(Source: COM)

Case study 2.12

An underage patient required a medication that was not listed on the Positive List of Medications. When purchased from abroad, the medication costs 150 euros. The patient's parents were unemployed; when the medication was purchased for the first time, the Health Insurance Fund granted their request for reimbursement. However, the Health Insurance Fund denied the parents' reimbursement request the second time the medication was purchased, stating that the medication was not on the Positive List of Medications. The parents filed a complaint with the Ministry of Health, but the ministry denied the complaint, arguing that the medication was not on the Positive List of Medications and that a substitute medication existed on the list. The parents then filed a court motion to dispute the issue. The Supreme Court of the Republic of Macedonia overturned the ministry's decision and returned the case to the ministry for review, citing a lack of evidence and expert opinion, pointing out the fact that the medication showed positive therapeutic results, and questioning the inconsistency of the Health Insurance Fund's rulings on the matter (the fund decides first to reimburse the parents, then to deny their request).

(Source: Macedonian Helsinki Committee)

Case study 2.13

Stigma and discrimination by healthcare providers has a profound effect on the accessibility and quality of healthcare services for sex workers. In recent years, a series of situations has demonstrated that the quality of treatment for sex workers in

healthcare facilities often relies on whether healthcare providers know the person's health condition, than on the fact whether that person has health insurance. An NGO named HOPS witnessed situations in which healthcare providers request additional (or, according to providers, mandatory) testing for HIV or hepatitis if they are unaware of the sex worker's health status. If sex workers require a biopsy or colonoscopy, they are asked to return at the end of the working day in order to be the last to use the equipment involved in the procedures (even though it is mandatory for medical instruments to be sterilized after each patient). HOPS has also documented cases in which a pregnant sex worker attends a regular pregnancy monitoring session and is advised or pressured not to keep the baby.

(Source: HOPS)

Case study 2.14

A client of HOPS's Program for Support of Sex Workers is a 34-year-old unemployed woman who lacks a formal education and has no health insurance or material or social protection. The client is unmarried and is the single mother of one child. She has worked as a sex worker for a long time.

On April 4, 2005, she was kidnapped by two unknown persons and was taken by car to an unknown location where she was beaten and raped by the two kidnappers and another three persons who were present at the scene. After the incident, the client immediately contacted a legal advisor from the Program for Support of Sex Workers and was told to report to the local city hospital for examination. At the hospital, the woman was denied an examination on the grounds that city hospitals do not have the authority to perform examinations in cases of rape. She was then told to seek an examination at the state hospital or polyclinic in the municipality of Chair.

Since the client did not know where to go, she again contacted the legal advisor at the Program for Support of Sex Workers. The advisor met the client and went together to the state hospital, where the client was rejected treatment informing a physician that she had been raped. The doctor refused to perform an examination, explaining that certain protocols and laws prevented the state hospital from performing examinations of rape victims. The doctor said that such examinations should be performed by the Institute of Forensic Medicine, and he instructed the victim to visit the institute during its regular working hours (between 7:00am and 3:00pm). When the legal advisor objected to this explanation, the doctor asked them to leave, saying that she had to attend to an emergency medical case.

Immediately afterward, the rape was reported to the police, and an examination was performed by a physician specializing in forensic medicine. The examination took place at the Institute of Forensic Medicine, which is part of the Clinic Center in Skopje. The client was accompanied by the legal advisor from HOPS and a detective from the violent crimes unit of the Bitpazar Police Station. Since the laboratory technicians were unavailable at the time of the examination, the victim was asked to return the next day in order to provide the necessary samples.

The legal advisor consulted with the physician who performed the examination to

determine whether there was truly a ban on examinations of rape victims by other doctors or gynecologists; he was informed that such ban does not exist.

(Source: HOPS)

Case study 2.15

A Roma patient was examined at the Institute for Radiotherapy and Oncology, where he was given a clinical diagnosis of “limphadenopathy – classification group 5”. A cytomorphological test also showed that the patient had malignant lymphoma of the type ML-CLL. The patient was supposed to continue treatment at the hematology clinic, but because the patient lacked health insurance, she was asked to pay for treatment. The patient did not have sufficient finances to cover the cost of treatment. The case was reported to the Skopje regional office of the Health Insurance Fund (HIF) office, the Ministry of Health, and the Institute of Radiology and Oncology. The HIF issued written report stating that the patient was not covered by any type of health insurance, and the Ministry of Health informed the patient that treatment of her clinical diagnosis was not included under any of the programs financed by the state budget.

Based on these developments, a case was prepared for the Ombudsman, which has since acknowledged that treatment of the diagnosis in question was covered under a government-funded program using funds from the state budget. Thus, the patient had the right to apply for treatment if she presented the necessary documents and evidence of health insurance coverage to the Skopje office of the HIF.

Despite the findings of the Ombudsman, the patient was still forced to use her “connections” and find the blue-coupons⁵⁴ in order to receive treatment.

(Source: NGO Luludi)

Case study 2.16

After the public announcement of his HIV-positive status, a patient faced isolation and stigmatization by the environment and termination of his employment. The patient was forced to leave his job, even though he was capable of performing his usual work tasks. The public institution that employed the patient violated Article 23 of the Universal Declaration of Human Rights,⁵⁵ which states that “everyone has the right to work, to free choice of employment, to just and favorable conditions of work and to protection against unemployment.” The patient was discriminated against solely on the basis of his HIV-positive status. Through the efforts of the NGO H.E.R.A., the patient was able to return to his workplace. However, the patient’s right to work still is not respected in full; although the patient receives his usual monthly salary, he does not physically go to work, and he has no responsibilities within the institution.

(Source: H.E.R.A)

⁵⁴ The blue-coupons are confirmation that the person has paid the contributions for the health insurance.

⁵⁵ Universal Declaration of Human Rights, General Assembly of the United Nations, adopted December 10, 1948

Case study 2.17

In 1997, a three-year old child was injured while playing, and his parents took him to the hospital for emergency treatment without identifying documents. A doctor examined the child, but upon realizing that the child lacked identifying documents, he refused to issue referrals for further examination (e.g.: x-rays, examination by specialists) and advised the parents to return home and monitor the child's condition. The parents were told to bring their child back to the hospital if he continued to vomit. The child continued to vomit, and the parents followed the doctor's advice and brought him back to the hospital. The doctor then advised the parents to take the child immediately to the Pediatric Clinic in Skopje; however, the doctor did not provide transportation by ambulance due to the child's lack of health insurance. The parents, who are recipients of social welfare, finally managed to arrange transportation to Skopje, but the child died on the way to the clinic. The doctor's negligence, combined with his ignorance of the procedures and opportunities established under the Program for Persons Without Health Insurance and Emergency Medical Procedures, resulted in the death of the child.

(Source: HCAR Mesecina)

4) Practical notes

For more information, please see "Right to preventive measures", Practical notes.

3. Right to Information

a. Right as stated in the ECPR⁵⁶

“Every individual has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available.

Healthcare services, providers and professionals have to provide patient-tailored information, particularly taking into account the religious, ethnic or linguistic specificities of the patient.

The health services have the duty to make all information easily accessible, removing bureaucratic obstacles, educating healthcare providers, preparing and distributing informational materials.

A patient has the right of direct access to his or her clinical file and medical records, to photocopy them, to ask questions about their contents and to obtain the correction of any errors they might contain.

A hospital patient has the right to information which is continuous and thorough; this might be guaranteed by a ‘tutor’.

Every individual has the right of direct access to information on scientific research, pharmaceutical care and technological innovations. This information can come from either public or private sources, provided that it meets the criteria of accuracy, reliability and transparency.”

b. Right as stated in national laws/legislation

In the **Law on the Protection of Patients’ Rights**,⁵⁷ a special article (Article 7) establishes patients’ the right to information. According to this article, “the patient, during all stages of healthcare, shall have the right to be fully informed of the following:

- 1) his health status, including a medical assessment of the results and outcome of a particular medical intervention;
- 2) recommended medical interventions, as well as dates planned for their realization (including a treatment and rehabilitation program);
- 3) possible advantages and risks of the realization and non-realization of recommended medical interventions);
- 4) his right to decide upon recommended medical interventions;
- 5) possible replacements of recommended medical interventions;
- 6) reasons for possible differences in the result achieved by medical interventions as compared to the expected result;
- 7) the course of the procedure when providing healthcare;
- 8) his recommended lifestyle and
- 9) his right to healthcare and health insurance, as well as the procedure for exercising these rights.”

⁵⁶ European Charter of Patients’ Rights, available at: http://www.patienttalk.info/european_charter.pdf

⁵⁷ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

Information "...must be provided to the patient in an understandable and appropriate manner, minimizing technical or expert-level terminology, for the purpose of conveying data that is important for a patient's treatment. If the patient is not proficient in the official language used in the healthcare facility, then he has the right to use an interpreter or translator" (Article 8).

"The patient shall have the right to know the names, education levels, and residences of healthcare providers offering healthcare services. This information shall be made available through the mandatory public display of his medical license issued by the relevant chamber in the office where they work, as well as by other means that are understandable to the patient" (Article 10).

In accordance with his physical, mental and psychological status, a patient with diminished mental capacity shall have the right to information. This right shall also be granted to foster parents or legal guardians of such patients (Article 11).

The Law on the Protection of Patients' **Rights guarantees the right to refuse information**. According to Article 12 of the Law on the Protection of Patients' Rights, the patient has the right to refuse information on the nature of his health status and the expected outcome of proposed or undertaken medical interventions. The patient cannot renounce the right to information in cases when he must be made aware of the nature of his illness in order not to endanger the health of other people (Article 13). In such cases, the patient has the right, by means of written consent or other valid means, to appoint a person who shall be given the information instead.

The patient has the right to information even in cases when his consent is not required for the initiation of medical intervention (i.e.: in the event of an emergency).

Article 22 of the Law on the Protection of Patients' **Rights establishes the patient's right to be informed of his medical records** and grants the patient the right to access his medical records.

The patient has the right to receive an excerpt or copies of data and documents from his medical records; the patient is responsible for covering the cost of fulfilling the request, and the fee for this service must be charged at a reasonable rate.

The patient has the right to ask for clarification of data in his medical records.

Medical records shall be updated in such a manner that previously entered information is not overwritten upon the introduction of new data.

The right to access one's medical record may be limited, denied or temporarily suspended by the person currently in charge of maintaining the file if the release of such information could cause serious harm to the patient's health or if the file reveals information about a third person.

The patient has the right to authorize a third party to exercise the right to information

on his behalf, during and upon the discontinuation of the patient's treatment (Article 23, Para. 1).

Based on written request, the patient's spouse, domestic partner, next-of-kin, or adult sibling has the right to request access to the patient's medical record if they cannot access such data in any other way and if the data are necessary for identifying a medical issue that could affect the petitioner's life or health.

Unless explicitly prohibited by the patient, a spouse, domestic partner, adult child, parent, adult sibling, or legal guardian shall be granted the right to access the patient's medical record upon his death. Upon request, excerpts or copies of the patient's medical record may be provided to the aforementioned parties for a reasonable fee.

Article 24 of the Law on the Protection of Patients' Rights provides that anything not specifically outlined under the law shall be subject to the rules and regulations governing the protection of personal data.

c. Specific supporting laws and regulations

According to the **Law on Healthcare**,⁵⁸ if permanent consequences (e.g.: disability) arise during treatment, the patient or his family has the right to request an investigation of the level of proficiency in terms of the healthcare services provided (Article 54, Para. 1).

With regard to the right to information, the **Law on Blood Safety**⁵⁹ refers to the Law on the Protection of Patients' Rights; the rules and regulations stipulated in the latter document are applicable during transfusions of blood or blood components.

The **Law on Biomedically Assisted Reproduction (BAR)**⁶⁰ also regulates the issue of providing information to the patient. Article 11 of the law states: "Prior to the procedure of allogeneic BAR where donor's germinative cells or sperm cells are being used, there is mandatory legal and psychological counseling for the married couples, out-of-wedlock partners, or women from Article 9, Paragraph 3 of this law. The counselor is required to inform the persons from Paragraph 1 of this article of the possible psychological reactions caused by the allogeneic BAR procedure. For the counseling provided, the counselor is required to give a written statement. The lawyer is required to inform the persons from Paragraph 1 of this article of possible legal implications and possible consequences of compliance to the planned procedure of allogeneic BAR, as well as with parental rights emerging from the medical procedure. The lawyer is required to give a written statement for the given legal advices. The healthcare facility which provides the BAR procedure is required to provide legal and

58 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

59 Official Gazette of the Republic of Macedonia, no. 110/07

60 Official Gazette of the Republic of Macedonia, no. 37/08

psychological counseling and if the institution cannot provide such counseling, it is required to direct the persons from Paragraph 1 of this article to another healthcare facility that can provide appropriate counseling.”

Article 21 of the **Law on Mental Health**⁶¹ governs the patient's right to information: “The healthcare facility shall provide information to the person suffering from mental illness according to Article 19 of this law, if that information does not cause deterioration of the patient's mental health condition.”

d. Relevant international/regional provisions

In international regulations, the patient's right to information is established through prohibitions on interfering arbitrarily in a patient's privacy, family, home, or correspondence, and violating a patient's honor or reputation. Failing to inform the patient about a medical intervention after it was performed by a healthcare provider constitutes interference with the patient's privacy. In such cases, the healthcare provider bears responsibility for the consequences, except in cases when emergency medical assistance is needed. The issue of providing information that is relevant for one's health is outlined explicitly in the European Covenant for Human Rights and Biomedicine (1997/99).⁶²

e. Relevant provisions of healthcare providers' codes of ethics

According to Article 21 of the **Code of Ethics of the Macedonian Chamber of Medicine**,⁶³ “prior to treatment, the doctor shall inform the patient about the type of his illness, about his current situation and the outcome of the illness. The patient shall provide informed consent voluntarily about the appropriate treatment that he should receive.

Informing the patient about his health condition should be done exceptionally for his well-being. Special care and precision shall be used in explanation of diagnostic and therapeutic methods related to risk. When the patient is under exceptional psychological condition, explanation is not recommended as it may influence the treatment negatively. In such cases, one should inform the patient's relatives. It is not permissible for the doctor to avoid informing the patient and for the patient to be informed by other supporting medical personnel. If the patient's condition is terminal, the doctor shall inform the patient's family in case the patient does not decide to do so. The patient's must not be denied further treatment and he should be supported morally.”

In addition, Article 23 of the **Code of Ethics of the Macedonian Chamber of Medicine** states that “the doctor is obliged to inform the patient upon admission to the health[care] facility of the routine procedures, the ways of treatment and for the medical-technical capabilities of the healthcare facility.”

61 Official Gazette of the Republic of Macedonia, no. 71/06

62 Convention on Human Rights and Biomedicine 1997, <http://conventions.coe.int/Treaty/EN/Treaties/html/164.htm>

63 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

In accordance with the **Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights**,⁶⁴ “prior to prescribing medication, the pharmacist must give professional advice to the patient in order to enable more effective usage of the medication. The pharmacist should provide appropriate (i.e.: the most effective) medications to the patient, and the medication should have minimal side effects” (Article 17).

According to Article 18, “the pharmacist shall answer to patient’s questions regarding the name of the medication, storing, usage, all side effects connected to alcohol interaction or interaction with other prescribed medications.”

According to Article 19, “the pharmacist shall inform the patient about the medication in written or oral form. This conduct is necessary while prescribing medications and it is of special importance when the medication is sold over -the -counter where the pharmacist as a specialist on medications should use his knowledge in the choose of the medication placing the patient’s health above the price of the medication.”

f. Examples and case studies

1) Examples of compliance

Example 3.1

The patient asks a healthcare provider for information regarding his medical condition, including the expected results of medical interventions suggested by the healthcare provider. The healthcare provider explains medical data to the patient and discusses anticipated results of the proposed intervention, with special emphasis on the possible side effects and risks.

Example 3.2

The healthcare provider explains medical data to the patient and suggests further interventions after conducting a diagnostic procedure. The patient is not interested in the explanation. The healthcare provider respects the patient’s desire to remain uninformed, except in the event that the patient is suffering from an infectious disease; in this case, the healthcare provider would advise the patient to undertake appropriate measures in order to contain the disease.

2) Examples of violations

Example 3.3

The patient asks a healthcare provider to explain a proposed medical intervention. The healthcare provider answers that the patient does not need to know about the intervention and that it would be better to if the patient simply listened to the healthcare provider and did not interfere with his work.

64 Available at: http://www.farmaceutskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

Example 3.4

A healthcare provider uses professional terminology (or Latin terms) when communicating to the patient. The patient tells the healthcare provider that he does not understand the information. The healthcare provider responds that the patient was informed of his condition and that it is the patient's problem if he does not understand.

3) Actual cases

Case study 3.1

A patient is admitted to hospital in Skopje. The patient has lost a large amount of blood, but he does not receive a blood transfusion. The patient is given 40 intravenous infusions and large amounts of fluids, even though he is 84 years old, suffers from a heart condition, and has trouble urinating. The patient is given 10 bags of sodium chloride, even though he has been avoiding salt for four years under doctor's orders. The cardiologist treating the patient is not consulted, and diuretics are given to the patient only after the fifth day of treatment, when the patient begins to experience swelling (i.e.: there is an occurrence of edema). The patient's health deteriorates, but he is left in his hospital room with a temperature of 37 degrees Celsius when he should be taken to intensive care. The swelling continues while he was still being treated with an infusion and he underwent dialysis on the seventh day of his admission. The attending physician did not inform the patient's family of the treatments when they were being performed. The attending physician also was generally unavailable and rude. Medical personnel performed check-ups only twice a day, even though the patient was in critical condition and the patient's family had complained about his treatment. The first blood transfusion was given to the patient on the last day of his admission, after he was given infusions and medication. The patient passed away.

The patient's family believes that the diagnosis was not consistent with either the symptoms presented or the cause of death. The patient's weight prior to death was three times his weight before admission. The attending doctor did not set diagnosis until the last moment. Criminal charges have been filed in this case.

(Source: COM)

4) Practical notes

The patient's right to access any type of information regarding his health, healthcare provision as well as available scientific research and technological innovations, must be taken seriously, since they represent the **basis** for the realization of patients' rights and for consent to medical interventions. This information also serves as the **basis for healthcare providers' liability** in cases when such information has not been provided.

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this right; these procedures are described in detail in Chapter 8 of this guide.

4. Right to Consent

a. Right as stated in the ECPR⁶⁵

“Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health; this information is a prerequisite for any procedure and treatment, including the participation in scientific research.

Healthcare providers and professionals must give the patient all information relative to a treatment or an operation to be undergone, including the associated risks and discomforts, side effects and alternatives. This information must be given with enough advance time (at least 24 hours notice) to enable the patient to actively participate in the therapeutic choices regarding his or her state of health.

Healthcare providers and professionals must use a language known to the patient and communicate in a way that is comprehensible to persons without a technical background. In all circumstances which provide for a legal representative to give the informed consent, the patient, whether a minor or an adult unable to understand or to will, must still be as involved as possible in the decisions regarding him or her. The informed consent of a patient must be procured on this basis. A patient has the right to refuse a treatment or a medical intervention and to change his or her mind during the treatment, refusing its continuation. A patient has the right to refuse information about his or her health status.”

b. Right as stated in national laws/legislation

The **Law on the Protection of Patients' Rights**⁶⁶ establishes the patient's right to take part in decision making. This right, according to Article 6 of the law, “...encompasses the right to information and the right to accept or reject certain medical intervention. The patient's right to take part in decision making may be limited only by exception when justified by the patient's health status, in cases and in a manner regulated by this law”.

According to Article 14 of the **Law on the Protection of Patients' Rights**, “the patient shall have the right to accept or reject certain medical intervention, except in cases of medical interventions whose delay or non-performance would endanger patient's life and health or the life and health of other people, or would cause temporary or permanent damage to [the patient's] health or the health of other people.” (Para. 4)

“A blind person, deaf person who does not know to read, mute person who does not know how to write, or deaf-mute person shall accept or reject certain medical interventions in the presence of a family member, foster parent, or legal guardian” (Article 14, Para. 4).

⁶⁵ European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

⁶⁶ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

“For an unconsciousness patient, a patient admitted to a healthcare facility without consent, for incompetent person, or an underage patient, the statement shall be signed by the patient’s parent, legal guardian, or foster parent. In the interest of the patient, the person may withdraw the statement at any time in the same manner in which it was given” (Article 15, Para. 1-2).

“When the interests of the patient and the interests of his parents, legal guardians, or foster parents are conflicted, the healthcare facility is obliged to immediately inform the relevant Social Work Center, which shall make a decision in compliance with the principle of urgency” (Article 15, Para. 3).

“If, due to the urgency of the condition, the consent of a parent, legal guardian, or foster parent cannot be obtained, the patient shall be subjected to medical intervention only if the non-performance of the intervention would immediately endanger the life or health of the patient or others persons. The intervention may be performed without a statement of consent from the patient’s parent, legal guardian, or foster parent only for the duration of the immediate danger” (Article 16).

Protection of the rights of patients participating in scientific research is specially regulated by the Law on the Protection of Patients' Rights. According to Article 17, Paragraph 1, “conscious, clear and voluntary consent must be provided by the patient in cases when he will be subjected to scientific research.”

For the purpose of this law, patient consent means a signed and dated written statement indicating the patient’s consent to take part in certain scientific research; the statement is based on precise and understandable information regarding the nature, significance, consequences, and risks of the research. According to Article 17, Paragraph 2, the statement of consent for a handicapped or underage patient’s participation in scientific research is given by his parent, legal guardian, or foster parent with the approval of the Social Work Center. The patient or his parent, legal guardian, or foster parent may withdraw the statement of consent at any time.

Article 19, Para. 2 stipulates the conditions necessary for subjecting patients to medical studies: “When there is no replacement for the research that would achieve the same or similar goal with humans; [when] risks to which the patient is exposed are proportionate to the possible benefit of the study; [when] the study is approved by the Ethics Committee of the Medical, Pharmaceutical or Dental Chamber in the [relevant] health field, after conducting an independent investigation of the study’s scientific value, the importance of the purpose of the study, and an assessment of the study’s ethical acceptability; [when] the patient who is to be subjected to the study is informed about his rights and protections in accordance with this law; [when] a statement of consent from the patient has been received [by those conducting the study].”

Patients who have been deprived from full legal capacity, are incapable of making rational decisions, or are underage may participate in a scientific study only if the above-mentioned conditions are met and if the results of the study might contribute

to the actual and immediate benefit of the patient's health. Furthermore, a statement of consent must be obtained from the patient's parent, legal guardian, or foster parent; approval must be given by the competent Center for Social Welfare; and the patient must not oppose participation in the study (Article 20, Para. 1).

As an exception Paragraph 2 of Article 20, regulates that in cases when a study might not produce results for the immediate benefit of the patient, the study may be approved under the above stated conditions, whereby the purpose of the study shall be the achievement of results that might benefit the patient or other patients in the same age group or with the same illness. Patients participating in such studies must bear minimal risk and burden.

According to Article 18 of the **Law on the Protection of Patients' Rights**, "in order to involve a patient in medical teaching, the patient must give conscious, clear and voluntary consent in writing or orally before two witnesses. Consent shall be given on the basis of precise and understandable information regarding the nature, significance, consequences, and risks of medical teaching; this information must be provided by the healthcare provider who intends to include the patient in medical teaching.

c. Specific supporting laws and regulations

The **Law on Healthcare**⁶⁷ establishes citizens' right to undergo surgical and other medical interventions only if written consent is granted prior to the procedure by the patient or by a parent or legal guardian in cases when the patient is underage or work-unable. An exception to this rule shall be made when the delay or non-performance of a medical intervention might endanger the patient's life; such interventions may be performed only upon the recommendation of at least two doctors (Article 50).

According to the **Law on Mental Health**⁶⁸ "a mentally ill person shall be admitted to a healthcare facility only if he consents to care, treatment, and rehabilitation; if he is admitted under a court order when care, treatment, and rehabilitation have been postponed; or if the current condition of his mental health might lead to the death, injury, or permanent impairment of that person or others or to considerable material damage" (Article 16).

According to the **Law on Blood Safety**,⁶⁹ "prior to the patient receiving blood or blood components, he shall provide a written statement that he has been informed about the transfusion, the possible consequences that may result from the procedure, and possibility of using his own blood, and that he is willing to undergo the transfusion. If the patient is not in a condition to give consent or the patient is underage, then consent shall be given by the patient's legal guardian or representative. In emergencies, the healthcare provider shall act in accordance with medical principles. The right to

67 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

68 Official Gazette of the Republic of Macedonia, no. 71/06

69 Official Gazette of the Republic of Macedonia, no. 110/07

information and other patients' rights shall be respected during the transfusion of blood or blood components" (Article 30).

According to the **Law on Biomedically Assisted Reproduction⁷⁰ (BAR)**, "married couples and out-of-wedlock partners shall be informed about all possibilities of treatment and other ways of parenting, including adoption, especially in cases of the simultaneous infertility of the man and woman, which renders them unable to produce offspring" (Article 10, Para. 1). "Prior to the BAR procedure, a certified doctor from the healthcare facility shall explain the procedure to the married couple or out-of-wedlock partners and the woman and shall also explain the possible consequences that could occur during and after the BAR procedure" (Article 10, Para. 2). In addition, "prior to an allogenic BAR procedure that uses donor germinative cells or sperm cells, married couples, out-of-wedlock partners and women must undergo mandatory legal and psychological counseling" (Article 11, Para. 1).

After counseling, it is mandatory to have consent from both the recipients and donors of the germinative cells and sperm cells in order to perform the BAR procedure (Art. 12), as well as consent from the donors, the donated germinative cells and sperm cells to be used for BAR procedure (Article 13).

According to Article 15, Paragraph 1 of the Law on Biomedically Assisted Reproduction, "the donation and use of germinative cells shall be performed only on the basis of the donors' voluntary written consent." Paragraph 2 stipulates that: "the donation and use of sperm cells may be performed only on the basis of the voluntary written consent of the man and woman who pass on their right to use the sperm cell." In Paragraph 7, Lines 1-3, the law requires that "a statement to withdraw the consent of the donors shall be given in written form."

According to Article 37, Paragraph 3 of the law, in order to have new experimental BAR procedures may be conducted only if the State Committee issues confirmation/ approval and the involved married couples or partners and women grant written consent.

d. Relevant international/regional provisions

In Macedonia, the following legally binding international and regional regulations apply to patients' right to consent: the Universal Declaration on Human Rights,⁷¹ Nurnberg Code,⁷² Helsinki Declaration,⁷³ the Guidelines of the Council of International Organizations of Medical Sciences (CIOMS),⁷⁴ the International Covenant on Civil and Political Rights,⁷⁵ the Convention on Human Rights and Biomedicine,⁷⁶ and the

70 Official Gazette of the Republic of Macedonia, no. 37/08

71 Universal Declaration of Human Rights, General Assembly of the United Nations, adopted December 10, 1948

72 Available at: <http://ohsr.od.nih.gov/guidelines/nuremberg.html>

73 Available at: <http://www.wma.net/en/30publications/10policies/b3/index.html>

74 Available at: http://www.cioms.ch/frame_guidelines_nov_2002.htm

75 International Covenant on Civil and Political Rights (ICCPR), December 19, 1966

76 Convention on Human Rights and Biomedicine 1997, available at: <http://conventions.coe.int/Treaty/EN/Treaties/html/164.htm>

Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Genetic Testing for Health Purposes.⁷⁷

e. Relevant provisions of healthcare providers' codes of ethics

According to the **Code of Ethics of the Macedonian Chamber of Medicine**,⁷⁸ “for every procedure, the healthcare provider shall request the conscious, clear, and voluntary written consent of the patient, once the patient has been informed about the testing, diagnosis, methods of treatment, and prognosis. Only in emergency cases, when the patient’s life is in danger and the patient is not in position to give consent, may the healthcare provider perform an intervention without consent. The healthcare provider shall give special care to underage patients and patients with legal guardians. In such cases [involving a parent or legal guardian], while planning intervention and treatment, the healthcare provider shall obtain special consent from the legal representatives of the patient, unless the patient is in immediate danger” (Article 22).

Other relevant information:

The **Law on the Protection of Personal Data**⁷⁹ holds that personal data processing may be performed upon previously obtained written consent by the personal data subject. Personal data processing may be also performed without [consent] ...when the processing is necessary for: the realization of a contract in which the personal data subject is a Contracting Party or upon a request by the personal data subject prior to his accession to the contract; the necessary fulfillment of the legal obligation of the Controller; the protection of the life or the physical and moral integrity of the personal data subject; the realization of issues of public interest or of official authorization of the Controller or of a third party to which the data are disclosed; or the fulfillment of legal rights and obligations of the Controller, of a third party, or persons to whom the data have been disclosed, unless it violates the freedoms and rights of the personal data subject (Article 6).

f. Examples and case studies

1) Examples of compliance

Example 4.1

A private foreign insurance company requests information regarding a client’s condition and health status from a Macedonian healthcare facility that provided treatment to the client. The healthcare facility requests written consent from the patient

⁷⁷ Available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/203.htm>

⁷⁸ Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

⁷⁹ Official Gazette of the Republic of Macedonia, no. 7/05 (unofficial translation found at: <http://www.ceecprivacy.org>)

in order to disclose his medical data to the insurance company, which is seeking to reimburse the patient for the costs of his treatment. The healthcare facility makes the correct decision not to disclose data to the insurance company without the patient's consent.

Example 4.2

A healthcare provider diagnoses a pregnant woman with acute leukemia. After explaining to the woman that she could die or that her child could suffer malformations as a result of the disease or treatment, the healthcare provider discusses the option of terminating the pregnancy. The patient's family disagrees with the doctor's advice and insists that the woman keep the child. The healthcare provider will only accept the patient's personal decision, and the patient is legally bound to provide written consent for any type of medical procedure.

2) Examples of violations

Example 4.3

A patient is admitted to an emergency ward with serious injuries from a traffic accident. The healthcare provider informs the media of the patient's condition, even though the accident is still under investigation and the patient did not provide consent. Disciplinary proceedings may be initiated against the healthcare provider, and charges may be filed under Article 150 of the Criminal Code⁸⁰ for revealing private medical data to the public.

Example 4.4

During a routine blood test, a patient gave 20 milliliters of blood; half of the blood is used for the testing, while the rest was used for scientific research without the written consent of the patient. This case may be examined by the authorized Bioethics Committee for Scientific Research.

3) Actual cases

Case study 4.1

A heart imaging procedure is performed with the **patient's consent**, after which two coronary stents are implanted. After the procedure, the patient develops a fever and is treated with antibiotics. The patient is released after six days and is directed to continue home treatment with a prescribed therapy. The patient's condition deteriorates, and two days after his release, he is re-hospitalized in a general hospital. Tests performed at the hospital indicate the presence of *Pseudomonas Aeruginosa* bacteria. Within four days of the second admission, the patient is released from the healthcare facility with a diagnosis of ineffective endocarditis/chemoculture of Gram-negative bacilli and is advised to continue treatment at a specialized clinic in Skopje. The patient claims that, during the entire course of his treatment, he has not been informed properly of his health condition. Documents issued to the patient

⁸⁰ Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

contain different diagnoses. Almost two months following the patient's release from the clinic, the discharge record is still in the possession of the clinic, which explains that the discharge record will be sent to the patient. However, the patient does not receive his discharge record and instead is given a hospital receipt outlining the recommended course of therapy; the patient is told that the discharge record will be ready the next day. The discharge record is eventually sent to the patient, but the patient claims that the data contained in the record are incorrect. The patient requests that an expert meeting be convened in order to discuss his case. The clinic denies his request and refuses to inform him of his treatment history. The Helsinki Committee intervenes on the patient's behalf, after which the clinic sends a chronological description of treatment. The clinic explains that medical data does not need to be given to citizens and patients, since all data are already stated in the release chart. (Source: Macedonian Helsinki Committee)

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to consent; these procedures are described in detail in Chapter 8 of this guide.

5. Right to Free Choice

a. Right as stated in the ECPR⁸¹

“Each individual has the right to freely choose from among different treatment procedures and providers on the basis of adequate information.

The patient has the right to decide which diagnostic exams and therapies to undergo, and which primary care doctor, specialist or hospital to use. The health services have the duty to guarantee this right, providing patients with information on the various centers and doctors able to provide a certain treatment, and on the results of their activity. They must remove any kind of obstacle limiting exercise of this right.

A patient who does not have trust in his or her doctor has the right to designate another one.”

b. Right as stated in national laws/legislation

According to Articles 6 and 14 of the **Law on the Protection of Patients' Rights**,⁸² the patient has the right to accept or reject certain medical intervention, except in cases when the delay or non-performance of medical intervention would endanger or damage the health of the patient or other persons.

The law also states that “the patient shall exercise his right to accept or reject certain medical interventions by signing a statement” (Article 14, Para. 2).

“A blind person, deaf person who does not know how to read, mute person who does not know how to write, or deaf-mute person shall accept or reject certain medical interventions in the presence of two witnesses” (Article 14, Para. 4).

The right to free choice is also protected as part of the patient's right “to refuse information on the nature of his health status and the expected outcome of proposed or undertaken medical interventions” (Article 12). Still, “the patient cannot renounce his right to information in cases when he must be made aware of the nature of his illness in order not to endanger the health of others” (Article 13).

The Law on the Protection of Patients' Rights guarantees the right of the patient to leave a healthcare facility voluntarily (Article 27, Para. 1). This right may be superseded by other laws in cases when a patient's decision to remain uninformed “is detrimental to his health or to the health and safety of other people.” The patient is obliged express his wish to leave the healthcare facility in a written statement. The statement must be issued in the presence of two adults, who then sign the statement for the purpose of verification. The written statement is kept in the patient's

81 European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

82 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

medical file. It is the duty of the healthcare provider to make a note in the patient's medical file indicating the patient's voluntary discharge from the healthcare facility without prior notice. If required by the patient's health status, the responsible healthcare provider is obliged to inform the person referred to in Article 25, Paragraph 6 of this law, of the patient's right to leave the hospital without prior notice; in cases stipulated by other regulations, the healthcare provider must inform the relevant authorities. If the patient is incapable of making rational decisions or is a minor, the healthcare facility is obliged to inform his parent, legal guardian, or foster parent and the Centre for Social Welfare about the voluntary discharge that occurred without prior notice.

c. Specific supporting laws and regulations

The **Law on Healthcare**⁸³ does not contain any specific terms pertaining to this right; existing regulations arise from the responsibility of the healthcare facility to provide services within the framework of the law upon a person's request (Article 46, Para. 1).

The **Law on Health Insurance**⁸⁴ establishes the right of the insured person to choose a primary care physician (Article 28, Para. 2) and to choose a specialist physician from a special healthcare facility with prior referral from his chosen primary care physician (Article 29, Para. 1).

According to the **Law on Biomedically Assisted Reproduction (BAR)**,⁸⁵ the BAR procedure shall be conducted upon prior written consent of the married couple, out-of-wedlock partners, or women; based on users' consent and upon the advice of a gynecologist (Article 12).

d. Relevant international/regional provisions

Legally binding international regulations pertaining to this issue include the International Covenant on Civil and Political Rights,⁸⁶ the Declaration on the Right to Development from 1986,⁸⁷ the Convention on the Rights of the Child,⁸⁸ the Universal Declaration of Human Rights,⁸⁹ and the International Covenant on Economic, Social, and Cultural Rights.⁹⁰

83 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

84 Official Gazette of the Republic of Macedonia, no. 25/00, 34/00, 96/00, 50/01, 11/02, 31/03, 84/05, 37/06, 18/07, 36/07, 82/08, 98/08, 6/09, 67/09

85 Official Gazette of the Republic of Macedonia, no. 37/08

86 International Covenant on Civil and Political Rights (ICCPR), December 19, 1966

87 Available at: <http://www.un.org/documents/ga/res/41/a41r128.htm>

88 Available at: <http://www2.ohchr.org/english/law/crc.htm>

89 Universal Declaration of Human Rights, General Assembly of the United Nations, adopted December 10, 1948

90 International Covenant on Economic, Social and Cultural Rights (ICESCR), December 19 1966

e. Relevant provisions of healthcare providers' codes of ethics

According to Article 15 of the **Code of Ethics of the Macedonian Chamber of Medicine**,⁹¹ “the doctor and healthcare facility shall provide continuous treatment and care, preferably by one doctor in accordance with the patient’s right to choose his doctor.” Article 28 states that “the doctor shall take into consideration the principle of free choice of one’s healthcare provider, and the institution and the doctor shall provide that right to the patient.”

f. Examples and case studies

1) Examples of compliance

Example 5.1

A healthcare provider conveys information verbally to an illiterate person, who then signs a written statement of consent for the acceptance or refusal of treatment in the presence of two witnesses.

2) Examples of violations

Example 5.2

A general practitioner withholds a patient’s medical data in order to prevent the patient from switching to another general practitioner. In this case, the patient may file a complaint with the relevant healthcare facilities, the Ministry of Health, the Health Insurance Fund, and the Ombudsman.

Example 5.3

A patient who is also a blood donor requires three units of blood during a medical intervention. By law, the patient should obtain the transfusion free-of-charge because he is a blood donor. Yet the intervention takes place in a private hospital, and the Institute of Transfusiology refuses to send the blood units to the patient free-of-charge. The institute asks the patient’s family members to transport the blood units themselves, which violates the blood cold chain. This scenario violates the patient’s right to free choice of healthcare provider or institution because it requires the patient either to obtain treatment in a public hospital or to pay for a service that should be free-of-charge.

3) Actual cases

Case study 5.1

A patient asks to be removed from the patient registry of his family’s chosen primary care physician. Despite his insistence, the patient’s request is denied by the healthcare provider. The patient complains to the media after he is unable to resolve the issue with the healthcare provider.

(Source: MMA)

⁹¹ Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

Every patient has the right to ask for a change in one's family physician if he is not satisfied with the work of the healthcare provider. If the patient's request is denied, he may file a complaint with the administration of the healthcare facility, with authorities from the relevant medical field, and with the Ombudsman. In such cases, the Ombudsman can act on legal grounds to take charge of the procedure in the interest of the patient in order to prevent further dissatisfaction.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to consent; these procedures are described in detail in Chapter 8 of this guide.

6. Right to Privacy and Confidentiality

a. Right as stated in the ECPR⁹²

“Every individual has the right to the confidentiality of personal information, including information regarding his or her state of health and potential diagnostic or therapeutic procedures, as well as the protection of his or her privacy during the performance of diagnostic exams, specialist visits, and medical/surgical treatments in general.

All the data and information relative to an individual's state of health, and to the medical/surgical treatments to which he or she is subjected, must be considered private, and as such, adequately protected.

Personal privacy must be respected, even in the course of medical/surgical treatments (diagnostic exams, specialist visits, medications, etc.), which must take place in an appropriate environment and in the presence of only those who absolutely need to be there (unless the patient has explicitly given consent or made a request).”

b. Right as stated in national laws/legislation

Article 25 of the **Law on the Protection of Patients' Rights**⁹³ establishes “the patient's right to confidentiality of his personal and medical data, which must be kept confidential after his death in compliance with the regulations on personal data protection” (Para. 1). A patient's data may be revealed only if “the patient has given written consent; his data are necessary for a medical intervention that is to be carried on another patient at another healthcare facility; his data are necessary for a particular type of processing, as stipulated by another law, by the healthcare facility that provides healthcare services to the patient; his data are used for historical, scientific, research, or educational purposes, provided that patient's identity cannot be traced and that the data are used in compliance with another law that aims to protect the lives, safety, and health of other persons” (Para. 2).

According to the law, data may be disclosed “in a manner and to an extent that is sufficient to accomplish the purpose of information disclosure” (Para. 3).

“Persons who will be aware of or in contact with such data shall keep the data in compliance with regulations for keeping professional and classified information, and in accordance with the Law on the Protection of Personal Data” (Para. 4).

“Human substances from which the patient can be identified must be kept confidential in compliance with regulations on the protection of personal data” (Para. 5). The patient has the right to give written or oral consent regarding the persons to

⁹² European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

⁹³ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

whom information regarding his health status or admission to an inpatient health-care facility may be disclosed. The patient may also list persons to whom such data should not be disclosed (Para. 6).

The personal data of patients must be processed in a manner that complies with personal data protection acts (Para. 8).

The right to privacy is stipulated in Article 28 of the Law on the Protection of Patients' Rights, according to which the patient has "the right to conditions providing privacy during medical interventions, especially when receiving personal care" (Para. 1). Thus, a medical intervention may be provided only in the presence of persons whose presence is necessary for the intervention, except when the patient has requested otherwise or has agreed to their absence (Para. 2).

Paragraph 3 states that "a patient admitted to an inpatient healthcare facility has the right to:

- be admitted in room separate from patients of opposite sex;
- if underage, be admitted in room separate from adult patients;
- dispose of clothing, personal hygiene items, and other items of personal need in line with his health status...".

In addition, according to Article 5 of the law, "the personality and dignity of each patient must be respected," (Para. 4) and "the patient has the right to personal safety while he is admitted to a healthcare facility" (Para. 5).

c. Specific supporting laws and regulations

The **Law on Healthcare**⁹⁴ has one regulation (Article 49) referring to the patient's right to respect for his dignity; the healthcare provider must comply with the guidelines of medical ethics and maintain professional confidentiality. The obligation to maintain confidentiality also applies to other medical staff working at the healthcare facility who are in contact with or aware of the contents of patients' medical records.

The **Law on Mental Health**⁹⁵ determines "the right to person's dignity and privacy of every person with mental illness. The person suffering from mental illness has the right to protection from any kind of molestation, degradation, and abuse, and he must not be discriminated against on the grounds of his mental health" (Article 7).

The law holds the healthcare facility responsible for maintaining the confidentiality of the date and time of admission of the mentally ill person, as well as that person's identity, his referral for treatment, medical reports detailing his mental health status, the plan and program for his treatment and rehabilitation, and other documents regarding his mental health condition. These medical data may be disclosed only

94 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

95 Official Gazette of the Republic of Macedonia, no. 71/06

if necessary and only to other healthcare providers to whom the patient is referred, to the relevant Centre for Social Welfare, or to other state bodies upon their written request (Article 18).

The **Law on Blood Safety**⁹⁶ regulates the protection and privacy of all personal, medical, and genetic data contained in the medical files of blood donors. These data and documents represent classified information, and they should be maintained in accordance with legal acts for the protection of classified information and for the protection of personal data (Article 17).

When handling medical records that contain personal, medical, or genetic data, the transfusion facility is responsible for complying with regulations involving the protection of **patients' rights, classified information, and personal data** (Article 17, Para. 3).

d.Relevant international/regional provisions

Respect for a person's dignity in the healthcare context includes the obligation to maintain the confidentiality of a patient's personal and medical data. Article 12 of the Universal Declaration of Human Rights⁹⁷ acknowledges that "[n]o person shall be subject to the arbitrary obstruction of his privacy, family, and correspondence." The right to privacy means that patients have control over the dissemination of their protected medical data to third parties. In the healthcare facility, the patient has the right to expect that his healthcare provider and other staff involved in his treatment will not abuse, disclose, or distribute medical data that might identify him without his prior consent.

e. Relevant provisions of healthcare providers' codes of ethics

According to Article 1, Line 5 of the **Code of Ethics of the Macedonian Chamber of Medicine**,⁹⁸ "the doctor is obliged to keep confidential all secrets that are disclosed to him while performing his duty."

The **Code of Ethics of the Macedonian Chamber of Medicine** also state that "the doctor is obliged by law to maintain professional confidentiality. Professional confidentiality regards all information that the healthcare provider and other supporting staff learn about the patient and his personal or family matters. Professional confidentiality applies to written records regarding the treatment of a patient and all results from medical examinations. The doctor shall withhold confidential information from members of the patient's family if it is in the best interest of the patient. Professional confidentiality continues after the patient's death" (Article 55).

96 Official Gazette of the Republic of Macedonia, no. 110/07

97 Universal Declaration of Human Rights, General Assembly of the United Nations, adopted December 10, 1948

98 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

According to Article 56, “when the patient releases a doctor from the obligation to maintain professional confidentiality, the doctor decides what information is potentially harmful to the patient and/or patient’s family and keeps it confidential.”

According to Article 57, “the doctor and his co-workers shall maintain professional confidentiality in the education process. These principles shall be transferred to students during their education, and students are also obliged to fully comply [with the standards of professional confidentiality].”

According to Article 58, “in scientific publications used for educational purposes, research data and results should be communicated in a manner that protects the anonymity of patients. The public display of a patient for scientific or educational purposes may be performed only with the patient’s consent, while maintaining professional confidentiality and showing respect for the person’s dignity.

f. Examples and Case studies

1) Examples of compliance

Example 6.1

Due to doctor-patient confidentiality, a gynecologist does not reveal a patient’s medical data or medical history (e.g.: a past abortion) to her husband/partner or her family members, except in cases when sharing such information is necessary to protect the health of the husband/partner or family members (e.g.: sexually transmitted infections).

2) Examples of violations

Example 6.2

A healthcare provider discloses the outcome of treatment of a publicly known person to another patient in order to illustrate the level of success achieved by a particular medical intervention that is relevant to the patient. The disclosure was made without the patient’s consent and without respect to the protection of the patient’s personal and medical data (i.e. without complying with the ethical principles of the doctor-patient relationship).

Example 6.3

A healthcare provider discusses the health condition of colleagues and co-workers with his spouse or partner, breaching the doctor-patient confidentiality principle.

Example 6.4

A doctor releases to the media information on a certain medical case. The information includes personal or medical data, and it was disclosed without the consent of the patient or a member of patient’s family.

3) Actual cases

Case study 6.1

In February 2006, H.E.R.A. publicly condemned the manner in which a daily newspaper reported the death of an HIV-positive patient. H.E.R.A believes that the newspaper breached the principles of professional ethics by damaging the integrity of the person through the disclosure of his HIV status. The newspaper also breached ethical reporting standards by describing the patient's condition ("his face was decomposing" and "the patient was placed under quarantine"). H.E.R.A announced that it would take all necessary legal steps to bring the case to the attention of the Ombudsman. At the same time, H.E.R.A issued an appeal to end the public persecution and discrimination of all people in Macedonia who are directly affected by HIV/AIDS.

As a result of these activities, the Ombudsman, in cooperation with H.E.R.A and 25 other NGOs, concluded that the newspaper had violated national legislation and several international documents: the Law on the Protection of Personal Data,⁹⁹ the European Declaration of Patient's Rights,¹⁰⁰ the Protection of Human Rights in the Context of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS),¹⁰¹ and the Declaration of Commitment on HIV/AIDS.¹⁰²

The Ombudsman called for all institutions and physical persons to consider carefully the use of personal data with respect to HIV/AIDS, given the nature of the consequences that could result from the inappropriate use of such information.

According to H.E.R.A., "Macedonia respects all of the above-mentioned declarations and documents, and the Ombudsman protects human rights guaranteed under national and international standards; in the future, the Ombudsman will take action to protect anti-discrimination principles."

(Source: H.E.R.A.)

Case study 6.2

The right to privacy and confidentiality was breached by medical personnel while providing dental services to a patient. The dentist sought details about the personal life of an HIV-positive patient, asking how she was infected, how many partners she had engaged in unprotected sex, whether she knew about her HIV status, and how she found out about the positive result of her HIV test.

Abusing his position and professional authority, the healthcare provider interfered with the patient's right to privacy by demanding and obtaining information that is not essential for the provision of the given medical service.

99 Official Gazette of the Republic of Macedonia, no. 7/05, 103/08

100 Available at: <http://www.ethique.inserm.fr/ethique/Ethique.nsf/397fe8563d75f39bc12563f60028ec43/901e922bf0f1db42c12566ac00493be8?OpenDocument>

101 Available at: <http://www.unhchr.ch/Huridocda/Huridoca.nsf/%28Symbol%29/E.CN.4.RES.2003.47.En?Opendocument>

102 Available at: <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html>

The patient did not initiate legal proceedings against the healthcare provider; the case was reported only as breach of human rights and did not entail any legal consequences.

(Source: H.E.R.A)

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to privacy and confidentiality; these procedures are described in detail in Chapter 8 of this guide.

7. Right to Respect for Patient's Time

a. Right as stated in the ECPR¹⁰³

“Each individual has the right to receive necessary treatment within a swift and predetermined period. This right applies at each phase of the treatment. The health services have the duty to fix waiting times within which certain services must be provided, on the basis of specific standards and depending on the degree of urgency of the case. The health services must guarantee each individual access to services, ensuring immediate sign-up in the case of waiting lists. Every individual that so requests has the right to consult the waiting lists, within the bounds of respect for privacy norms. Whenever the health services are unable to provide services within the predetermined maximum times, the possibility to seek alternative services of comparable quality must be guaranteed, and any costs borne by the patient must be reimbursed within a reasonable time. Doctors must devote adequate time to their patients, including the time dedicated to providing information.”

b. Right as stated in national laws/legislation

The right to timely treatment is derived from the patient's right to quality and continuous healthcare. If the patient does not receive treatment in a timely manner, the efficacy of the treatment itself decreases and loses its purpose. The right to timely treatment is connected to the right of access to healthcare as a precondition for treatment.

The **Law on Healthcare**¹⁰⁴ defines healthcare as measures, activities, and practices for the maintenance and improvement of health, life, and the working environment. The law also stipulates the rights and responsibilities related to health insurance, as well as the measures, activities, and practices implemented by institutions in the following fields: healthcare, disease control, injury control, early detection of illnesses and other medical conditions, and the **timely and effective treatment and rehabilitation using professional-medical procedures, treatments, and actions** (Article 2).

This right to timely treatment is guaranteed under the Law on the Protection of Patients' Rights, which states that “the protection of patients' rights is enabled through high quality and **continuous** healthcare in line with the latest achievements in healthcare and medical science” (Article 2). The Law on the Protection of Patients' Rights also outlines the principle of availability. According to this principle, healthcare services must be available and accessible **continuously** to all patients on an equal

103 European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

104 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

basis and without discrimination. The law also requires the **continuity** of healthcare, including cooperation among all healthcare providers, healthcare associates, and/or healthcare facilities that are included in the entire process of treatment of a certain condition or illness. Furthermore, the law stipulates a **just and fair procedure for choosing treatment, under conditions when the healthcare facilities have to select patients for special treatment which has limited availability (i.e.: waiting lists), whereby the selection is based on medical criteria and is performed without discrimination.** Finally, the law requires the availability of home treatment services or services in the community where the patient lives (Article 3, Para. 3).

“The patient has the right to care, treatment, and rehabilitation **according to his individual needs** and to the capabilities for improving his health status in order to achieve the highest attainable level of health, in line with available medical methods, and within the scope of the healthcare and health insurance regulations” (Article 5, Para. 3).

“Upon the admission of a patient, the healthcare facility is obliged to undertake all necessary diagnostic, treatment, and rehabilitation measures for that patient. A written record of the undertaken procedures must be kept in the patient’s medical records. The purpose of the treatment program is to improve the patient’s health status, at least to the extent that the patient can be treated and taken care of in the community where he lives. The program must also provide for regular medical examinations for the continuous monitoring of the patient’s health status” (Article 35).

c. Specific supporting laws and regulations

For information on this topic, see the section titled “The right of access to healthcare” earlier in this chapter.

d. Relevant international/regional provisions

Legally binding international regulations regarding the right to respect of a patient’s time include the Universal Declaration of Human Rights¹⁰⁵ and General Comment No. 14: The Right to the Highest Attainable Standard of Health, which was issued by the Committee on Economic, Social and Cultural Rights.¹⁰⁶ For additional information, please see Chapters 2 and 3 of this guide.

e. Relevant provisions of healthcare providers’ codes of ethics

The timely treatment of patients (i.e.: timely interventions) is not directly regulated in the codes of ethics of Macedonian healthcare providers.

¹⁰⁵ Universal Declaration of Human Rights, General Assembly of the United Nations, adopted December 10, 1948

¹⁰⁶ General Comment No. 14 (2000), The right to the highest attainable standard of health, 11/08/2000. E/C.12/2000/4. (General Comments)

f. Examples and case studies

1) Examples of compliance

Example 7.1

Based on a patient's health condition and the urgent need of medical procedures to improve that condition, the healthcare provider takes all necessary steps to provide timely treatment to the patient in accordance with the capabilities of the healthcare facility and its medical and support staff.

2) Examples of violations

Example 7.2

Waiting lists in the public healthcare facilities can be abused in order to receive certain healthcare services reserved for privately insured patients of public healthcare facilities. This situation represents a violation of the right to timely healthcare within the framework of the basic benefits package covered by the universal health insurance.

On a number of occasions, the Ombudsman has spoken about problem and has called on the Ministry of Health, the Health Insurance Fund, and healthcare facilities to resolve the problem through purchasing equipment and hiring additional professional staff to care for each patient. The Ombudsman has also called on these parties to allow for the provision of basic healthcare services under the health insurance, even in healthcare facilities that do not have a contract with the Health Insurance Fund but nonetheless have the necessary equipment to provide a particular health service; the provision of basic healthcare services by these facilities is important especially in emergency cases.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to respect for a patient's time; these procedures are described in detail in Chapter 8 of this guide.

8. Right to the Observance of Quality Standards

a. Right as stated in the ECPR¹⁰⁷

“Each individual has the right of **access to high quality health services** on the basis of the specification and observance of precise standards.

The right to quality health services requires that healthcare institutions and professionals provide satisfactory levels of technical performance, comfort and human relations. This implies the specification, and the observance, of precise quality standards, fixed by means of a public and consultative procedure and periodically reviewed and assessed.”

b. Right as stated in national laws/legislation

The right to the observance of quality standards is stipulated most explicitly in the **Law on the Protection of Patients’ Rights**,¹⁰⁸ which states that the patient has the right to care, treatment, and rehabilitation according to his individual needs and capabilities. Care, treatment, and rehabilitation must improve the patient’s health status to the highest possible level, **in line with available medical methods and capabilities**, and in accordance with healthcare and health insurance regulations (Article 5, Para. 3).

c. Specific supporting laws and regulations

The **Law on the Protection of the Population against Communicable Diseases**¹⁰⁹ requires healthcare facilities and providers to take measures for the control and prevention of infectious diseases using **methods and means in line with the latest scientific and medical achievements** in compliance with this law or other health-care-related laws (Article 7).

The **Law on Blood Safety**¹¹⁰ states that “blood and blood components must be of **high quality and safety** so they do not endanger the recipient’s life. The specific criteria regarding the quality and safety of blood and blood components are specified by the Minister of Health” (Article 20).

The **Law on Medications and Medical Devices**¹¹¹ “regulates the medications and medical devices used in human medicine; the **conditions and methods to provide their quality, safety, and efficiency**; and the method and conduct of their production, testing, distributing, purchasing, pricing, quality control, labeling, and inspection” (Article 1, Para. 1).

107 European Charter of Patients’ Rights, available at: http://www.patienttalk.info/european_charter.pdf

108 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

109 Official Gazette of the Republic of Macedonia, no. 66/04, 139/08, 99/09

110 Official Gazette of the Republic of Macedonia, no. 110/07

111 Official Gazette of the Republic of Macedonia, no. 106/07

The **Law on Biomedically Assisted Reproduction (BAR)**¹¹² states that BAR must be conducted “for purposes of reproduction in accordance with scientific and technological developments and medical science with a special emphasis on human rights” (Article 2, Para. 2).

The **Law on Conditions of Extracting, Exchange, Transportation and Transplantation of Human Body Parts for Medical Treatment Purposes**¹¹³ “determines the conditions to transplant tissue, organs, and human body parts in order to have quality and safe medical procedures” (Article 1, Lines 1-3).

The **Law on the Termination of Pregnancy**¹¹⁴ also sets quality standards for healthcare while performing medical interventions.

d. Relevant international/regional provisions

Article 11, Point 1 of the International Covenant on Economic, Social, and Cultural Rights guarantees “the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing, and to the continuous improvement of living conditions.”¹¹⁵

For other relevant international documents touching upon this right, see “Relevant international/regional provisions” in the section of this chapter titled “Right to preventive measures.”

e. Relevant provisions of healthcare providers' codes of ethics

The right to the observance of quality standards is not mentioned directly in the codes of ethics of Macedonian healthcare providers.

f. Examples and case studies

1) Examples of compliance

Example 8.1

A healthcare provider uses medical materials, equipment, and medications in accordance with the prescribed regulations for evidence-based medicine after those materials are provided by the healthcare facility.

Example 8.2

A patient who undergoes as part of his treatment for hepatitis B requests to be transferred to a dialysis center that is located closer to his home. Due to a lack of technical

112 Official Gazette of the Republic of Macedonia, no. 37/08

113 Official Gazette of the Republic of Macedonia, no. 30/95, 139/08

114 Official Gazette of the Republic of Macedonia, no. 19/77, 15/95

115 International Covenant on Economic, Social and Cultural Rights (ICESCR), December 19, 1966

capabilities (the lack of an open time slot for the dialysis of hepatitis B patients), the patient is placed on a waiting list until a time slot becomes available at the desired dialysis center.

2) Examples of violations

Example 8.3

In lack of appropriate devices and medical material, healthcare provider from dialysis centre is forced to use dialysis filter that is not appropriate for the patient, besides the existing standards and clinical guidelines.

3) Actual cases

Case study 8.1

A pregnant patient was admitted to hospital after her water broke, but according to the patient's medical record, the child was not delivered until five days after her admission. The patient did not receive any form of therapy during this time. When the newborn was delivered through induced labor, it was diagnosed with right-side paresis of the plexus bronchialis. Following the delivery of her child, the patient was moved to the healthcare facility's pediatric ward. The patient's surgical incision from Caesarian section then re-opened and closed off by sutures; three days later, the same complications occurred and were followed by vaginal bleeding. The patient asked to be hospitalized, but her request was denied. The next day, she received directions from her chosen physician to seek hospitalization, but her request was denied again, and she was treated only with an ergotamine injection. Given her deteriorated health condition, the patient decided to seek treatment at a private hospital, where she was admitted and treated over the course of six days. After the patient's condition stabilized, she was informed that there is evidence (discharge document) from the public general hospital for the same time-period she spent in the private hospital. The patient reported the case in the Ministry of Health and was told that a committee of doctors would be formed in order to investigate the case. However, the patient has received no feedback since then, except for a telephone call from the public general hospital informing her that she was no longer responsible for the medical costs related to the episode.

The Helsinki Committee reported the case to the Ministry of Internal Affairs and the Ministry of Health. So far, the committee has not received a response from either ministry.

(Source: Macedonian Helsinki Committee)

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to the observance of quality standards; these procedures are described in detail in Chapter 8 of this guide.

9. Right to Safety

a. Right as stated in the ECPR¹¹⁶

“Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards. To guarantee this right, hospitals and health services must continuously monitor risk factors and ensure that electronic medical devices are properly maintained and operators are properly trained. All healthcare providers must be fully responsible for the safety of all phases and elements of a medical treatment. Medical doctors must be able to prevent the risk of errors by monitoring precedents and receiving continuous training. Healthcare staff that reports existing risks to their superiors and/or peers must be protected from possible consequences.”

b. Right as stated in national laws/legislation

The **Law on the Protection of Patients' Rights**¹¹⁷ establishes the patient's right to safety by stating that “the personality and dignity of each patient must be respected” (Article 5, Para. 4), and that “the patient has the right to personal safety while he is admitted in a healthcare facility” (Article 5, Para. 5).

The Law on the Protection of Patients' Rights justifiably distinguishes between a patient's personal safety (security) and the safety of the patient with regard to healthcare services provided in a healthcare facility.

The right to safety is not expressed explicitly in any other article of Macedonian legislation. The right to safety may be related to the right to quality healthcare and to the issue of medical error and malpractice. Medical error is defined under the guidelines of healthcare providers' responsibilities (see Chapter 7) and under the Criminal Code of the Republic of Macedonia.¹¹⁸

Only the **Law on the Protection of the Population against Communicable Diseases**¹¹⁹ provides special measures for the protection of the population against communicable diseases (Article 13). Specifically, the law calls for “1) early detection of sources of contamination or infection (ill persons and carriers) and the establishment of an etiological diagnosis; 2) the reporting of communicable diseases; 3) epidemiological research; 4) isolation, health surveillance, quarantine, transport, and compulsory treatment; 5) immuno-prophylaxis and chemoprophylaxis; 6) disinfection,

116 European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

117 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

118 Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09.

119 Official Gazette of the Republic of Macedonia, no. 66/04, 139/08, 99/09

disinsection, and derattisation; 7) undertaking mass health sanitary examinations; 8) monitoring and surveillance of **nosocomial infections**, and taking countermeasures for their prevention; and 9) health education.” According to the law, healthcare facilities are responsible for implementing these measures.

“Preventive disinfection is obligatory in healthcare facilities, school and pre-school facilities, social centers, tourist and food-preparation facilities, and public places (e.g.: airports, train stations, markets), as well as on premises that are used for the production, trade, and storage of food. Preventive disinfection must be performed every six months. Disinfection is mandatory for secretions, excretions, objects, and rooms that have come in contact with a person suffering from cholera, parasitic infection, viral hemorrhagic fever, viral hepatitis, diphtheria, intestinal typhus, paratyphus, salmonella, cerebral palsy, dysentery, anthrax, rabies, or tuberculosis while in its contagious stage; [disinfection is also mandatory for] entire facilities during epidemics of any of these diseases” (Article 39).

Other measures for disinfection and safety are described in the Articles 40–49 of this law.

Every healthcare provider is obliged to inform his patients about preventive measures for protection against communicable diseases, as well as the importance of vaccinations and other measures of protection.

It is obligatory to examine donors of blood, tissues, organs, and sperm that is used in artificial insemination and in vitro fertilization for the presence of causative agents of syphilis, viral hepatitis B and C, HIV, and other infections that are transmitted via human material.

Examination of the human material [listed above] is also obligatory in cases when extraction of the human material is not performed in Macedonia (i.e. when there is no proof that the examinations performed have tested negative for the presence of above-mentioned infections) (Article 51).

c. Specific supporting laws and regulations

According to the **Law on Mental Health**,¹²⁰ the mentally disabled patient has the right to safety during his stay at a healthcare facility (Article 14).

d. Relevant international/regional provisions

Legally binding documents related to the right to safety are listed in the section titled “Right to Preventive Measures” earlier in this chapter.

120 Official Gazette of the Republic of Macedonia, no. 71/06

e. Relevant provisions of healthcare providers' codes of ethics

Article 36 of the **Code of Ethics of the Macedonian Chamber of Medicine**¹²¹ and Article 38 of the **Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights**¹²² state that, in accordance with the principles of safety and fellowship, all doctors regardless of their position and proficiency must be ready immediately to provide healthcare services in the event of an emergency. The codes also require that all doctors are aware of their moral and human responsibilities.

f. Examples and case studies

1) Examples of compliance

Example 9.1

The testing of donated blood and blood components is a mandatory part of the patient safety system.

Example 9.2

A pharmacist or another person working to prepare and dispense medications directly to patients are responsible for informing the patient about how to use the medication and about any possible side effects resulting from its use. In addition, due to patient safety concerns, the pharmacist or the person dispensing medications to patients is responsible for checking the expiration date of the medicine.

2) Examples of violations

Example 9.3

A healthcare provider or pharmacist issues prescription medications in cases when patients lack the necessary prescriptions. This represents both a breach of legal regulations and a risk of the safety of the patient, especially when the medications have strong side effects or when the medication is known to have particularly harmful effects in the event of an overdose.

Example 9.4

The correctness of the sterilization process and the sterility of the instruments are subject to permanent control.

Unsterilized or inadequately sterilized instruments are used for the treatment of multiple patients, especially in dental practices, posing risks to the safety of the patient, healthcare provider/dentist, and dental technician. The proper sterilization of instruments is reviewed repeatedly for compliance.

121 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

122 Available at: http://www.farmacevtskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to safety; these procedures are described in detail in Chapter 8 of this guide.

122 European Charter of Patients' Rights, http://www.patienttalk.info/european_charter.pdf

123 Службен весник на РМ бр. 82/08, 12/09

124 Службен весник на РМ, бр. 25/00, 34/00, 96/00, 50/01, 11/02, 31/03, 84/05, 37/06, 18/07, 36/07, 82/08, 98/08, 6/09, 67/09

10. Right to Innovation

a. Right as stated in the ECPR¹²³

“Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.
The health services have the duty to promote and sustain research in the bio-medical field, paying particular attention to rare diseases.
Research results must be adequately disseminated.”

b. Right as stated in national laws/legislation

The **Law on the Protection of Patients' Rights**¹²⁴ states that “the patient has the right to care, treatment, and rehabilitation according to his individual needs and capabilities. Care, treatment, and rehabilitation must improve the patient's health status to the highest possible level, in line with available medical methods and capabilities, and in accordance with healthcare and health insurance regulations” (Article 5, Para. 3).

The right to innovation should be analyzed together with the right to quality of healthcare (No. 8, earlier in this Chapter).

c. Specific supporting laws and regulations

Although this right is not stipulated explicitly in current Macedonian legislation, the **Law on Health Insurance**¹²⁵ permits medical care abroad (Article 30) in cases when comparable healthcare is not available domestically, thus enabling access to innovative diagnostic procedures and treatment.

According to Article 30 of the Law on Healthcare, the patient may seek healthcare in other countries with the consent of the Health Insurance Fund if the illness or condition cannot be treated in Macedonia but can be treated abroad (Para. 1).

A health insurance beneficiary who is working abroad temporarily may use healthcare services in the host country to a degree determined by law. Health insurance beneficiaries who are abroad temporarily may only make use of the emergency medical assistance in the host country. The conditions governing the use of medical services abroad are defined under a general act of the Health Insurance Fund that is subject to approval by the Minister of Health.

¹²³ European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

¹²⁴ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

¹²⁵ Official Gazette of the Republic of Macedonia, no. 25/00, 34/00, 96/00, 50/01, 11/02, 31/03, 84/05, 37/06, 18/07, 36/07, 82/08, 98/08, 6/09, 67/09

d. Relevant international/regional provisions

Legally binding documents related to the right to innovation are listed in the section titled “Right to preventive measures.”

e. Relevant provisions of healthcare providers’ codes of ethics

According to the **Code of Ethics of the Macedonian Chamber of Medicine**,¹²⁶ “the doctor shall continuously improve and deepen his professional and scientific knowledge. The doctor is responsible for maintaining and improving his proficiency and ethics, for issuing public and open warnings about diseases, and for actively cooperating in the containment and eradication of diseases. The doctor shall look after healthcare education and raise public awareness of healthcare and good health habits. The doctor shall try to prevent all potential harms to human health and shall act against the general incompetence and fraudulent practices of other doctors” (Article 4).

According to Article 31, “medical personnel shall **educate** the patient... about efficient and effective treatment within the scope of **current medical knowledge and capabilities**.” The patient may be made aware of treatment options while at home or in a healthcare facility.

Article 59 of the **Code of Ethics of the Macedonian Chamber of Medicine** states that every doctor has a duty to “learn about and comply with achievements in medicine and professional development. The doctor shall also transfer the acquired knowledge to his colleagues and other healthcare providers. The continuous development and improvement of the medical profession and science requires the continuous development and education in the field of medical theory and practice through work in professional associations and in scientific and professional institutions.”

In accordance with Article 60 of the code of ethics, the doctor is responsible for the improvement of his own personal knowledge and skills. The doctor shall make every effort to improve his knowledge of humanities and the social and natural sciences.

f. Examples and case studies

1) Examples of compliance

Example 10.1

Based on the opinions of physician specialists, a healthcare provider recommends that a patient undergo a surgical intervention (in this case, a lens transplant). Since this procedure is not performed in Macedonia but is covered by the patient’s health insurance, the healthcare provider directs the patient to have the operation per-

¹²⁶ Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

formed abroad in a clinic that has signed a memorandum of cooperation with Macedonia. Once the patient is referred for treatment abroad, 80% of the cost of the operation is covered by the Health Insurance Fund, while the remaining 20% is paid by the patient.

2) Examples of violations

Example 10.2

A patient who has survived a brain aneurism requires ophthalmic surgery. Due to the patient's complicated health condition and neurological problems resulting from the stroke, the patient is advised to undergo the operation in a neighboring country, where a physician specialist with experience performing such medical operations has been identified.

Despite the fact that a consilliary opinion was issued to refer the patient for treatment abroad, the Health Insurance Fund does not reimburse the cost of the operation. The Health Insurance Fund explains that the necessary operation can be performed in Macedonia; the fund does not taking into consideration the complexity of the patient's health condition and the possible risks associated with the operation. In this case, the patient may file a complaint with the Ministry of Health to protest the decision of the Health Insurance Fund to reject reimbursement for treatment abroad. In the event that the ministry decides in favor of the fund, the patient may submit a complaint to the Ombudsman. If the Ombudsman cannot help the patient, then he may initiate administrative proceedings to reverse the decision.

3) Actual cases

Case study 10.1

A patient has had three unsuccessful operations in Macedonia for a medical condition. For further treatment, the patient required an intra-operative enteroscopic intervention, but the equipment at the patient's clinic was inoperative.

An expert meeting was called, and the patient was directed to seek treatment abroad. Citing the opinion of the expert commission, the patient requested permission from the Health Insurance Fund to seek treatment abroad. The fund denied his request, stating that possibilities of treatment in Macedonia had not been exhausted.

The patient filed a complaint with the Ministry of Health, which sided with the fund in its decision to deny permission to seek treatment abroad, despite the fact that the equipment necessary for the procedure was out of order. The patient brought the case to court, where a decision is still pending.

(Source: Macedonian Helsinki Committee)

Case study 10.2

A patient has long suffered from eye-related problems. Treatment in Macedonia for his condition did not produce any positive results, so the patient was referred for treatment in Russia. According to the diagnosis– keratoconus with advanced cathar-

acsis with sight reduction to 40% on the right eye– the illness could not be treated in Macedonia. Due to the urgency of the situation, administrative inefficiencies, and lengthy administrative procedures, the patient traveled to Russia before obtaining clearance from the Health Insurance Fund to undergo the procedure. Russian doctors operated on the patient, who later sought reimbursement for the cost of procedure from the fund. The Health Insurance Fund denied the request because the patient obtained the operation in Russia without prior clearance.

The Ministry of Health denied the patient’s complaint, offering the same explanation as the fund. Currently, the case is awaiting a court hearing.

(Source: *Macedonian Helsinki Committee*)

4) Practical notes

It is necessary for healthcare to be provided within the realistic capabilities of the state, the state healthcare system, and their respective financing structures. Article 5 of the Law on the Protection of Patients’ Rights holds that the patient has the right to care, treatment, and rehabilitation according to his individual needs and capabilities, and that care, treatment, and rehabilitation must improve the patient’s health status to the highest possible level, **in line with available medical methods and capabilities, and in accordance with healthcare and health insurance regulations.** This right is not absolute; instead, it is realized within certain realistic frameworks that are usually connected to financial capacity (e.g.: of the state or of the patient). In Macedonia, patients may exercise their rights within the frameworks of the healthcare system and of health insurance programs that are governed by appropriate regulations. Any medical procedure that falls outside of such framework must be paid for by the patient. The motto that “there shall be no cheap medications for poor patients” and the fact that everyone has the right to highest achievable standard of healthcare should be considered within the above-mentioned context. A goal of healthcare policy is the continued improvement of healthcare systems, but this must be viewed in realistic terms.

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to innovation; these procedures are described in detail in Chapter 8 of this guide.

11. Right to Avoid Unnecessary Suffering and Pain

a. Right as stated in the ECPR¹²⁷

“Each individual has the right to avoid as much suffering and pain as possible, in each phase of his or her illness. The health services must commit themselves to taking all measures useful to this end, like providing palliative treatments and simplifying patients' access to them.”

b. Right as stated in national laws/legislation

The **Law on the Protection of Patients' Rights**¹²⁸ defines the principle of humane relations between the patient, healthcare provider, and healthcare assistant; stipulates the right of the patient to express pain and seek the relief of unnecessary pain using the state-of-art medical knowledge; and guarantees the humane healthcare of terminally ill patients (Article 3).

c. Specific supporting laws and regulations

The **Law on Mental Health**¹²⁹ explicitly does the following: “a) forbids every form of torture, inhumane and degrading conduct and punishment; b) forbids performing clinical and experimental trials upon a mentally ill person; c) forbids the sterilization of a mentally ill person; d) forbids discrimination against a person suffering from mental illness on the basis of gender, language, religion, political or other affiliation, national or social background, financial or societal status, or any other status.”

Article 20 of the law also forbids performing medical or surgical interventions or electro-convulsive therapy without the consent of the mentally disabled person or his legal guardian or representative, except in cases when such interventions or therapy are necessary to save the patient's life or to prevent his condition from deteriorating.

d. Relevant international/regional provisions

For information on this topic, see Chapters 2 and 3 of this guide.

e. Relevant provisions of healthcare providers' codes of ethics

Article 20 of the **Code of Ethics of the Macedonian Chamber of Medicine**¹³⁰ stipulates that “the patient justifiably expects the doctor to be supportive and to dedicate his time and patience [to the patient]. The efficiency of treatment depends largely on the patient's trust in his doctor and his treatment. The doctor's actions should be based entirely on **measures that help reduce the patient's suffering and improve his health**. The doctor-patient relationship must not be conditioned by the doctor's personal needs, ambitions, or gains. The doctor must not abuse the influence that he has over the patient.”

127 European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

128 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

129 Official Gazette of the Republic of Macedonia, no. 71/06

130 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

f. Examples and case studies

1) Examples of compliance

Example 11.1

A healthcare provider prescribes morphine to a terminally ill patient at the patient's request due. The morphine is provided based on the patient's subjective feeling of pain, even though there is no indication of the need to administer such therapy.

Example 11.2

At a patient's request, a dentist administers combined (injection and spray) local anesthetic during dental intervention in order to relieve the patient's subjective feeling of nausea.

Example 11.3

A gynecologist informs a pregnant patient about the option to request epidural or spinal anesthesia during normal childbirth for the purpose of decreasing labor pains; based on the patient's consent, the gynecologist prescribes a short-term anesthetic to be administered by anesthesiologist.

2) Examples of violations

Example 11.4

A patient decides to give birth by caesarian section in order to decrease the pain associated with childbirth, but her doctor refuses the request because that there is no objective need for such a procedure. This is an incorrect interpretation of the principle of humane relations and a violation the patient's right to avoid unnecessary pain and suffering.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

The treatment of terminally ill patients is of great importance, but in Macedonia, it is not regulated by law. In addition to the Law on the Protection of Patients' Rights, the Law on Healthcare and its associated Book of Rules provide some form of protection of the right to avoid unnecessary suffering, as they set requirements for rooms and other conditions at healthcare facilities that treat terminally ill patients. This issue should be viewed in connection with the right to quality healthcare and the right to personalized treatment.

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to avoid unnecessary suffering and pain; these procedures are described in detail in Chapter 8 of this guide.

12. Right to Personalized Treatment

a. Right as stated in the ECPR¹³¹

“Each individual has the right to diagnostic or therapeutic programs tailored as much as possible to his or her personal needs.
The health services must guarantee, to this end, flexible programs, oriented as much as possible to the individual, making sure that the criteria of economic sustainability does not prevail over the right to healthcare.”

b. Right as stated in national laws/legislation

The **Law on the Protection of Patients' Rights**,¹³² states that the patient has the right “to care, treatment, and rehabilitation, according to **his individual needs and capabilities**, that improve his health status in order to achieve the highest possible level of personal health, in line with available medical methods, and with healthcare and health insurance regulations” (Article 5, Para. 3).

This law regulates the right to personalized treatment through the principles of the right to privacy. Namely, Article 28, Paragraphs 1 and 2 state that “the patient has the right to conditions providing privacy during medical interventions, especially when receiving personal care. Medical intervention or personal care may be provided only in presence of persons necessary for conducting the intervention or personal care, except when the patient has agreed to or requested otherwise.” The Law on the Protection of Patients' Rights generally stipulates **a personalized approach toward every patient**, especially in exercising his rights through all principles.

c. Specific supporting laws and regulations

According to the **Law on Mental Health**,¹³³ “every person with a mental illness has the right to care, treatment, and rehabilitation appropriate to his individual needs and capabilities that improve his condition and mental health with the aim of reintegrating him into the community” (Article 9).

According to the same law, following his admission to a healthcare facility, the mentally disabled person is placed under the supervision of a team of specialists for treatment and rehabilitation in order to improve his health status to a degree that the person may be treated further within the community. The program includes regular check-ups to be performed at least once per month in order to follow the person's mental health condition. The team of specialists is responsible for preparing a **personalized program** for the treatment and rehabilitation of the mentally disabled person (Article 23).

131 European Charter of Patients' Rights, . , available at: http://www.patienttalk.info/european_charter.pdf

132 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

133 Official Gazette of the Republic of Macedonia, no. 71/06

d. Relevant international/regional provisions

For information on this topic, see the section titled “Right to preventive measures: Relevant international/regional provisions.”

e. Relevant provisions of healthcare providers’ codes of ethics

The **Code of Ethics of the Macedonian Chamber of Medicine**¹³⁴ references personalized treatment in Articles 14 and 26. Namely, doctors should be involved in the processes of patient admission and discharge, treatment, and rehabilitation, and they **should take into consideration the patient’s disabilities, including those caused by the illness**. Such patients shall be treated with the utmost care (Article 14).

“The doctor shall provide special medical treatment, education, and **care to children, especially if they have a physical or mental disability or adverse health condition**. The doctor shall coordinate the treatment of the child with the child’s family (mother). In addition, the doctor shall take additional care of the child if he does not understand the nature of illness and is uncooperative in treatment. The doctor shall not release an underage patient or a patient under the custody of a legal guardian if, according to his medical opinion, the health of the patient or others is endangered. The discharge of the patient is regulated by his attending doctor” (Article 26).

f. Examples and case studies

1) Examples of compliance

Example 12.1

A patient with a complicated health condition and a chronic neurological illness underwent an operation abroad, even though the operation in question (eye cataraxis) is a simple procedure. This scenario represents one form of personalized treatment, since the patient required a high level of professional medical care during the operation and the period of recovery.

Example 12.2

An example of personalized treatment in Macedonia is the allocation of kidney dialysis slots according to the patient’s health condition. A person with hepatitis B cannot be treated using a dialysis machine that is also used by patients without this disease; this is done in order to prevent the spread of the disease to other patients. The careful provision of dialysis also represents a patient safety measure; thus, these two rights ought to be viewed as complementary.

2) Example of Violation

Example 12.3

A small number of patients require specialized orthopedic devices that are available in Macedonia, but the equipment is not placed on the list of orthopedic devices

¹³⁴ Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

covered by the Health Insurance Fund due to low demand. Thus, patients must buy these devices using their own funds – a practice that does not demonstrate the principle of personalized treatment of patients.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to personalized treatment; these procedures are described in detail in Chapter 8 of this guide.

13. Right to Complain

a. Right as stated in the ECPR¹³⁵

“Each individual has the right to complain whenever he or she has suffered a harm and the right to receive a response or other feedback.

The health services ought to guarantee the exercise of this right, providing (with the help of third parties) patients with information about their rights, enabling them to recognize violations and to formalize their complaint.

A complaint must be followed up by an exhaustive written response by the health service authorities within a fixed period.

The complaints must be made through standard procedures and facilitated by independent bodies and/or citizens’ organizations and cannot prejudice the patients’ right to take legal action or pursue alternative dispute resolution.”

b. Right as stated in national laws/legislation

The **Law on the Protection of Patients’ Rights**¹³⁶ has an entire chapter on the right to complain, according to which the patient has the right to submit an oral complaint to the manager of a healthcare facility in cases when his rights have been violated; this complaint may be submitted by the patient himself or through a parent or legal guardian (Article 47). According to Article 48 of this law, the patient also has the right to submit a written complaint to the manager of a healthcare facility within eight days of the violation of his rights, or within eight days of learning that his rights were violated; this complaint may be issued by the patient directly or a through a parent or legal guardian. The manager of the healthcare facility is obliged to review the complaint and inform the patient or legal custodian of his decision within 15 days of the receipt of the complaint.

The patient and his parent or legal guardian also have the right to send complaints, proposals, or other submissions regarding the care, treatment, and rehabilitation provided by a healthcare facility to the Ministry of Health, relevant state authorities, or other institutions (Article 49).

For healthcare facilities that admit patients, the Minister of Health appoints a councilor for the protection of patients’ rights from a list of ministry employees (Article 45, Para. 1).

The Health Insurance Fund must provide professional assistance to insured patients for the exercise and protection of rights that are covered by the health insurance. Every regional office of the fund must set up an area clearly labeled as “the Office for Expert Assistance to Insured Patients for the Implementation and Protection of Their Rights Regarding Health Insurance.” The office must be located in an easily accessible location. The Health Insurance Fund is responsible for maintenance of all necessary conditions for the operation of the office (Article 52, Para. 2).

¹³⁵ European Charter of Patients’ Rights, available at: http://www.patienttalk.info/european_charter.pdf

¹³⁶ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

Regarding exercising the **right to health insurance**, the law refers to the related laws on health insurance, where the protection of this right is further referred to in the Law on General Administrative Procedure.

The **Law on Health Insurance**¹³⁷ stipulates that the State Sanitary and Health Inspectorate is responsible for responding to the citizen complaints regarding exercising their rights in health insurance.

In addition to guaranteeing the right to file a written complaint, the **Law on the Protection of Patients' Rights**¹³⁸ also states that “the patient has the right to court protection for the violation of his rights in a manner and procedure stipulated by law” (Article 53).

c. Specific supporting laws and regulations

The right to complain is established by the **Law on Healthcare**,¹³⁹ according to which a patient who is not satisfied with the healthcare he received or with the conduct of an employee of the healthcare facility may file a complaint with the director of the facility. The complaint may be filed in written or oral form. The patient shall receive a response within three days of filing the complaint; in emergency cases, the response should be issued immediately. If the patient is not satisfied with the director's decision, he may submit a request to the Ministry of Health to investigate the case (Article 52).

According to the **Law on Mental Health**,¹⁴⁰ the patient suffering from mental illness has the right to submit, personally or through his legal representative, a written complaint to the manager of a healthcare facility within eight days of the date when his rights were violated or when he learned that his rights had been violated. The manager of the healthcare facility is obliged to review the complaint and inform the patient or his legal representative within a period of 15 days after the receipt of the complaint (Article 27).

The mentally disabled patient and his legal guardian have the right to send complaints, proposals, or other submissions regarding his care, treatment, and rehabilitation to the Ministry of Health, competent authorities, or other institutions focusing on care delivered by healthcare facilities. The Ministry of Health must examine the submission and inform the patient or his legal representative of their decision in the case within a period of 30 days (Article 28).

The law also provides for court protection: “The patient suffering from mental illness has the right to court protection for the violation of his rights in a manner and procedure stipulated by law” (Article 29).

137 Official Gazette of the Republic of Macedonia, no. 25/00, 34/00, 96/00, 50/01, 11/02, 31/03, 84/05, 37/06, 18/07, 36/07, 82/08, 98/08, 6/09, 67/09

138 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

139 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

140 Official Gazette of the Republic of Macedonia, no. 71/06

d. Relevant international/regional provisions

Legally binding international and regional regulations regarding the right to complain include the International Covenant on Civil and Political Rights;¹⁴¹ the Optional Protocol of the International Covenant on Civil and Political Rights;¹⁴² the International Covenant on Economic, Social, and Cultural Rights;¹⁴³ the Geneva Convention for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field; the Convention on the Prevention and Punishment of the Crime of Genocide;¹⁴⁴ the UN Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment;¹⁴⁵ the Convention on the Elimination of All Forms of Discrimination Against Women;¹⁴⁶ the Convention on the Rights of the Child;¹⁴⁷ and the UN Charter.¹⁴⁸

e. Relevant provisions of healthcare providers' codes of ethics

In the relevant professional codes of ethics, no stipulations refer directly to this issue. However, this right is cited in the statutes of the Macedonian Chamber of Medicine and the Dental Chamber of the Republic of Macedonia. The right is exercised through respective chambers' ethical-legal committees and courts of honor.

f. Examples and case studies

1) Examples of compliance

Example 13.1

A patient complains about his treatment by a healthcare provider when informing the patient of about his condition and the possibilities for treatment. The patient submits his complaint to the Office for the Protection of Patients' Rights at the relevant healthcare facility, and the healthcare provider addresses the complaint.

2) Examples of violations

Example 13.2

A patient files a written complaint with the director of a healthcare facility. The director responds to the complaint verbally rather than in writing, and the response is issued 15 days after the complaint is made.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this Guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to complain; these procedures are described in detail in Chapter 8 of this guide.

141 International Covenant on Civil and Political Rights (ICCPR), December 19 1966

142 Official Gazette of the Republic of Macedonia, no. 7/1971 (ratified in 1994)

143 International Covenant on Economic, Social and Cultural Rights (ICESCR), December 19 1966

144 Official Gazette of the Republic of Macedonia, no. 2/1950 (ratified in 1994)

145 Official Gazette of the Republic of Macedonia, no. 9/1991 (ratified in 1994)

146 Official Gazette of the Republic of Macedonia, no. 11/1981 (ratified in 1994)

147 Official Gazette of the Republic of Macedonia, no. 15/1990 (ratified in 1993)

148 Available at: <http://www.un.org/en/documents/charter/index.shtml>

14. Right to Compensation

a. Right as stated in the ECPR¹⁴⁹

“Each individual has the right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical or moral and psychological harm caused by a health service treatment. The health services must guarantee compensation, whatever the gravity of the harm and its cause (from an excessive wait to a case of malpractice), even when the ultimate responsibility cannot be absolutely determined.”

b. Right as stated in national laws/legislation

The **Law on Healthcare**¹⁵⁰ establishes the patient's right to seek compensation for medical damages, errors, or inadequate treatment adversely affecting the patient's health, in accordance with the obligation relationship (Article 55).

c. Specific supporting laws and regulations

The **Law on Obligation Relationships**¹⁵¹ does not directly enumerate the right to compensation for damages that occur during treatment or medical interventions; however, it includes stipulations that regulate in detail the issue of compensation for damages caused in such cases. Thus, Article 9 states that “every person is obliged to refrain from a conduct that can cause harm or damage to another person” and that “**the person who causes proven harm or damage to another person must issue compensation for such harm or damage**” (Article 141, Para. 1). The law defines damage as “a decrease in one's property (plain damage), the prevention of an increase in one's property (loss of value), and the **harm or violation of one's personal rights** (non-material damage)” (Article 142). “Personal rights, according to this law, are the rights to life, physical and mental health, honor, respect, dignity, personal name, the privacy of one's personal and family life, freedom, intellectual property, and other rights.” (Article 9-A, Para. 2).

d. Relevant international/regional provisions

For information on relevant international and legal provisions, see Chapters 2 and 3 of this guide.

e. Relevant provisions of healthcare providers' codes of ethics

No stipulations referring directly to the right to compensation exist in the relevant professional codes of ethics.

149 European Charter of Patients' Rights, available at: http://www.patienttalk.info/european_charter.pdf

150 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

151 Official Gazette of the Republic of Macedonia, no. 18/01, 4/02, 5/03, 84/08, 81/09

f. Examples and case studies

1) Examples of compliance

Example 14.1

A patient is reimbursed for purchases of medications included in the Positive List of Medications for regular therapy within the protocol of treatment. The insured patient is reimbursed for his expenditures on medications that are not stocked by pharmacies under contract with the fund.

2) Examples of violations

Example 14.2

A patient with health insurance requires a laparoscopic operation and is asked to purchase disposable medical supplies due to a lack of medical materials at the healthcare facility. The patient has the right to seek for compensation from the Health Insurance Fund, but the healthcare provider asks the patient to sign a statement renouncing his right to compensation so that the healthcare facility can charge the patient for the supplies.

3) Actual cases

Case study 14.1

Based on the results of a cytological test, a patient was diagnosed with breast cancer (class 5) and was referred to a surgeon for further treatment. During the operation, the patient's breast and 22 lymph nodes were removed. Hysto-pathological results showed that the patient did not have breast cancer, but rather she had a mammary-fibroadenome.

This information is conveyed to the patient, who then filed a court complaint. The court requested a medical-forensic investigation to be conducted by the court-medical board. The patient complained about the impartiality of the board, as one of its members was a healthcare provider from the hospital where the operation was performed, but the court denied this complaint. The patient refused to pay for the forensic investigation due to the aforementioned reasons, and the results of the forensic analysis were not sent to the court.

The Helsinki Committee, which provided legal advice to the patient on this matter, has not yet received a ruling in the case.

(Source: Macedonian Helsinki Committee for Human Rights).

Case study 14.2

Due to poor communication and a lack of adequate information regarding payment and reimbursement procedures for medicine purchases through the Health Insurance Fund, patients bear the cost of medications that are included in the Positive List of Medications, resulting in the absence of compensation for medicine purchases made by members of Roma community.

HCAR Mesecina has recommended that doctors to make an additional effort to educate patients about what drugs are included in the Positive List of Medications and about the procedure for reimbursement in case the patient must buy the medication using his own funds. These steps will lessen the financial hardship of the patients. (Source: HCAR Mesecina)

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to compensation; these procedures are described in detail in Chapter 8 of this guide.

15. Right to Second Professional Opinion and Medical Consiliar Opinion

a. Right as stated in national laws/legislation

Article 9 of the **Law on the Protection of Patients' Rights**¹⁵² establishes the patient's right to seek a second professional opinion regarding his health status under the conditions stipulated through healthcare and health insurance regulations for the provision of the first professional opinion. When requested by a patient verbally or in writing, the second professional opinion must be provided by a healthcare provider with at least the same level of education as the physician who provided the first professional opinion. The healthcare provider responsible for issuing the second opinion must not have taken part in the initial medical intervention.

b. Specific supporting laws and regulations

According to the **Law on Healthcare**,¹⁵³ the patient **has the right to request during his treatment an examination by a medical council or a consultation with another doctor whom he has chosen**, so long as as the nature of the illness is severe, an operation is suggested, or the patient's condition is deteriorating. The patient's request must be reviewed and decided upon by the manager of the healthcare facility (Article 51).

c. Relevant international/regional provisions

For information on relevant international and regional provisions on the topic of the patient's right to a second professional opinion, see Chapters 2 and 3 of this guide.

d. Relevant provisions of healthcare providers' codes of ethics

Within the codes of ethics of the relevant professional associations, there are no provisions that refer directly to this right.

e. Examples and case studies

1) Examples of compliance

Example 15.1

A patient is diagnosed with hepatocellular carcinoma and consults a specialist to seek a liver transplant abroad. A request is submitted for a consiliary opinion, and the consilium deems the treatment possible and necessary in order to save the pa-

152 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

153 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

tient's life. A referral is made for the patient to have the transplantation operation abroad.

2) Examples of violations

Example 15.2

A patient who suffers from a chronic kidney disorder and is a long-time dialysis recipient requests a consiliary meeting to approve a kidney transplant from a compatible donor (in this case, a family member). The consilium denies the patient's request without an explanation, ignoring the medical evidence submitted by the patient.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to a second professional opinion; these procedures are described in detail in Chapter 8 of this guide.

16. Right to Maintain Contacts

a. Right as stated in national laws/legislation

Article 26 of the **Law on the Protection of Patients' Rights**¹⁵⁴ establishes the patient's right to maintain contact with persons within and outside of the healthcare facility. While admitted in the hospital, the patient has the right to: receive visitors; forbid visits of a certain person or persons; receive and send mail and make telephone calls at his own cost; listen to the radio and watch television programs; participate willingly in religious activities; and make use of weekend leave in accordance with his health status. The patient's right to maintain contacts is subject to the internal rules and capabilities of the healthcare facility. The healthcare facility determines its internal rules by means of a general act issued in compliance with its statute.

b. Specific supporting laws and regulations

According to the **Law on Mental Health**,¹⁵⁵ the mentally disabled patient has the right to: maintain contact with other people within and outside of the healthcare facility; receive and send mail and make telephone calls at his own cost; and listen to the radio and watch television programs in accordance with the hospital's capabilities (Article 14).

c. Relevant international/regional provisions

For information on relevant international and regional provisions on the topic of the patient's right to a second professional opinion, see Chapters 2 and 3 of this guide.

d. Relevant provisions of healthcare providers' codes of ethics

Within the codes of ethics of the relevant professional associations, there are no provisions that refer directly to this right.

e. Examples and case studies

1) Examples of compliance

Example 16.1

Based on the resources available, public and private healthcare facilities enable patients' access to public media outlets (e.g.: television, radio, newspapers, and magazines) and paid telephone communication service.

2) Examples of violations

154 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

155 Official Gazette of the Republic of Macedonia, no. 71/06

Example 16.2

A mentally disabled person, while admitted to a healthcare facility, is deprived of all items for personal use, including a mobile phone; the patient is told that the items would cause a disturbance among the other patients. In accordance with the Law on Mental Health and the Law on the Protection of Patients' Rights, the patient has the right to keep his personal belongings and to maintain contact with others during his admission to a healthcare facility; the possibility that a patient might abuse these rights should not be considered.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of the right to maintain contact with others

Under the administrative procedure, subjects seeking to exercise their rights or whose rights have been violated file a case with the responsible administrative body or with the body which has the public authority. The actual steps that must be undertaken are described first in the specific law regulating the legal issue, whereas the Law on General Administrative Procedure is used in cases dealing with legal situations that are not regulated by separate specific laws (Article 3, Para. 2).

Chapter 8 of this guide describes the administrative procedure in more detail. While an administrative procedure is pending review by state government bodies or other bodies and organizations with public authority, patients may request that the Ombudsman protect their rights. Such requests may be submitted in response to a protracted administrative procedure or when one's rights are violated through the actions or neglect of the aforementioned bodies. In case a court procedure has been initiated, the Ombudsman does not act according to complaint. For more information, see the section titled "Alternative mechanisms for protection/exercising of rights and obligations" in Chapter 8 of this guide.

A misdemeanor charge may be filed by the responsible government body,¹⁵⁶ either as part of a regular investigation, upon the claim of an authorized civil servant, or upon the claim of an authorized civil servant in conjunction with the aggrieved party. This kind of procedure may be initiated when misdemeanor responsibility is enumerated in a specific law, for physical person, legal person and the individual of the legal person, responsible for violation of the right regulated and guaranteed under the spe-

¹⁵⁶ The responsible body, in terms of the Law on Misdemeanors (Official Gazette of the Republic of Macedonia, no. 62/06 and 69/06), are the Public Prosecutor, the bodies of the state administration and local government, and other bodies that perform a public duty and are authorized to execute or supervise of execution of misdemeanor law. The responsible bodies are responsible for making a request to open a misdemeanor case every time there is reasonable doubt that misdemeanor has been committed.

cific law in question. Misdemeanor bodies are the courts, and public institutions and other institutions authorized for public responsibilities, authorized for pronouncement of misdemeanor sanctions, and which authority is regulated in separate law.

If a misdemeanor violation of one's rights contains elements of a criminal case, the responsibility is considered criminal. The elements that must be present in order to open a criminal case are enumerated either in the specific law regulating the issue or in the Criminal Code of the Republic of Macedonia.¹⁵⁷ For the procedure determining the criminal responsibility, see details in Chapter 8.

If a misdemeanor violation of one's rights has caused material or non-material damage, then responsibility for such damage is determined under civil procedure. This procedure is described in Chapter 8.

¹⁵⁷ Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

6.2 Patient Responsibilities

1. Responsibility to Care about Patient's Own Health, Life, and the Health of Others

a. Responsibility as stated in national laws/legislation

According to Article 29 of the **Law on the Protection of Patients' Rights**,¹⁵⁸ while the patient is admitted to healthcare facility, he is obliged, in line with his health status, to care about his health.

In this respect, according to the same article, it is also the patient's responsibility to assist healthcare providers responsible for his care and to follow the advice of healthcare providers with regard to his care, treatment, and rehabilitation.

b. Specific supporting laws and regulations

The **Law on Mental Health**¹⁵⁹ establishes the admitted patient's responsibility for following healthcare providers' advice with regard to care, treatment and rehabilitation, respect code of conduct and internal rules of the healthcare facility and must, in line with his health status, accept an engagement if it is part of his rehabilitation (Article 15).

According to the **Law for the Protection of the Population against Communicable Diseases**,¹⁶⁰ a person who represents a potential danger to the lives and health of other people is responsible for undergoing a health examination and obtaining immunization, in accordance with the relevant provisions. According to Article 34 of this law, protection with specific immunoglobulin is obligatory for persons with medical indications stipulated in this Article.

Health and sanitary examinations are performed for the prevention of communicable diseases; examinations are performed on persons, facilities, premises, objects, as well as samples taken for specific laboratory testing. Examinations are compulsory for:

- 1) persons working in educational or healthcare facilities where these two activities are performed;
- 2) persons having contact with food during its production and distribution; facilities for the supply of drinking water and persons having direct contact with the population's source of drinking water;
- 3) persons involved in the production, preparation, and dispensing of medications; persons who come in direct contact with medications; facilities where these medication is produced, prepared, or dispensed; and
- 4) persons working in the fields of sanitation or cosmetic product production, persons performing recreational activities for general population, and facilities in which these activities are performed.

¹⁵⁸ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

¹⁵⁹ Official Gazette of the Republic of Macedonia, no. 71/06

¹⁶⁰ Official Gazette of the Republic of Macedonia no. 66/04, 139/08, 99/09

If a communicable disease is in danger of being spread, compulsory health examinations is obligatory for all persons enumerated in Articles 45 and 46, until the epidemiological indications exist.

c. Examples and case studies

1) Examples of compliance

Example 1.1

Following the recommendation of his family physician, a patient suffering from diabetes mellitus and obesity becomes actively involved in caring for his health and takes steps to improve the quality of his diet in order to regulate his body weight.

Example 1.2

Due to the nature of his illness, a patient suffering from diabetes mellitus who does not experience difficulty performing daily activities is advised to measure the level of his blood glucose regularly using a home monitor. The patient reports the results regularly to his endocrinologist, who uses the information to determine the patient's course of therapy, monitor his condition, and manage his disease.

2) Examples of violations

Example 1.3

A family physician and cardiologist advise a patient with a genetic predisposition to hypertension and heart attacks to decrease his tobacco use and completely stop smoking. The patient does not follow the doctor's recommendations, and in time, his health condition deteriorates. Each citizen has the constitutional obligation to take care of and improve his health and the health of others.

Example 1.4

A patient with hypertension is advised to take prescription medication regularly and to decrease his intake of salt and liquids. The patient does not follow the doctor's recommendations, and his condition soon deteriorates. Thinking that the previous doctor had treated the condition unsuccessfully, the patient requests a second professional opinion regarding his health complaint. Each citizen has the constitutional obligation to take care of and improve his health and the health of others.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

2. Responsibility to Inform and Report/Notify

a. Responsibility as stated in national laws/legislation

According to Article 29 from the **Law on the Protection of Patients' Rights**,¹⁶¹ while admitted to a healthcare facility, the patient must, in line with his health status, provide truthful and sufficient data on his health status.

b. Specific supporting laws and regulations

According to Article 31 of the **Law on the Protection of the Population against Communicable Diseases**¹⁶², “persons returning from countries that have had reported occurrences of pest, viral hemorrhagic fevers, cholera, or malaria are subject to health surveillance and must report to a healthcare facility for screening; if necessary, they may be subject to clinical and laboratory examinations.”

Article 32 of the law states that “persons who travel to countries where they are at risk of contracting any of the infections listed in Article 31 are responsible for protecting themselves before, during, and after their trip. Furthermore, these persons must undergo health surveillance in accordance with this law and related legal documents.”

c. Examples and case studies

1) Examples of compliance

Example 2.1

A person returning from a trip to a country with a high prevalence of Legionnaires' disease reports to a regional healthcare facility for a routine check-up.

2) Examples of violations

Example 2.2

A parent of a child who has contracted viral meningitis goes to the regional healthcare office to report the case. Instead of directing the parent to the right place, healthcare staff at the facility argue with the parent about the seriousness of the case. The parent, who is under stress, does not know steps to take in the case and continues to treat his child while unintentionally violating his responsibility to report the case.

3) Actual cases

Case study 2.1

A patient experiencing severe abdominal pain was admitted to an abdominal surgery clinic under the suspicion that she was suffering from appendicitis. After the patient was taken to the operating room, healthcare providers discovered that the patient

161 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

162 Official Gazette of the Republic of Macedonia, no. 66/04, 139/08, 99/09

was pregnant and that the anesthesia and medications she was given might endanger the health of the fetus. The patient, who was seven months into her pregnancy, did not provide accurate information regarding her health condition, thus endangering her health and the health of her child, and creating conditions that could potentially harm the reputation of her healthcare providers. Criminal charges may be filed against the patient in this situation.

(Source: *Macedonian Chamber of Medicine*)

4) Practical notes

The responsibility of the patient to provide accurate information should be considered according to the patient's ability to communicate such information and the healthcare provider's ability to obtain the maximum possible amount of information from the patient. **It is inexcusable for the healthcare provider to provide inappropriate treatment because he was unable to obtain necessary information from an uncommunicative patient.** Healthcare providers should be trained to understand the psychological condition of patients with certain health conditions or illnesses in order to obtain accurate and sufficient information about the patient and his medical history.

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

3. Responsibility to Respect Code of Conduct and the Healthcare facility's House Rules

a. Responsibility as stated in national laws/legislation

According to Article 29, Point 5 of the **Law on the Protection of Patients' Rights**,¹⁶³ while admitted in a healthcare facility, the patient must respect the code of conduct and internal rules of the healthcare facility insofar as his medical condition allows.

b. Specific supporting laws and regulations

According to Article 56 of the **Law on Healthcare**¹⁶⁴, during the provision of treatment or other medical services, patients must follow the rules and regulations of healthcare facilities.

Article 15 of the **Law on Mental Health**¹⁶⁵ states that patients suffering from mental illness must respect code of conduct and internal rules of the healthcare facility insofar as their medical conditions allow.

¹⁶³ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

¹⁶⁴ Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

¹⁶⁵ Official Gazette of the Republic of Macedonia, no. 71/06

c. Examples and case studies

1) Examples of compliance

Example 3.1

A patient who is hospitalized in a healthcare facility for an extended period of time due to the necessity of preparation for surgery and post-operative recovery requests weekend leave to perform activities that she cannot complete on hospital grounds due to a lack of resources (e.g.: observing a religious holiday). If doctors determine that leaving the grounds of the healthcare facility would not adversely affect the patient's health condition, and they approve his request for weekend leave, then the patient has the right to leave hospital grounds. Otherwise, the patient should act in accordance with the recommendations given by his doctors.

2) Examples of violations

Example 3.2

A patient is admitted to an intensive care unit, where his condition stabilizes after medical intervention and therapy. Despite his steps toward recovery, the patient refuses to be transferred to a regular ward due to differences in the level of care provided in the intensive care unit and the general ward. The patient's behavior violates the internal rules of the healthcare facility, including a rule governing the triage of medical cases.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

4. Responsibility to Accept Work/Engagement

a. Responsibility as stated in national laws/legislation

According to Article 29 of the **Law on the Protection of Patients' Rights**,¹⁶⁶ while admitted to a healthcare facility, the patient must, in line with his health status, accept any engagement that is part of his rehabilitation and re-socialization, for the purpose of reactivating his social skills and respecting the professional and human dignity of healthcare providers.

Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

b. Specific supporting laws and regulations

Article 15 of the **Law on Mental Health**¹⁶⁷ states that, while admitted to a healthcare facility, the mentally disabled patient must, in line with his health status, accept an engagement if it is part of his rehabilitation.

c.Examples and case studies

1) Examples of compliance

Example 4.1

A patient with experience as a psychologist is treated in the hospital's prisoners' ward. Due to his previous experience, the hospital hired him in order to help newly admitted patients with alcohol and drug problems. The patient is paid for his services, which at the same time are part of his re-socialization programme.

2) Examples of violations

Example 4.2

A patient experiencing psychosomatic problems is advised to seek employment at a certain workplace in order to improve his mental health. The patient rejects the advice, explaining that he does not want to work there, despite the recommendations of healthcare providers. Although the situation infringes on the patients' right of free choice, the patient should respect his duty to consider the advice and recommendations given to him by healthcare providers who are looking out for his well-being and health.

Example 4.3

A healthcare provider working in an institution for mentally ill patients assigns the patients chores that do not comply with the work engagement doctrine. Patients do not receive adequate compensation for their work as required by law. The patients have the right not to follow the healthcare provider's advice, considering the improper course of their therapy, which is only partially useful for them.

3) Actual cases

No violations of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

¹⁶⁷ Official Gazette of the Republic of Macedonia, no. 71/06

7

National Providers' Rights and Responsibilities

This section focuses on providers' rights, including the rights to work in decent conditions, freedom of association, due process, and other relevant country-specific rights. The concept of human rights in patient care refers to the application of general human rights principles to all stakeholders in the delivery of health care and recognizes the interdependence of patients' and providers' rights. Health workers are unable to provide patients with good care unless their rights are also respected and unless they can work under safe and respectful conditions. For each right outlined in the section, there is a brief explanation of how that right relates to health providers; and examination of its basis in country legislation, regulations and ethical codes; examples of compliance and violation; and practical notes for lawyers on litigation to protect provider rights.

The rights and responsibilities of healthcare providers are regulated by regulations from the area of labor law (**the Labor Relations Act**¹ and its supporting bylaws, **the Collective Agreement for Healthcare in the Republic of Macedonia**²) and healthcare legislation (**the Law on Healthcare**³ in Article 155, Article 155a, Article 156 and other laws and bylaws).

1 Official Gazette of the Republic of Macedonia, no. 62/05, 106/08, 161/08, 114/09

2 Official Gazette of the Republic of Macedonia, no. 60/06

3 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

7.1 Healthcare Providers' Rights

1. Right to Association

a. Right as stated in national laws/legislation

Health workers' ability to form, join, and run associations without undue interference is critical to their ability to effectively defend their rights and provide good care. The right of association is guaranteed by the Macedonian Constitution,⁴ which states: "Citizens are guaranteed freedom of association to exercise and protect their political, economic, social, cultural, and other rights and convictions" (Article 20).

According to the **Law on Healthcare**,⁵ "**doctors of medicine, dentists, and graduated pharmacists shall associate in the Chamber of Medicine, Dental Chamber, and Chamber of Pharmacists** in order to protect and improve their proficiency, ethical responsibilities, and rights for improving the quality of healthcare, protecting the interests of their profession, and maintaining the quality relationship of the healthcare provider with society and citizens.

The Chamber of Medicine, Dental Chamber, and Chamber of Pharmacists are legal entities and are registered in the Central Registry of the Republic of Macedonia" (Article 155, Para. 1-2).

According to the **Law on Healthcare**, "due to the protection and improvement of their proficiency, ethical responsibilities, and rights for improving the quality of healthcare, protecting the interests of their profession, and maintaining the quality relationship of the healthcare provider with society and citizens, **healthcare providers with a secondary education and additional professional courses in the area of medicine, dentistry, and pharmacy shall be permitted to associate in chamber of healthcare providers with a secondary education and professional medical courses**" (Article 155-a, Para. 1).

The chambers have broad legal powers, especially in the licensing of healthcare providers. For more information on this topic, see the section of this guide titled "Responsibility for Licensing, Continuing Medical Education, and Re-licensing."

Other relevant information

The Chamber of Medicine and Dental Chamber have the power to issue, renew, and terminate basic practice licenses. They must also maintain a registry of issued, renewed, and terminated licenses.

The Chamber of Pharmacists has the power to issue, renew, and terminate

4 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

5 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

practice licenses and must maintain a registry of issued, renewed, and terminated licenses.

The form and content of each registry is defined by the relevant chamber through a general act approved by the Minister of Health.

Each chamber has the power to terminate licenses of healthcare providers if it is determined that they violated the chamber's code of ethics or the standards and quality of healthcare.

Persons who are dissatisfied with decisions of the Chamber of Medicine, Dental Chamber, and Chamber of Pharmacists, may file a complaint with the Minister of Health.

The chambers create statutes and codes of professional ethics, determine healthcare providers' rights and responsibilities, and establish a Court of Honor and other supporting bodies and acts, as stipulated by law.

The chambers are responsible for producing and presenting biannual reports to the Ministry of Health regarding the issuance, renewal, and termination of practice licenses.

Healthcare providers associate in the Macedonian Medical Association (MMA), as well as specialists' associations within the MMA, in order to exchange information about the latest achievements and developments in various medical fields.

Acting through professional and other associations, the MMA organizes several methods for the professional upgrading of healthcare providers, prepares professional bylaws for various specialties, and proposes measures for the improvement of various medical specialties (Article 156).

b. Relevant international/regional regulations

For information on this topic, see Chapters 2 and 3 of this guide.

c. Relevant provisions of healthcare providers' codes of ethics

Healthcare providers' codes of ethics define the professional rights and responsibilities of doctors and pharmacists. In Macedonia, these codes include the Code of Ethics of the Macedonian Chamber of Medicine⁶, the Code of Ethics of the Dental Chamber of Macedonia,⁷ and the Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights.⁸

These codes are important have because current legislation in Macedonia regulates the responsibilities of healthcare providers and refers to their application of medical ethics. Namely, the **Code of Ethics of the Macedonian Chamber of Medicine** is necessary because, according to the Law on the Protection of Patients' Rights,⁹ "the healthcare provider performing a direct medical intervention on a patient is responsible for performing his duty in accordance with the rules of medical ethics with the

6 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

7 Available at: <http://stomatoloskakomora.org/?strana=statut>

8 Available at: http://www.farmaceutskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

9 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

singular goal of protecting and improving the patient's health" (Article 38, Para. 1, Point 2). Furthermore, the first articles of the **Code of Ethics of the Dental Chamber of Macedonia** and the **Code of Ethics of the Macedonian Chamber of Medicine** determine the responsibilities of healthcare providers. For more information on this topic, see Chapter 5 of this guide.

Other relevant information

The Law on Citizens' Associations and Foundations¹⁰ determines the manner, conditions, and procedure for the founding, registration, operation, and termination of citizens' associations and foundations (Article 1).

The Central Registry of the Republic of Macedonia is an institution that was formed in accordance with the Law for Central Registry¹¹; as legal entity, the Central Registry has rights and responsibilities determined by law. The registry itself is a regularly updated database that contains the following information: data regarding the rights of ownership over real estate and actual rights over other people's belongings (e.g.: securities, mortgages, administrative rights, real wages, long-term rentals, transfers of ownership of objects, and transfers of rights due to security); information on the status of trade companies or other legal entities, and data on annual payments.

The Central Registry is based in Skopje and has a network of offices (ten regional registry offices and twenty registry offices) in the country's largest cities.

d. Examples and case studies

1) Examples of compliance

Example 1.1

Healthcare providers who have a university education and practice in the fields of medicine, dentistry, and pharmacy exercise their right to association by establishing the professional chambers.

Example 1.2

The establishment of the Macedonian Medical Association and similar associations represents another example of the right of association. Within the Macedonian Medical Association, there exist a number of professional associations, such as the Association of Doctors of Occupational Health, that are designed to oversee various mechanisms for the professional development of specialists in a particular field; these mechanisms include conferences, seminars, workshops, and courses that are offered as continuing medical education (CME); the preparation of clinical guidelines (e.g.: the Tasks of Occupational Health Specialists During Heatwaves; the Workplace Risk Assessment); and the preparation of methods for the improvement of clinical and other professional guidelines.

10 Official Gazette of the Republic of Macedonia, no. 31/98, 29/07

11 Official Gazette of the Republic of Macedonia, no. 50/01, 49/03, 109/05, 88/08

Example 1.3

Nurses and midwives are associated in the Macedonian Association of Nurses and Midwives.

2) Example of Violation

Example 1.4

The denial of a request to register an association of healthcare providers in the Central Registry would constitute a violation of the right of association, unless there exist legal issues that would pose an obstacle to registering such an association.

3) Actual cases

The working group responsible for preparing this guide did not come across any information regarding actual violations of healthcare providers' right of association. Evidence of various forms of association indicates that healthcare providers in Macedonia exercise this right freely.

4) Practical notes

The association of healthcare providers is enabled by an administrative procedure lead by the Central Registry of the Republic of Macedonia, in accordance with the **Law on Central Registry**¹² (registering citizen association), the **Law on Citizen Associations and Foundations**¹³ (procedure on establishing citizens' association) and the **Law on Healthcare**¹⁴ (the right of association and functions of the chambers).

2. Right to Due Process**a. Right as stated in national laws/legislation**

Health care and service providers are potentially subject to a range of civil and administrative proceedings—disciplinary measures, medical negligence suits, administrative measures such as warnings, reprimands, suspension of activities, etc.—and are entitled to enjoyment of due process and a fair hearing. **The right to due process** may be viewed either as healthcare providers' ability to protect their rights when fulfilling their professional duties or as healthcare providers' obligation to enable and support the realization of patients' rights.

The Constitution of the Republic of Macedonia¹⁵ guarantees the right to due process for healthcare providers as citizens of Macedonia.

The right to freedom is irrevocable. No person's freedom may be restricted except through a court decision or in cases and procedures determined by law.

12 Official Gazette of the Republic of Macedonia, no. 50/01, 49/03, 109/05, 88/08

13 Official Gazette of the Republic of Macedonia, no. 31/98, 29/07

14 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

15 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

Persons who are summonsed, arrested, or detained shall be informed immediately of their rights and of the reasons for the summons, arrest, or detention. These persons may not be forced to give a statement, and they have the right to an attorney in when dealing with police and court personnel.

The detainee must be brought before a court within 24 hours of his detention; the court must decide without delay on the legality of the detention. The court must also decide on the period of detention, which may last up to 90 days. Under conditions determined by law, the detainee may be released from custody for the purpose of conducting his legal defense (Article 12).

An indicted person is presumed innocent until his guilt is established under a legally valid court verdict. A person who is unlawfully detained, arrested, or convicted has the right to legal redress and other rights determined by law (Article 13).

No person may be punished retroactively for conduct that was not regulated by law when it was originally performed. No person may be tried twice for the same crime on which there is an effective court decision (Article 14).

Citizens have the right to appeal decisions of courts, administrative bodies, or other public institutions (Article 15).

Citizens are guaranteed the freedom of personal belief, conscience, opinion, and public expression. Freedom of speech, public address, public information, and the establishment of institutions for public information is guaranteed. Free access to information and the freedom of the reception and transmission of information are also guaranteed. The right of reply via mass media and the right to a correction in mass media is guaranteed. Mass media organizations have the right to protect a source of information. Censorship is prohibited (Article 16).

Furthermore, the freedom and confidentiality of correspondence and other forms of communication are guaranteed. Only a court decision may authorize exceptions to this rule for use in a criminal investigation or for the purpose of protecting national security (Article 17).

The security and confidentiality of personal information are guaranteed by law. Citizens are guaranteed **protection from any violation of their personal integrity** deriving from the registration of personal information through data processing (Article 18).

Every citizen has the right to file a petition with state institutions and other public bodies; the right to receive a response to the petition is also guaranteed. A citizen may not be held accountable for or suffer adverse consequences from attitudes that are expressed in petitions, unless they entail the commission of a criminal offense (Article 24).

Every citizen has the right to invoke the protection of freedoms and rights established by the Constitution before regular courts and the Constitutional Court through

a procedure based on the principles of priority and urgency. Judicial protection of the legality of individual acts undertaken by state administration bodies and other public institutions is guaranteed by law. Every citizen has the right to be informed about basic human rights and freedoms and to actively contribute, individually or jointly, to the promotion and protection of those rights and freedoms (Article 50).

The freedoms and rights of individuals and citizens may be restricted only in cases that are mentioned explicitly in the Constitution (e.g.: in wartime or during a state of emergency). The restriction of freedoms and rights may not discriminate against any person on the grounds of gender, race, language, religion, national or social origin, or property or social status. The following rights may not be restricted under any circumstance: the right to life; the prohibition of torture, inhuman, and humiliating behavior and punishment; the legal determination of punishable offenses and sentences; the freedom of personal belief, conscience, opinion, and religious confession (Article 54).

Protection of healthcare providers' labor rights is regulated by legislation regarding labor relations (e.g.: **the Labor Relations Act**,¹⁶ **the Law on Health and Safety at Work**,¹⁷ **and the Collective Agreement on Healthcare in the Republic of Macedonia**¹⁸).

Protection of healthcare providers' right to due process is regulated by the Law on Healthcare¹⁹ and applicable clauses of regulations on the financial activities of trade companies.

Protection of the rights of healthcare providers who are not Macedonian citizens is regulated through the Law on Foreign Citizens,²⁰ which states: "A permanent residence permit enabling work or self-employment may be issued to a foreign citizen who provides a proof of an existing working license or other necessary license in accordance with the law, unless otherwise determined by a signed international agreement. The license referred to in paragraph 1 of this Article shall be valid for the timeframe of the issued license but not longer than one year, with the possibility for extension if the conditions determined in Article 57 of this law have been fulfilled" (Article 58).

If a foreign citizen does not understand the language used during the procedure of his deportation, the Ministry of Internal Affairs is obligated to provide an explanation in a language that the foreign citizen understands. The cost of translation is covered by the Ministry of Internal Affairs (Article 141).

In cases of deportation, the deferral of a foreign citizen's right to reside in the Republic of Macedonia, or the restriction of a foreign citizen's right to freedom, the foreign

16 Official Gazette of the Republic of Macedonia, no. 62/05

17 Official Gazette of the Republic of Macedonia, no. 92/07

18 Official Gazette of the Republic of Macedonia, no. 60/06

19 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

20 Official Gazette of the Republic of Macedonia, no. 35/06, 66/07, 117/08, 92/09

citizen must be informed of his right to legal assistance and his right to contact a representative of his native country in the Republic of Macedonia (Article 142).

The operating license of the healthcare provider may not be revoked without properly examining the reasons for revocation. The Law on Healthcare defines the conditions under which a license may be revoked and outlines the procedure for revoking a healthcare providers' license (Article 153-zh, 153-dz, and 153-i). The law also restricts the term of a temporary revocation to a maximum of seven years. A temporary revocation may occur as the result of administrative or other violations (e.g.: failure to apply on time for the renewal of a license, failure to complete required additional educational courses, forgery of documents required for the renewal of a license, performance of medical procedures without a valid license, violation of the code of ethics). A court may approve the permanent revocation of an operating license if a healthcare provider's error or malpractice causes the death or permanent disability of a patient (Article 153-dz). The law also states that a healthcare provider may appeal the revocation of his license by the relevant professional chamber by filing a complaint with the Minister of Health within 15 days of the chamber's decision to revoke the license (Article 153-i).

Since the Constitution²¹ guarantees the protection of certain rights, including the right to complain, a healthcare provider may seek to overturn the decision of the Ministry of Health by filing an administrative case in court.

Thus, healthcare providers have the legal right to due process in cases involving the revocation of an operating license; administrative, civil, and criminal procedures may be used to protect this right (see Chapter 8 for further details).

b. Specific supporting laws and regulations

Additional regulations specifically involving the right to due process include the **Law on Ionizing Radiation Protection and Safety**,²² which establishes standards for the special protection of healthcare providers who work with sources of radiation. The law also contains stipulations for the protection of their rights according to the specific conditions of their work.

c. Relevant international/regional regulations

For more information on this topic, see Chapters 2 and 3 of this guide.

d. Relevant provisions of healthcare providers' codes of ethics

Healthcare providers' codes of ethics contain stipulations for determining the right to due process in the ethics procedures of professional chambers. For example, the

21 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

22 Official Gazette of the Republic of Macedonia, no. 48/02, 135/07

dentist has the right and responsibility through professional and other organizations to obtain appropriate valorization of his work, social status, and **protection from professional risks** (Article 13 of the *Code of Ethics of the Dental Chamber of Macedonia*²³). The code also states that, “in cases when a healthcare provider’s error in treatment or diagnosis is objectively determined, the dentist must submit a written opinion either to the expert and management bodies of the public healthcare provider where he works or to the Dental Chamber if the dentist works at a private practice.

It is impermissible and professionally unacceptable for a healthcare provider to issue a verbal statement of opinion on the adequacy of treatment to the patient, support staff, and the general public. A negative opinion regarding treatment must be expressed in the presence of the doctor responsible for the alleged error. The opinion must be objective, well-argued, and without personal discredit or assault” (Article 54).

The codes of ethics of the Medical Chamber and Chamber of Pharmacists have similar stipulations.

Other relevant information

The Chamber of Medicine and Dental Chamber are currently discussing the adoption of a law tentatively titled “the Law on Healthcare Profession,” which would resolve certain issues regarding doctors’ rights and responsibilities that are established through other regulations (dispersed legislation). Such an approach may improve to clarify existing rights and responsibilities rather than establish new rights and responsibilities.

e. Examples and case studies

1) Examples of compliance

Example 2.1

The right to due process is exercised when a criminal charge is filed against a healthcare provider; the charge shall be filed in a manner that is consistent with the Criminal Code.

2) Examples of violations

Example 2.2

Information regarding a healthcare provider who is under suspicion of medical malpractice is released while the investigation is still in progress.

²³ Available at: <http://stomatoloskakomora.org/?strana=statut>

3) Actual cases

Case study 2.1

Electronic media show live footage of the incarceration of healthcare providers who are suspected of a crime; footage shows the face of one of the accused healthcare providers.

This action violates the healthcare provider's right to a fair trial and the **presumption of innocence** guaranteed by the **Constitution of the Republic of Macedonia**.²⁴

A person who is incarcerated, placed in police custody, or indicted unlawfully has the right to compensation for damages and other rights determined by law (Article 13). The *Criminal Code*²⁵ states that no one may be accused and punished unlawfully, and that a person found guilty of a crime must be sentenced under the guidelines set by the **Law on Criminal Procedure**²⁶ and in accordance with the principle of due process. Prior to the rendering of a court verdict, the rights and liberties of the accused and other persons may be limited only to the extent that is necessary and under the conditions stipulated in the Criminal Code. The accused shall be considered innocent until his guilt is established by a legally valid court verdict. The case shall be formed by the existence or lack of facts, and the court must base its verdict on regulations contained in the Criminal Code²⁷ (Articles 1 and 2).

This case study also encompasses a violation of the **Law on the Protection of Personal Data**.²⁸

4) Practical notes

Healthcare providers may open administrative, civil, and criminal cases in order to protect their right to due process, just as patients may file administrative, civil, and criminal cases in order to protect their rights.

In cases involving the healthcare provider's right to due process, one must act in accordance with appropriate legislation.

For performing their duty, attorneys who usually give legal advice to healthcare providers on how to protect their rights and based on the interests and court procedures, the state bodies and other legal entities are obliged to act in accordance with the **Law on Lawyer Practice**.²⁹

24 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

25 Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

26 Official Gazette of the Republic of Macedonia, no. 15/97, 83/08, 67/09

27 Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

28 Official Gazette of the Republic of Macedonia, no. 7/05, 103/08

29 Official Gazette of the Republic of Macedonia, no. 59/02, 60/06, 29/07, 106/08

The **Law on the Ombudsman**³⁰ establishes guidelines for the involvement of the Ombudsman in cases of the protection of healthcare providers' rights. The law states: "The Ombudsman is a body in the Republic of Macedonia that protects the constitutional and legal rights of citizens and all other persons when these rights are infringed upon by the actions and omissions of state administration bodies and other public bodies and organisations, and who undertakes actions and measures for the protection of the principle of non-discrimination and for adequate and equitable representation of community members in state administration bodies, local self-government units, and public institutions and agencies" (Article 2).

3. Right to Work in Adequate Conditions

a. Right as stated in national laws/legislation

Health workers enjoy a range of rights related to decent, safe, and healthy working conditions when providing care.

The right to work in adequate conditions is established as by the **Labor Relations Act**,³¹ which states that "the employer must provide conditions for the safety of the life and health of workers in accordance with the special regulation for work protection and other regulations" (Article 42).

The Law on Health and Safety at Work³² sets workplace safety measures, employer liabilities, and employee rights and responsibilities in the field of occupational health and safety. The law also establishes preventive measures against professional risks by eliminating accident risk factors; informing, consulting, and training workers and their representatives about workplace safety; and engaging workers and their representatives in the planning and implementation of measures for occupational health and safety.

The Law on Ionizing Radiation Protection and Safety³³ sets standards for the special protection of the healthcare providers who work with sources of radiation. The law also contains stipulations for the protection of their rights according to the specific conditions of their work.

The Collective Agreement of Healthcare Profession in the Republic of Macedonia³⁴ regulates a number of rights in the area of healthcare provider protection. Article 25 states: "An employee who performs exceptionally difficult, hard, and harmful activities that have harmful effects on his health cannot be terminated outright and shall have shorter/limited working hours reciprocal to the harmful effects upon his health and working ability, not shorter than 30 hours per week.

30 Official Gazette of the Republic of Macedonia, no. 60/03, 114/09

31 Official Gazette of the Republic of Macedonia, no. 62/05, 106/08, 161/08, 114/09

32 Official Gazette of the Republic of Macedonia, no. 92/07

33 Official Gazette of the Republic of Macedonia, no. 48/02, 135/07

34 Available at: http://ssm.org.mk/index.php?option=com_content&view=article&id=128&Itemid=156

The following conditions are considered exceptionally difficult, hard, and harmful: work with sources of radiation, work with communicable diseases or infectious materials, performing surgical interventions in an operating room, psychiatric work, work with persons suffering from advanced psychophysical disabilities, and work in medical forensics and pathology.

Approval to work shorter/limited working hours that are mentioned in paragraph 2 of this Article shall be given by a state administration body in the field of healthcare, with previous opinion submitted to the body of occupational health and syndicate opinion. The working hours shall be regarded as full-time” (Article 25).

Article 40 stipulates that employers must organize the process of labor and the manner in which occupational health and safety is provided to employees, create working conditions that comply with scientific methods, up-to-date achievements, proposed regulations, and normative and other universally recognized measures that ensure the personal safety and good physical and mental health of employees.

The employee has the right to refuse work if his life or health are in immediate danger and proposed workplace safety measures have not been implemented (Article 43). The employer is the responsible for adjusting the work of his employees to fit the working environment, equipment, and working and technological processes; for reducing factors that are harmful to employees’ health; and for enabling regular check-ups of employees who come into contact with patients, toxic materials, and substances that may cause harm to one’s health or the safety of food products (Article 44).

b. Specific supporting laws and regulations

The Law on Healthcare,³⁵ by means of the **Book of Regulations on Spatial Conditions, Equipment, and Human Resources (Minimal Standards) for the Establishment and Functioning of Healthcare Facilities**,³⁶ indirectly protects the safety of healthcare providers because it sets minimal requirements for space and equipment at healthcare facilities.

c. Relevant international/regional regulations

For information on this topic, see Chapters 2 and 3 of this guide.

d. Relevant Provisions of Providers’ Codes of Ethics

The Code of Ethics of the Macedonian Chamber of Medicine³⁷ (Article 12) and the **Code of Ethics of the Dental Chamber of Macedonia**³⁸ (Article 13) state that “doctors have the right and responsibility through professional and other organiza-

35 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

36 Official Gazette of the Republic of Macedonia, no. 11/92

37 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

38 Available at: <http://stomatoloskakomora.org/?strana=statut>

tions to fight for the appropriate valorization of their work and to be protected from professional risks.”

e. Examples and case studies

1) Examples of compliance

Example 3.1

According to the Collective Agreement on Healthcare Profession in the Republic of Macedonia, healthcare providers (e.g.: a nurse in hospital dialysis center) have the right to limited working hours, as they work in positions that require the performance of “exceptionally difficult, hard and harmful activities.”

2) Examples of violations

Example 3.2

Due to her condition, a pregnant woman who works as a healthcare provider is not allowed to perform her duties full-time, especially in difficult working conditions (e.g.: working as a nurse in a surgical operating room).

3) Actual cases

No cases have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

In accordance with the Law on Civil Procedure,³⁹ labor dispute proceedings may be initiated in cases when an employer violates the rights of an employee. Labor dispute proceedings are initiated after all other mechanisms for the protection of an employer's rights have been exhausted. In labor dispute cases, especially in setting the hearings, the court must pay special attention to the priorities of resolving the dispute. In accordance with this principle, the reply to a labor suit must be within eight days. In cases involving the termination of a contract, the main hearing of the suit must take place within 30 days of receiving the response to the lawsuit. The court's first hearing of a labor suit must be completed within six months; appeals of the initial finding must be decided upon within 30 days. Second instance court is responsible to reach a decision upon an appeal against the first instance court's decision within 30 days of the day the appeal has been admitted i.e. within two months after the second instance court hearing. During the hearing, the court may suggest temporary measures for prevention of violent behavior or irreplaceable damages if it receives such a request from each of the parties involved. The court's decision must be carried out within eight days. Appeals of court decisions in labor disputes must be lodged within eight days. The court has the right not to postpone the execution of its original decision during the appeals process, but it must explain the reasoning for such a decision.

³⁹ Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

4. Right to Protest

a. Right as stated in national laws/legislation

The right to protest is guaranteed by the **Constitution of the Republic of Macedonia**⁴⁰ (Article 38). The right to protest is also established by the **Labor Relations Act**⁴¹ (Article 236).

The special conditions under which healthcare providers may exercise their right to protest are determined by the Law on Healthcare⁴², which states that “employees in healthcare facilities may exercise their right to protest under conditions that do not endanger their lives or the lives of the citizens seeking healthcare services” (Article 171-a).

The law continues: “For the prevention of the harmful consequences that could be caused by limited healthcare services during a time of protest, the managing body of the healthcare facility is responsible for providing urgent medical care and ensuring the basic functioning of all organizational elements of the healthcare facility.

Based on the measures taken, employees of healthcare facilities are responsible for acting upon appropriate orders.

If employees act in accordance with appropriate orders, the director of the facility is responsible for ensuring the functioning of the work process using replacement employees.

Employees who do not perform their duties cause greater harm to working discipline, which represents a basis for the termination of their employment contracts. Activities aimed at eliminating the harmful consequences that could occur as a result of the lack of available healthcare services for citizens at the time of protest shall be determined by the healthcare facility under a general act”(Article 171-b).

b. Specific supporting laws and regulations

The **State Sanitary and Health Inspectorate (SSHI)** ensures that the regulations are applied adequately with regard to the provision of healthcare services in times of protest. According to the **Law on Sanitary and Health Inspection**:⁴³ “Sanitary and health inspection encompasses the examination of the **proper implementation of the law and other sanitation- and health-related regulations**. The inspection includes the examination of space, facilities, rooms, equipment, activities, and persons performing healthcare services, as well as the sanction of any person who may have a harmful influence on people” (Article 2).

40 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

41 Official Gazette of the Republic of Macedonia, no. 62/05, 106/08, 161/08, 114/09

42 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

43 Official Gazette of the Republic of Macedonia, no.71/06

44 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

c. Relevant international/regional regulations

For information on this topic, see Chapters 2 and 3 of this guide.

d. Relevant provisions of healthcare providers' codes of ethics

The Code of Ethics of the Macedonian Chamber of Medicine⁴⁴ establishes healthcare providers' right to warn the patient or, in extreme cases, to terminate treatment in cases when a patient behaves inappropriately and it is not a medical emergency. If there is no clear danger to the life of the patient and an emergency intervention is not necessary, the doctor has the right to recuse himself from further treatment of the patient in the following cases: if the patient is a close friend or relative; by request of the patient or his family or legal guardian, since they violate the postulates of the medical ethnics and the Penal Code; when there exists a mutual legal dispute between the patient and doctor; or if the doctor believes his professional ability is insufficient to provide the necessary treatment. The doctor shall submit a written statement indicating his recusal to the manager of the healthcare facility (Article 30).

e. Examples and case studies

1) Examples of compliance

Example 4.1

Healthcare providers organize a protest to defend their right to a pay increase based on changes in the Collective Agreement of the Healthcare Profession. At the same time, the healthcare providers show respect the principle of the uninterrupted provision of healthcare services to patients because they still provide emergency healthcare services and other limited services.

2) Examples of violations

Example 4.2

Despite the fact that a protest was announced by healthcare providers who are employees of public healthcare facilities, and that the protesting healthcare providers have complied with all of the conditions necessary for staging such a protest, some of the protesters receive notification of the termination of their employment. The notice of termination states that the healthcare providers have failed to fulfill their obligations during the protest.

3) Actual cases

No cases involving the violation of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

In accordance with the Law on Civil Procedure,⁴⁵ labor dispute proceedings may be

⁴⁵ Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

initiated in cases when an employer violates the rights of an employee. Labor dispute proceedings are initiated after all other mechanisms for the protection of an employer's rights have been exhausted. In labor dispute cases, especially in setting the hearings, the court must pay special attention to the priorities of resolving the dispute. In accordance with this principle, the reply to a labor suit must be within eight days. In cases involving the termination of a contract, the main hearing of the suit must take place within 30 days of receiving the response to the lawsuit. The court's first hearing of a labor suit must be completed within six months; appeals of the initial finding must be decided upon within 30 days. Second instance court is responsible to reach a decision upon an appeal against the first instance court's decision within 30 days of the day the appeal has been admitted i.e. within two months after the second instance court hearing. During the hearing, the court may suggest temporary measures for prevention of violent behavior or irreplaceable damages if it receives such a request from each of the parties involved. The court's decision must be carried out within eight days. Appeals of court decisions in labor disputes must be lodged within eight days. The court has the right not to postpone the execution of its original decision during the appeals process, but it must explain the reasoning for such a decision.

5. Right to Benefitted Length of Service

a. Right as stated in national laws/legislation

The right to a benefitted length of service is established by the **Law on Pension and Disability Insurance of the Republic of Macedonia**,⁴⁶ which states: "The length of service shall be with benefits to employees performing exceptionally difficult work and work that is harmful to the health, as well as employees in age-dependent professions who cannot successfully perform the duties of their job after a certain age. The level of employee benefits depends on the difficulty and harmfulness of the work and the nature of the work, such that 12 months of effective work is calculated as 14, 15, 16, 17, or 18 months [of work]" (Article 125).

b. Specific supporting laws and regulations

The introduction of a multi-tiered pension system in Macedonia has brought about changes in the calculations benefits based on the length of service. However, legislation related to the second and third tier of the pension system is not elaborated upon in this guide.

c. Relevant international/regional regulations

For information on this topic, see Chapters 2 and 3 of this guide.

⁴⁶ Official Gazette of the Republic of Macedonia, no. 80/93, 3/94, 14/95, 71/96, 32/97, 24/00, 96/00, 50/01, 85/03, 50/04, 4/05, 84/05, 101/05, 70/06, 153/07, 152/08, 161/08

d. Relevant provisions of healthcare providers' codes of ethics

Existing professional codes of ethics do not contain provisions that refer specifically to this right.

e. Practical Examples

1) Examples of compliance

Example 5.1

The benefitted length of service is properly calculated for healthcare providers in public and private practices, in accordance with the law and based on accurate records of working hours spent in conditions for which a benefitted length of service is calculated.

2) Examples of violations

Example 5.2

Due to the improper recording of working hours spent on the night shift – a condition that qualifies for benefitted length of service – a healthcare facility fails to calculate properly the benefitted length of service for a healthcare provider and therefore fails to disburse the appropriate financial compensation for the employee's time.

3) Actual cases

No cases involving the violation of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

In accordance with the Law on Civil Procedure,⁴⁷ labor dispute proceedings may be initiated in cases when an employer violates the rights of an employee. Labor dispute proceedings are initiated after all other mechanisms for the protection of an employer's rights have been exhausted. In labor dispute cases, especially in setting the hearings, the court must pay special attention to the priorities of resolving the dispute. In accordance with this principle, the reply to a labor suit must be within eight days. In cases involving the termination of a contract, the main hearing of the suit must take place within 30 days of receiving the response to the lawsuit. The court's first hearing of a labor suit must be completed within six months; appeals of the initial finding must be decided upon within 30 days. Second instance court is responsible to reach a decision upon an appeal against the first instance court's decision within 30 days of the day the appeal has been admitted i.e. within two months after the second instance court hearing. During the hearing, the court may suggest temporary measures for prevention of violent behavior or irreplaceable damages if it receives such a request from each of the parties involved. The court's decision must be carried out within eight days. Appeals of court decisions in labor disputes must

47 Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

be lodged within eight days. The court has the right not to postpone the execution of its original decision during the appeals process, but it must explain the reasoning for such a decision.

6. Right to Independently Provide Healthcare Services

a) Rights as stated in national laws/legislation

The Law on Healthcare⁴⁸ states that healthcare providers who have received an appropriate level of professional education (i.e.: persons who have obtained a medical degree, taken medical proficiency courses, and completed secondary medical education in the field of medicine, dentistry, or pharmacy), completed a medical internship, passed a medical placement exam required for the issuance of an operating license (for healthcare providers with a university education), or achieved specialization and/or sub-specialization for certain duties may individually and independently provide healthcare services (Article 138–140).

b. Specific supporting laws and regulations

The Law on Healthcare also regulates the rights, responsibilities, and status of interns practicing in healthcare facilities.

The law states: “Healthcare facilities and healthcare providers performing individual healthcare services may employ healthcare provider interns and may conclude a work contract with interns and volunteers for professional education and proficiency following their completion of a proficiency examination.

Internships of healthcare providers with a university education may be conducted in healthcare facilities that fulfill the necessary conditions” (Article 141).

According to Articles 142 and 143 of this law, healthcare provider interns must take proficiency examinations following the completion of their internships. The proficiency examination must be taken before an examination committee established by the relevant professional chambers. A person with a medical or dental degree must pass the proficiency examination in order to apply for a basic practice license.

Internships and proficiency examinations that are taken by healthcare provider interns abroad may be accredited entirely or partially if the curriculum does not deviate to a great degree from the curriculum and proficiency examination prescribed by this law. The Ministry of Health is responsible for approving internships and proficiency examinations taken abroad (Article 145).

48 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

c. Relevant international/regional regulations

For information on this topic, see Chapters 2 and 3 of this guide.

d. Relevant provisions of healthcare providers' codes of ethics

The Code of Ethics of the Macedonian Chamber of Medicine⁴⁹ and **the Code of Ethics of the Dental Chamber of Macedonia⁵⁰** guarantee the right to provide healthcare services independently. Article 5 of the Chamber of Medicine's code of ethics states that doctors shall be independent in conducting their profession within the boundaries of the areas of proficiency and work, and they shall be responsible for their work before their own conscience, the patient, the bodies of Chamber of Medicine, and society. Article 5 of the code of ethics for dentists states that dentists shall be independent in conducting their profession within the boundaries of the areas of proficiency and work. Dentists shall be responsible for their work in their own conscience and before the patient, bodies of Dental Chamber of Macedonia, and applicable laws.

e. Examples and case studies

1) Examples of compliance

Example 6.1

According to healthcare legislation, a person with a medical degree receives an operating license after completing a medical internship and passing the proficiency examination.

2) Examples of violations

Example 6.2

A healthcare provider's request to operate an independent practice is denied, even though the healthcare provider meets all of the necessary requirements.

3) Actual cases

No cases involving the violation of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

In accordance with the Law on Civil Procedure,⁵¹ labor dispute proceedings may be initiated in cases when an employer violates the rights of an employee. Labor dispute proceedings are initiated after all other mechanisms for the protection of an employer's rights have been exhausted. In labor dispute cases, especially in setting the hearings, the court must pay special attention to the priorities of resolving the

49 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

50 Available at: <http://stomatoloskakomora.org/?strana=statut>

51 Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

dispute. In accordance with this principle, the reply to a labor suit must be within eight days. In cases involving the termination of a contract, the main hearing of the suit must take place within 30 days of receiving the response to the lawsuit. The court's first hearing of a labor suit must be completed within six months; appeals of the initial finding must be decided upon within 30 days. Second instance court is responsible to reach a decision upon an appeal against the first instance court's decision within 30 days of the day the appeal has been admitted i.e. within two months after the second instance court hearing. During the hearing, the court may suggest temporary measures for prevention of violent behavior or irreplaceable damages if it receives such a request from each of the parties involved. The court's decision must be carried out within eight days. Appeals of court decisions in labor disputes must be lodged within eight days. The court has the right not to postpone the execution of its original decision during the appeals process, but it must explain the reasoning for such a decision.

7. Right to Specialization and Sub-specialization

a. Rights as stated in national laws/legislation

According to the **Law on Healthcare**,⁵² "healthcare providers and medical staff with a university education may specialize and sub-specialize in certain branches of medicine, dentistry, and pharmacy" (Article 146, Para.1).

b. Specific supporting laws and regulations

Supporting laws and regulations determine the form, criteria, and credits for receiving specialization and for renewing operating licenses; they also determine the conditions for conducting proficiency examinations of medical doctors, dentists, and pharmacists (See: *Bibliography*).

Additionally, Articles 146 through 153 of the Law on Healthcare stipulate the following:

Specialization and sub-specialization of healthcare providers is performed in accordance with regulations on post-graduate studies, if not otherwise determined by this law.

The fields of specialization and sub-specialization and their duration and curricula are defined by the Ministry of Health after consultation with the relevant institution of higher education.

Specialization and sub-specialization of healthcare providers and healthcare collaborators is conducted based on syllabi and curricula that are approved by the relevant institutions of higher education.

⁵² Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

For specialization and sub-specialization, part of the theoretical and practical education is conducted at the institution of higher education, while the other part is conducted in healthcare facilities that have appropriate space, staff, and equipment.

Healthcare providers and other medical staff may choose to specialize if they have completed a proficiency examination and have one year of experience working in a medical practice after the completion of the examination.

Based on the criteria and curriculum, the healthcare facilities and other healthcare institutions determine the curricula for the proficiency examination, specialization, and sub-specialization of healthcare providers and other medical staff.

Specialization and sub-specialization of healthcare providers and other medical staff can be planned and approved only by the branches of medicine, dentistry, and pharmacy and other areas that compose the activities of the healthcare or other institution.

Healthcare providers and other medical staff can be referred for specialization only by healthcare facilities and other organizations that provide healthcare services, under the general act as described in this law.

The healthcare facility or other organization sends its decision to refer the healthcare provider for specialization, along with evidence of the fulfillment of required criteria and evidence that the specialization has been approved in accordance with paragraph 1 of this Article, to the appropriate institution for higher education for purposes of enrollment in specialization courses.

The institution of higher education maintains a registry of healthcare providers who are enrolled in specialization courses during each academic period, together with the specialization curricula.

Healthcare providers working in private practices may apply for specialization if they fulfill the conditions of this Law.

The Ministry of Health can approve the specialization for healthcare providers who are citizens of foreign countries and have a professional education in medicine, dentistry, and pharmaceutical sciences.

The Law on Healthcare⁵³ determines the conditions for obtaining the professional title of "primarius." The title may be granted to healthcare providers who meet the following criteria: a professional-level education; at least 15 years of experience with the improvement, organization, and provision of healthcare services; successful completion of a specialist examination; publication of scientific or academic publications; and the achievement of positive results in the education of their colleagues. The

53 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

title of *primarius* may be given to doctors, dentists, and pharmacists who have not taken a specialist examination if they meet the above-listed criteria and have at least 15 years of successful work experience. The title of *primarius* is granted by a special commission formed by the Minister of Health. The specific conditions for granting the title of *primarius* are determined by the Ministry of Health (Article 160).

c. Relevant international/regional regulations

For information on this topic, see Chapters 2 and 3 of this guide.

d. Relevant provisions of healthcare providers' codes of ethics

According to **Code of Ethics of the Macedonian Chamber of Medicine**,⁵⁴ “the doctor shall continuously improve and deepen his professional and scientific knowledge. The doctor is responsible for maintaining and improving his proficiency and ethics, for issuing public and open warnings about diseases, and for actively cooperating in the containment and eradication of diseases. The doctor shall look after healthcare education and raise public awareness of healthcare and good health habits. The doctor shall try to prevent all potential harms to human health and shall act against the general incompetence and fraudulent practices of other doctors” (Article 4).

According to Article 31, medical personnel’s education and the organization of the work, should provide efficient and effective treatment to the patients within the hospitals or their homes, within the scope of current medical knowledge and capabilities.

Article 59 states that every doctor has a duty to “learn about and comply with achievements in medicine and professional development. The doctor shall also transfer the acquired knowledge to his colleagues and other healthcare providers. The continuous development and improvement of the medical profession and science requires the continuous development and education in the field of medical theory and practice through work in professional associations and in scientific and professional institutions.”

In accordance with Article 60 of the code of ethics, the doctor is responsible for the improvement of his own personal knowledge and skills. The doctor shall make every effort to improve his knowledge of humanities and the social and natural sciences.

e. Examples and case studies

1) Examples of compliance

Example 7.1

A foreign citizen is allowed to specialize in abdominal surgery after it is determined that he fulfills the conditions set by the Law on Healthcare⁵⁵ and the relevant book of rules regarding specialization and sub-specialization in the medical sciences.

⁵⁴ Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

2) Examples of violations

Example 7.2

A university-trained pharmacist is not allowed to specialize in the field of pharmacy at the Faculty of Medicine. The pharmacist is told he does not meet the conditions for specialization, even though the specialization is in an area that is familiar to the healthcare provider.

3) Actual cases

No cases involving the violation of this right have been reported or are otherwise known to the working group responsible for preparing this guide.

4) Practical notes

In accordance with the Law on Civil Procedure,⁵⁶ labor dispute proceedings may be initiated in cases when an employer violates the rights of an employee. Labor dispute proceedings are initiated after all other mechanisms for the protection of an employer's rights have been exhausted. In labor dispute cases, especially in setting the hearings, the court must pay special attention to the priorities of resolving the dispute. In accordance with this principle, the reply to a labor suit must be within eight days. In cases involving the termination of a contract, the main hearing of the suit must take place within 30 days of receiving the response to the lawsuit. The court's first hearing of a labor suit must be completed within six months; appeals of the initial finding must be decided upon within 30 days. Second instance court is responsible to reach a decision upon an appeal against the first instance court's decision within 30 days of the day the appeal has been admitted i.e. within two months after the second instance court hearing. During the hearing, the court may suggest temporary measures for prevention of violent behavior or irreplaceable damages if it receives such a request from each of the parties involved. The court's decision must be carried out within eight days. Appeals of court decisions in labor disputes must be lodged within eight days. The court has the right not to postpone the execution of its original decision during the appeals process, but it must explain the reasoning for such a decision.

8. Right to the Peaceful Resolution of Disputes

a. Rights as stated in national laws/legislation

The Law on Health and Safety at Work⁵⁷ allows for arbitration in labor disputes, as it states that "for the commission of a misdemeanor... state inspectors may offer arbitration to the healthcare provider that would enable the elimination of the causes and consequences of the aforementioned misdemeanor" (Article 55).

55 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

56 Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

57 Official Gazette of the Republic of Macedonia, no. 92/07

The Law on the Peaceful Resolution of Labor Disputes⁵⁸ defines and regulates the procedure for collective and individual labor disputes. According to Article 2, paragraph 1, “a collective labor dispute is a dispute over changes of a contract or alterations to a collective agreement that grants the right to professional association and protest.” Article 3 states: “An individual labor dispute is the dispute that results from the termination of employment or the failure to pay minimum wage to an individual person.”

The Law on Mediation⁵⁹ defines the principle of mediation as an alternative mechanism for conflict resolution. The law also establishes conditions for becoming a mediator, the process of mediation, and the organization of mediators.

The law is applicable to civil, commercial, labor, consumer, and other disputes between physical and legal entities, regardless of whether mediation is conducted by mutual agreement of the parties or at the suggestion of a court, council of arbitration, or other body, unless otherwise indicated by law (Article 1).

b. Relevant international/regional regulations

For information on this topic, see Chapters 2 and 3 of this guide.

c. Relevant provisions of healthcare providers’ codes of ethics

There are no specific provisions related to this right in the the relevant professional codes of ethics.

d. Examples and case studies

1) Examples of compliance

Example 8.1

Councilors for the protection of patients’ rights are present in every healthcare facility in Macedonia, thus offering a means of resolving disputes between patients and healthcare providers.

2) Examples of violations

Example 8.2

A patient files a lawsuit against a healthcare provider, claiming that the doctor cause irreparable damage to his health. The court should not order mediation if alternative mechanisms, such as a consultation with the councilor for the protection of patients’ rights, have been already exhausted.

3) Actual cases

No cases involving the violation of this right have been reported or are otherwise known to the working group responsible for the preparation of this guide.

58 Official Gazette of the Republic of Macedonia, no. 87/07

59 Official Gazette of the Republic of Macedonia, no. 60/06, 22/07, 114/09

4) Practical notes

In accordance with the Law on Civil Procedure,⁶⁰ labor dispute proceedings may be initiated in cases when an employer violates the rights of an employee. Labor dispute proceedings are initiated after all other mechanisms for the protection of an employer's rights have been exhausted. In labor dispute cases, especially in setting the hearings, the court must pay special attention to the priorities of resolving the dispute. In accordance with this principle, the reply to a labor suit must be within eight days. In cases involving the termination of a contract, the main hearing of the suit must take place within 30 days of receiving the response to the lawsuit. The court's first hearing of a labor suit must be completed within six months; appeals of the initial finding must be decided upon within 30 days. Second instance court is responsible to reach a decision upon an appeal against the first instance court's decision within 30 days of the day the appeal has been admitted i.e. within two months after the second instance court hearing. During the hearing, the court may suggest temporary measures for prevention of violent behavior or irreplaceable damages if it receives such a request from each of the parties involved. The court's decision must be carried out within eight days. Appeals of court decisions in labor disputes must be lodged within eight days. The court has the right not to postpone the execution of its original decision during the appeals process, but it must explain the reasoning for such a decision.

9. Other Rights in Working Relations

In addition to the above-mentioned rights, healthcare providers and other professionals have the following work-related, as stipulated by the **Labor Relations Act**:⁶¹

- the right to a salary (Article 105);
- the right to fixed working hours (Articles 116 and 118);
- the right to a daily break and annual vacation time (Articles 132 and 137);
- the right to attend employee education programs, and the right to paid leave for educational purposes (Articles 154 and 155).

From the perspective of labor rights protection, it is important to note that employees may contact the State Labor Inspectorate if their rights are violated. In accordance with the **Law on Labor Inspection**,⁶² the agency conducts inspections regarding the application of laws and other regulations pertaining to labor relations, employment and occupational health, collective agreements, employment agreements, and other documents that determine the rights, and responsibilities of employees and employers in the field of labor relations, employment, and occupational health (Article 1).

60 Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

61 Official Gazette of the Republic of Macedonia, no. 62/05, 106/08, 161/08, 114/09

62 Official Gazette of the Republic of Macedonia, no. 35/97 and 29/02

7.2 Providers' Responsibilities

The responsibilities of healthcare providers are regulated by the healthcare and labor legislation.

The Law on Healthcare⁶³ determines “citizen’s right to healthcare, the rights and responsibilities incurring from health insurance, the process of providing healthcare services, and the system and organization of healthcare” (Article 1). The law does not directly discuss the responsibilities of healthcare providers.

1. Responsibility to Provide Healthcare

a. Responsibility as stated in national laws/legislation

The **Law on Healthcare**⁶⁴ establishes the responsibility of the healthcare facility to provide healthcare services at the request of an individual; in other words, **the healthcare facility is obliged to provide health services to every person who requests treatment.** According to this law, “healthcare” includes continuous, 24-hour medical services and medications and sanitary materials for emergency healthcare. The healthcare facility has the responsibility to transport and admit the patient to another healthcare facility if there is a need for such action (Article 46, Para. 1, 2 and 3). **These responsibilities are indivisible from the obligation of the healthcare provider to provide healthcare services at the healthcare facility where he works.**

If a person requests hospitalization, the healthcare facility shall provide it; in the event of an emergency, the facility must enable the patient’s hospitalization at another healthcare facility (Article 47, Para. 1). If a healthcare facility refuses a request for hospitalization, it must provide a written explanation of the grounds for refusal (Article 47, Para. 2).

The Law on Healthcare⁶⁵ also established the **responsibility of healthcare providers to take care of patients who are receiving healthcare services,** to respect their dignity, and to comply with medical ethics and the principle of confidentiality (Article 49, Para. 1).

b. Specific supporting laws and regulations

Specific responsibilities of the healthcare providers are enumerated in the **Law on the Protection of Patients’ Rights**⁶⁶. The law guarantees the protection of patients’ rights during the provision of healthcare services; outlines the rights and respon-

63 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

64 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

65 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

66 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

sibilities of patients, healthcare facilities, healthcare providers, and other medical staff; determines the role of the municipalities and the Health Insurance Fund in advancing and protecting patients' rights; establishes the procedure for the protection of patients' rights; and sets conditions for supervising compliance with the law (Article 1).

The Law on the Protection of Patients' Rights⁶⁷ determines the responsibilities of healthcare providers who perform immediate medical interventions on patients: When undertaking a medical intervention, a healthcare provider must protect the patient's rights stipulated by this law, consciously perform his duties in compliance with medical ethics rules for the singular purpose of protecting and improving the patient's health... grant a second professional opinion in cases and under circumstances stipulated this law... and establish humane relations with the patient based on ethical and deontological principles (Article 38, Points 1,2,4, and 11).

The Law on Mental Health⁶⁸ outlines the conditions that healthcare facilities must provide to persons suffering from mental illnesses in order to ensure their ability to exercise their rights as patients (Article 19).

The Law on Mental Health⁶⁹ also defines the responsibilities of the healthcare facilities and establishes indirectly the responsibility of healthcare providers to provide healthcare services to persons suffering from mental illnesses.

According to the same law, after being admitted to a healthcare facility, the person suffering from a mental illness must be placed under the supervision of team of specialists for treatment and rehabilitation; these specialists must work to improve the health status of the person to a degree that he may be treated further in the community. If a person suffering from a mental illness was admitted previously to a healthcare facility, the prior admission may not be considered as a basis for re-admission. The program includes regular check-ups performed least once per month in order to follow the person's mental health condition. The team of specialists involved in the patient's care is responsible for creating individualized program for treatment and rehabilitation; this program must be specified in writing (Article 23).

c. Relevant provisions of healthcare providers' codes of ethics

The Code of Ethics of the Macedonian Chamber of Medicine⁷⁰ provides introductory and general stipulations regarding the responsibilities of healthcare providers (Articles 1–3). Detailed information about healthcare providers' obligations to the patient is provided in a special chapter of the code (Article 19–32).

“The healthcare provider is required to perform his professional duties responsibly, precisely, and consciously, regardless of a patient's age, gender, religion, nationality,

67 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

68 Official Gazette of the Republic of Macedonia, no. 71/06

69 Official Gazette of the Republic of Macedonia, no. 71/06

70 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

race, political affiliation, sexual orientation, disability, or socio-economic status, or the personal relationship between the physician and the patient or his family. The healthcare provider must take into consideration the most up-to-date medical and scientific achievements and the codes of professional conduct, and he may freely choose the method of treatment. While determining the proper method of treatment, the healthcare provider must rely solely on his knowledge of medicine, and his decision must be independent of outside influences and the inappropriate wishes of the patient, the patient's family, or others.

The healthcare provider is obligated to refuse to perform healthcare services that, according to his professional opinion and good judgment, might violate ethical rules or cause harm to the patient” (Article 19).

In addition, “the healthcare provider must has a responsibility to help the patient exercise his health and social rights. The doctor is forbidden from engaging in abuse, fraud, or the counterfeiting of documents” (Article 32).

The Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights⁷¹ states that the principle ethical rule for pharmacists is to consideration for a patient's health and the benefit of society (Article 34). The pharmacist should consider the honor and dignity of his profession, and he may not take part in activities that would place his profession under suspicion or would objectively undermine the profession's ethical norms (Article 35, Para. 1).

Other relevant informaiton

The **Law on Healthcare**⁷² sets conditions that must be met by healthcare providers and institutions in order to provide healthcare services; these conditions are enumerates in Articles 8, 113, 115a, 115b, 138-153, 153a-153l, 154-156, 159, 171a, 171b, and 173. Healthcare services may be provided only by healthcare providers and support staff who fulfill the conditions set by this law (Article 8).

Under a general act, the healthcare facility is responsible for resolving the following issues: the organization and method of providing urgent medical care; the usage and maintenance of medical equipment; patient care, including home care; the method of admitting patients for primary, specialist, consultative, and hospital healthcare services; the organization of internal supervision over the work of the healthcare providers; and the selection and use of protective garments for healthcare providers and other employees (Article 113).

A specialist healthcare provider with over seven years of professional experience in his field who is employed by a healthcare facility that conduct specialist-consultative and medical healthcare services may provide healthcare services as additional activity in accordance with the facility's operating license; these services maybe performed at the healthcare facility where he is employed or

71 Available at: http://www.farmaceutvskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

72 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

at another healthcare facility that is registered to provide same type of service. These activities may take up no more than eight hours of the healthcare provider's time per week (Article 115-a).

The relationship between the healthcare provider mentioned in the above paragraph and the facility where he provides healthcare services for additional work must be defined by a contract.

A healthcare provider who is employed by a public healthcare facility may provide healthcare services in another public healthcare facility that is registered to provide the same type of service; this relationship requires the conclusion of a contract between the healthcare facility that employs the healthcare provider and the contracting healthcare facility (Article 115-b).

In order to improve the quality of healthcare providers' professional work, to establish scientific-medical doctrine, to evaluate professional work in accordance with medical and scientific doctrine and conditions for the provision of healthcare services, the healthcare and other institutions that according to this Law provide healthcare and in private practice, based on professional work, the professional work of healthcare providers and support staff is evaluated for efficiency, rationality, and the use of medical and other types of documentation and evidence. Healthcare providers and support staff are responsible for the quality of their professional work (Article 159).

Autopsies may be performed only by certified persons and their assistants who are appointed by the Ministry of Health. An autopsy may be performed by healthcare providers with a university education, and in certain cases, by other healthcare providers who are trained to perform the procedure. An attending doctor may not perform an autopsy on a patient whom he treated immediately before death (Article 173).

2. Responsibility to Inform and Obtain Informed Consent

a. Responsibility as stated in national laws/legislation

The Law on the Protection of Patients' Rights⁷³ establishes the healthcare provider's responsibility to inform. The law requires healthcare providers to give patients information outlined in Article 7, Paragraphs 1, Point 1–9 and Article 10 of the law; to respect a patient's wishes regarding information and medical interventions; to provide information in accordance with Article 17, Paragraph 2 in cases of scientific research and with Article 18 in cases of medical education; to inform the person from Article 25, Paragraph 6 of this law and in cases described by other regulations and other legislative bodies when patient leaves the healthcare facility without giving prior notice (Article 38, Points 3, 5, 6, and 10).

In addition, Article 7, paragraph 1 of the law states that "the patient, during all stages of healthcare, shall have the right to be fully informed of the following:

⁷³ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

- 1) his health status, including a medical assessment of the results and outcome of a particular medical intervention;
- 2) recommended medical interventions, as well as dates planned for their realization (including a treatment and rehabilitation program);
- 3) possible advantages and risks of the realization and non-realization of recommended medical interventions);
- 4) his right to decide upon recommended medical interventions;
- 5) possible replacements of recommended medical interventions;
- 6) reasons for possible differences in the result achieved by medical interventions as compared to the expected result;
- 7) the course of the procedure when providing healthcare;
- 8) his recommended lifestyle; and
- 9) his right to healthcare and health insurance, as well as the procedure for exercising these rights.”

According to Article 10 of the law, the patient has the right to know the names, education levels, and residencies of healthcare providers offering healthcare services. This informational shall be made available through the mandatory public display of his working license issued by the relevant chamber in the office where they work, as well as by other means that are understandable to the patient.

The Law on the Protection of Patients’ Rights⁷⁴ determines the right of the patient to accept or reject information. Specifically, the law states that the patient has the right to accept or reject certain medical interventions, except in cases when the delay or non-performance of a medical intervention would endanger or damage the health of the patient or other persons. (Article 14).

b. Specific supporting laws and regulations

Article 21 of the **Law on Mental Health**⁷⁵ establishes the patient’s right to information: The healthcare facility shall provide information to the person suffering from mental illness if the information does not lead to the deterioration of the patient’s mental health condition.

The healthcare facility is responsible for reporting the admission of a person suffering from a mental illness to his parents, legal guardians, and other persons related to or living with him. If the person was admitted against his will, the healthcare facility is obligated to report the admission to a court. If the court decides not to approve that the admission, the institution must release the mentally ill person (Article 22).

According to the **Law on Mental Health**⁷⁶, a healthcare facility has the responsibility to release a mentally ill patient if a team of experts determines that the mental health condition of the patient has improved to a degree that he can be referred for further treatment and care within the community. Prior to his release, **the patient**

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shall be informed of his mental health status and directed to exercise his rights at the community level of the healthcare system and social protection systems. In addition, the healthcare facility is responsible for informing the patient's parents, legal guardians, and other persons related to or living with him of his release. The healthcare facility may release an admitted patient suffering from a mental illness without his consent only if the decision is based on a court ruling with the prior backing of a team of experts (Article 24).

The Law on Population Protection against Communicable Diseases⁷⁷ requires every doctor to inform the patient about preventive measures for protection against communicable diseases, the importance of vaccines, and other protection measures (Article 50, Para. 1).

The Law on Termination of Pregnancy⁷⁸ states that the healthcare provider is responsible for warning a pregnant woman and her spouse about the possible harmful effects of pregnancy termination on the woman's life and health. The healthcare provider is obligated to inform them about possibilities and methods of contraception (Article 7).

The Law on Blood Safety⁷⁹ requires the Institution for Transfusion, prior to starting a blood donation procedure, to inform the donor about the procedure, ask for personal identification data and other information regarding the donor's health condition, seek information about the donor's history of diseases, and obtain the signed consent of the blood donor to taking part in the procedure (Article 16, Para. 1).

The Institution for Transfusion is responsible for giving blood donors information about blood donation and any other information they request. The institute must also provide information on other measures regarding blood donation that are relevant to the donor, and it must obtain the written consent of blood donors to use their blood. Professional counseling must be available for donors at the time and place of the blood donation (Article 16, Para. 3 and 4).

According to the **Law on Biomedically Assisted Reproduction (BAR)**⁸⁰, healthcare facilities that are certified to conduct the BAR procedure are responsible for appointing a person to provide information to the donor prior to the initiation of the donation procedure. The information must be conveyed in a clear and unambiguous manner using terms that are understandable to the donor.

The person who is chosen to provide information to the donor must discuss the following topics with the donor prior to the start of the procedure: the goal and nature of the donation, possible risks and consequences of donation, analytical tests needed for the donation, data protection and medical confidentiality, therapeutic goals and possible benefits, donor protection measures, the donor's right to receive results of the analytical tests in an understandable format, the legal consequences of using

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78 Official Gazette of the Republic of Macedonia, no. 19/77 and 15/95

79 Official Gazette of the Republic of Macedonia, no. 110/07

80 Official Gazette of the Republic of Macedonia, no. 37/08

donated germinative cells or embryos, and voluntary written consent to take part in the donation procedure (Article 14).

According to the **Law on Biomedically Assisted Reproduction (BAR)**, a certified doctor must inform married couples, domestic partners, and donors taking part in BAR about the procedure, the average level of success of the procedure, and possible consequences and risks that could occur during or after any stage of the procedure (Article 10. Para. 2).

The Law on Conditions of Receiving, Exchange, Transport and Transplant of Human Body Parts for Medical Treatment Purposes⁸¹ is especially rigorous in establishing the responsibilities of the healthcare providers in this field, as it prescribes criminal sanctions for violations. A doctor who harvests body parts from a person who is not yet pronounced dead by a medical committee for the purpose of transplantation shall be punished criminally and subject to a period of incarceration lasting from six months to three years. The same punishment may be given to a healthcare provider who harvests body parts from a deceased person **who had previously signed a written statement forbidding the donation of his body parts**. Harvesting organs or body parts from a deceased child or mentally disabled person **without the prior written consent** of a parent or legal guardian is also forbidden and carries the same sentence listed above (Article 27).

A healthcare provider who harvests body parts from living adults **without their prior written consent** shall be subject to a prison term of three months for the offense. The same punishment may be given to healthcare providers who harvest the organs or other body parts of a living child, mentally disabled person, incapacitated person without the prior consent of a parent or legal guardian; the removal of bone marrow from a child without consent of a parent is also forbidden. Healthcare providers may be sentenced to three months to three years of incarceration for failing to obtain written consent from the transplant host or his parent or legal guardian prior to the transplantation procedure, or if the transplantation is performed on a person who had written a statement explicitly refusing organ transplantations. The same punishment may be prescribed for an employee of a healthcare facility who harvests or transplants body parts in order to examine whether the organs could be matched to a recipient, or if the institution does not fulfill the conditions prescribed by the Law on Conditions of Receiving, Exchange, Transport and Transplant of Human Body Parts for Medical Treatment Purposes and the regulations that are based on it (Article 28).

c. Relevant Provisions of Providers' Codes of Ethics

According to the **Code of Ethics of the Macedonian Chamber of Medicine⁸²** and **the Code of Ethics of the Dental Chamber of Macedonia⁸³**, the healthcare provider must inform the patient prior to treatment about the nature of the illness, the patient's current health status, and the possible outcomes of the illness. The patient

81 Official Gazette of the Republic of Macedonia, no.30/95, 139/08

82 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

83 Available at: <http://stomatoloskakomora.org/?strana=statut>

must voluntarily provide his informed consent about the appropriate treatment that he will receive (Article 21 and Article 28).

Healthcare providers are obligated to inform the patient about his health condition for the purpose of ensuring the patient's well-being. Special care and accuracy must be used when explaining diagnostic and therapeutic methods as they relate to risk. If the patient is suffering from an exceptional psychological condition, then an explanation of his health status is not recommended, as it may influence treatment negatively. In such cases, healthcare providers should inform the patient's relatives of the extent of the illness (Article 21, Para. 2). In addition, according to Article 23 of the Code of Ethics of the Macedonian Chamber of Medicine, doctors must inform patients upon their admittance of routine procedures, methods of treatment, and the healthcare facility's medical and technical capabilities.

The Code of Ethics of the Dental Chamber of Macedonia⁸⁴ requires the dentist to inform the patient about the nature of his illness. The dentist must also inform the patient of the outcome of the illness if it is untreatable. It is also the responsibility of the dentist to provide necessary medical care and moral support to his patients (Article 29).

According to Article 22 of the **Code of Ethics of the Macedonian Chamber of Medicine⁸⁵**, the healthcare provider may request the written consent of patients upon informing them about testing procedures, diagnoses, methods of treatment, and prognoses. Healthcare providers may perform medical interventions without prior consent only in emergency cases when the patient is not in a position to give consent because his life is in danger. The healthcare provider must provide special care to underage patients and patients who have a legal guardian. In such cases, while planning the intervention and treatment, the healthcare provider must obtain the explicit consent of the patient's legal guardian, unless the life or health of the patient is in immediate danger.

The Code of Ethics of the Dental Chamber of Macedonia⁸⁶ also requires dentists to ask for written consent for certain interventions. Dentists must the request the written consent of a parent or legal guardian to perform interventions on underage (Article 30, Para. 1). Written consent is not required in when the patient's life is in danger (Article 30, Para. 2).

According to Article 19 of the **Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights⁸⁷**, the pharmacist must inform patients about their medications orally or in writing. This standard is necessary for dispensing prescribing medications, and it is of special importance when the medication is sold over-the-counter. As the pharmacist is a specialist on medications, he should apply his knowledge in the field toward directing the patient to purchase the medication that

84 Available at: <http://stomatoloskakomora.org/?strana=statut>

85 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

86 Available at: <http://stomatoloskakomora.org/?strana=statut>

87 Available at: http://www.farmaceutskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

best fits his medical needs rather than focusing on the price of the medication (Article 19).

In addition, the pharmacist is obligated to refuse to issue a medication to a patient if he believes that the medication may be used in a manner that is harmful or unethical. The doctor's actions must be based entirely on measures to relieve a patient's suffering and improve his health. The pharmacist must rely on his knowledge and conscience, and he must act independently of outside influences or the inappropriate wishes of a patient, a relative of the patient, or other persons (Article 20).

Other relevant sources

In order to protect the health of blood donors and recipients, the **Law on Blood Safety**⁸⁸ regulates issues regarding the storage of serum samples from every unit of blood that is issued for testing for a period of five years (Article 23). The law also prohibits the distribution of blood and blood components whose origin cannot be traced, and it ensures that blood and blood products comply with the conditions set by the law (Article 24). The law also enables the traceability of blood and blood components, as the the Institution for Transfusionology is responsible for ensuring the traceability of blood and blood components that are collected, stored, and distributed in Macedonia (Article 25, Para. 1). The healthcare facility where blood and blood components are distributed is responsible for enabling the traceability of the donations and the identification of recipients (Article 25, Para. 2).

Traceability is ensured through a system of identification that can flawlessly identify every individual donation of blood and blood components.

The Law on the Protection of Patients' Rights⁸⁹ includes a special section that stipulates the responsibility of the healthcare facility for protecting patients' rights and providing legal advice and legal assistance so that patients can exercise their rights (Article 33). The law also establishes the responsibility of the healthcare facility to appoint a councilor for the protection of patients' rights (Article 44) who has clearly defined responsibilities: providing legal advice and assistance to patients regarding the exercise and protection of their rights; reviewing oral and written complaints submitted by patients, and providing an plan for their resolution to the manager of the healthcare facility; mediating an amicable resolution of disputes between patients and healthcare providers by hearing verbal complaints; keeping records of all verbal or written complaints submitted by patients; initiating other legal procedures for the protection of patients' rights at the healthcare facility (upon completion of the procedure, the legal records may be included in a patient's medical file); informing and training healthcare providers from the healthcare facility about patients' rights under this law; and performing other activities for the purpose of protecting the rights of patients who are admitted to a healthcare facility. Healthcare facilities must allocate accessible space for the creation of clearly labeled offices for the

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patients' rights councilor.

In order to fulfill its obligations under the **Law on the Protection of Patients' Rights**⁹⁰, a healthcare facility that does not admit patients is responsible for performing the following activities: providing legal advice and assistance to patients regarding the exercise and protection of their rights; reviewing verbal and written complaints submitted by patients; submitting opinions for the resolution of patients' complaints to the healthcare facility manager; mediating an amicable resolution of issues between patients and the healthcare providers that were raised by means of verbal complaints; keeping records of all verbal or written complaints submitted by patients and other legal procedures that were initiated for the protection of patients' rights within the healthcare facility (upon the completion of the procedure, the relevant documents shall be added to the patient's medical file); informing and training healthcare providers employed by the healthcare facility about the exercise and protection of patients' rights under this law; and performing other activities to protect the rights of patients who are being treated in a healthcare facility. The healthcare facility is obligated to post a copy of the law in a visible and easily accessible location (Article 45).

d. Examples and case studies

1) Examples of compliance

Example 2.1

A dentist uses understandable language to inform his patient about the risks of a surgical intervention involving a wisdom tooth that has grown into the upper jaw.

Example 2.2

A pharmacist provides information about the effects, dosage, administration, and possible side effects of an over-the-counter medication to a person purchasing the product.

2) Examples of violations

Example 2.3

A dentist fails to request a written statement from a patient prior to performing a surgical intervention that involves the use of a powerful local anesthetic.

3) Actual cases

No cases involving the violation of this responsibility have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

⁹⁰ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

3. Responsibility for Keeping Health Records and Compulsory Notification

a. Responsibility as stated in national laws/legislation

According to the **Law on the Protection of the Population against Communicable Diseases**,⁹¹ state administration bodies, municipal bodies, the city of Skopje, healthcare facilities, and other persons and legal entities are responsible within the frameworks of their authorities, rights, and obligations to cooperate and exchange information for the implementation of measures for the prevention, early detection, containment, and eradication of communicable diseases and infections listed in this law (Article 3).

A healthcare provider who diagnoses a patient with a communicable disease or suspects that the patient is suffering from a disease after reviewing clinical and epidemiological data is responsible for immediately taking measures to contain the spread of the disease.

In cases when a healthcare provider diagnoses or suspects that the patient has a communicable disease, he must to confirm the diagnosis through microbiological testing and through the application of defining criteria.

Defining criteria are determined by the Minister of Health. Microbiological testing for the causes of communicable diseases are conducted in cases of an actual or potential disease epidemic (Article 15).

The healthcare provider is responsible for reporting persons who are suffering from the following diseases: typhus abdominalis, paratyphus, hepatitis B and C, HIV, and malaria (Article 19).

The healthcare provider must immediately report the outbreak of any communicable disease or intra-hospital infection. Directors of healthcare facilities must report any post-immunological complications that surpass the level of a normal post-immunological reaction. Directors must also report when a person is bitten or otherwise injured by animal that may be infected with rabies (Article 20).

Healthcare providers and facilities that provide emergency healthcare services to foreign citizens or place such persons under quarantine are responsible for immediately informing state authorities for internal affairs (Article 54).

b. Specific supporting laws and regulations

According to the **Law on Mental Health**,⁹² a healthcare facility that admits a patient suffering from a mental illness is responsible for determining the patient's identity

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by checking his identification documents; this is done for the purpose of protecting the patient's rights and entering his data in a register in accordance with healthcare regulations (Article 17).

The law also holds the healthcare facility accountable for documenting and maintaining the confidentiality of the following patient information: the date and hour of admission, the identify of the patient, his medical history and health status reports, the plan and program for treatment and rehabilitation, and other information regarding his mental health condition. (Article 18, Para. 1).

The Law on the Protection of Patients' Rights⁹³ also regulates the responsibilities that healthcare facilities have, and in Article 33, Point 7 is regulated that the healthcare facility must keep a medical record for each patient, as well as to update the data in the medical record (Article 33, Point 9).

The healthcare facility must keep a record for each procedure that has been carried out (Article 35, Para. 2).

In addition, the healthcare providers have the responsibility to include the written statement referred to in Article 27 paragraph 2 of this Law in the patient's medical file, to enter in the patient's medical file data regarding the patient's decision to leave the healthcare facility without prior notice, to inform the person, referred to in Article 25 paragraph 6 of this Law, and in certain cases, to inform the authorities of a patient's decision to leave the healthcare facility without prior notice (Article 38).

The healthcare facility has the responsibility to keep a record for each oral or written complaint from the patients regarding the protection of their rights, as well as a record regarding other legal procedures undertaken. These records become part of the patients' medical record after the completion of the legal procedures (Article 45).

According to the **Law on Blood Safety**,⁹⁴ healthcare providers who administer the transfusion of blood or blood components **must register every used unit of blood or blood components in the patient's medical file**. Healthcare providers must also include the patient's written consent to the procedure, results from immuno-hematological and other tests, notes on the positive effects resulting from the transfusion of blood and blood components, information about serious side effects and reactions, and other data regarding the transfusion of blood and blood components. Healthcare facilities that use blood and blood components are responsible for making available all data regarding blood and blood components, as requested by the Institution for Transfusion Medicine for the purposes of ensuring the traceability of blood and blood component donations (Article 31).

The **Law on Termination of Pregnancy**⁹⁵ states that healthcare providers are responsible for registering the performance of abortions, in accordance with regulations

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pertaining to healthcare registries (Article 7).

c. Relevant Provisions of Providers' Codes of Ethics

In accordance with the **Code of Ethics of the Macedonian Chamber of Medicine**⁹⁶ and the **Code of Ethics of the Dental Chamber of Macedonia**⁹⁷, in the event of an epidemic, natural disaster, or other catastrophe, doctors and dentists must report to the authorities and provide assistance to those affected by the occurrence (Article 34 and 40)

d. Examples and case studies

1) Examples of compliance

Example 3.1

Upon diagnosing a case of viral hepatitis, a healthcare facility issues a field report and takes samples for analysis. The analysis is used to determine the procedures that should be followed in order to prevent the spread of the disease within the facility.

2) Examples of violations

Example 3.2

A healthcare provider working at a private healthcare facility diagnoses a patient who recently traveled to an area with a high risk of leishmaniasis infection. The healthcare provider does not report the case to the proper authorities; instead, he advises the patient to report to the regional healthcare center.

In this case, the healthcare provider does not have the right to direct the patient to another healthcare facility for treatment. Furthermore, the healthcare provider should report possible cases of communicable diseases to the authorities, in accordance with the Law on the Protection of the Population Against Communicable Diseases.

3) Actual cases

No cases involving the violation of this responsibility have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

⁹⁶ Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

⁹⁷ Available at: <http://stomatoloskakomora.org/?strana=statut>

4. Responsibility to Maintain Confidentiality and Professional Secrets

a. Responsibility as stated in national laws/legislation

The ***Law on the Protection of Patients' Rights***⁹⁸ states that the healthcare provider is responsible for maintaining the confidentiality of data regarding a patient's health status, medical condition, diagnosis, prognosis, treatment, and other information of a personal nature, even after a patient's death, in accordance with regulations for maintaining professional and business secrets and ensuring the protection of personal data (Article 38, Point 7).

In accordance with the ***Law on the Protection of Patients' Rights***⁹⁹, the patient has the right to confidentiality of personal and medical data. This information must be kept confidential even after the patient's death (Article 25). However, in exceptional cases, this data may be revealed. For more information on this topic, see the section titled "Right to Privacy and Confidentiality" in Chapter 6 of this guide.

b. Specific supporting laws and regulations

The ***Law on Healthcare***¹⁰⁰ contains only one stipulation referring to the patient's right to respect of his dignity: the healthcare provider must comply with medical ethics and maintain professional confidentiality. This responsibility also applies to other employees of the healthcare facility who process medical records or otherwise have access to personal data (Article 49).

According to the ***Law on Termination of Pregnancy***,¹⁰¹ healthcare providers must maintain professional confidentiality and respect the dignity of the pregnant woman (Article 4).

The Law on Blood Safety¹⁰² states that the Institution for Transfusion Medicine shall maintain the confidentiality of data during the storage, handling, archiving, and destruction of medical documentation, in accordance with regulations on personal data protection and the protection of patients' rights (Article 32, Para. 2).

The Law on Blood Safety also states that the Institution for Transfusion Medicine and healthcare facilities that use blood and blood components for clinical purposes must establish data protection measures to prevent the disclosure of the identity of a blood donor or recipient, the release of information regarding the process of ensuring the traceability of blood and blood components, any unauthorized release of profession-

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101 Official Gazette of the Republic of Macedonia, no. 19/77, 15/95

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al documents or information regarding blood donors and blood recipients. All of the above-mentioned data must be accurate and unaltered (Article 38).

According to the ***Law on Biomedically Assisted Reproduction***,¹⁰³ ***authorized health-care facilities are responsible for protecting the personal, medical, and genetic data of the donor and recipient, and for taking appropriate measures not to reveal the identity of the donor, recipient, or their families.***

These data are classified information and are stored in accordance with the regulations pertaining to the protection of confidential information and personal data. Healthcare facilities must respect the confidentiality of personal, medical, and genetic data when using or disclosing this information (Article 17).

All persons who are involved in conducting the BAR procedure are responsible for treating the relevant data as classified information. The personal and health data of the sperm and embryo donors and recipients, as well as the child conceived as a result of the procedure, are especially protected (Article 46).

Authorized healthcare facilities are responsible for ensuring the protection of the personal, medical, and genetic data of donors and any other persons listed in the documentation of the procedure (Article 50, Para. 1). Healthcare facilities must also protect registered data pertaining to the donation of sperm, ova, and embryos that were collected for the purpose of traceability. (Article 51, Para. 1)

Authorized healthcare facilities are also responsible for establishing necessary data protection measures, including measures to prevent the unauthorized disclosure, handling, or alteration of a donor's file or the transfer of this information. Healthcare facilities must also establish procedures for resolving discrepancies in data and for preventing the unauthorized disclosure of information regarding the traceability of donations (Article 52).

The Law on the Protection of Personal Data¹⁰⁴ has a separate chapter on privacy and protection of personal data processing. Article 23 of this law states that each person that has access to a collection of personal data, he/she must provide confidentiality and protection of these data, as well as to process them according to his/her authorization and instructions received.

In order for the confidentiality and protection of the personal data to be guaranteed, the person processing the data must apply techniques and organizational measures appropriate to the equipment and costs necessary for the processing of the personal data (Article 24).

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c. Relevant provisions of providers' codes of ethics

Article 1 of the **Code of Ethics of the Macedonian Chamber of Medicine**¹⁰⁵ states that doctors must maintain the privacy of all information they are given while performing their professional duties.

The **Code of Ethics of the Macedonian Chamber of Medicine** states that “the doctor is obliged by law to maintain professional confidentiality. Professional confidentiality regards all information that the healthcare provider and other supporting staff learn about the patient and his personal or family matters. Professional confidentiality applies to written records regarding the treatment of a patient and all results from medical examinations. The doctor shall withhold confidential information from members of the patient’s family if it is in the best interest of the patient. Professional confidentiality continues after the patient’s death” (Article 55).

According to Article 56, “when the patient releases a doctor from the obligation to maintain professional confidentiality, the doctor decides what information is potentially harmful to the patient and/or patient’s family and shall remain confidential.”

According to Article 57, “the doctor and his co-workers shall maintain professional confidentiality in the education process. These principles shall be transferred to students during their education, and students are also obliged to fully comply [with the standards of professional confidentiality].”

According to Article 58, “in scientific publications used for educational purposes, research data and results should be communicated in a manner that protects the anonymity of patients. The public display of a patient for scientific or educational purposes may be performed only with the patient’s consent, while maintaining professional confidentiality and showing respect for the person’s dignity.”

The Code of Professional Ethics of Macedonian Pharmacists’ Obligations and Rights¹⁰⁶ states that the pharmacist must respect the confidentiality and personal nature of his professional documents. Any patient data that is provided to the pharmacist must be considered confidential and kept as a professional secret. However, in cases when it is in the best interest of the patient or the law to disclose the data, the information may be released to the appropriate persons. (Article 37).

d. Examples and case studies

1) Examples of compliance

Example 4.1

After the death of HIV-positive patient, the healthcare provider and facility maintain

¹⁰⁵ Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

¹⁰⁶ Available at: http://www.farmaceutskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

the patient's medical and personal data as a professional secret, in accordance with regulations on the protection of personal data.

2) Examples of violations

Example 4.2

The head nurse of a healthcare facility's department of surgery places information about HIV-positive patients on a bulletin board in order to inform healthcare providers about the need to take extra precautions when treating or performing interventions on these patients.

This scenario represents a violation of the privacy and confidentiality of personal and medical data, regardless of the patients' HIV status and overall health condition. The healthcare provider is responsible for applying the highest standards of safety when performing medical interventions that involve contact with blood or intact organs.

3) Actual cases

For information on this topic, see case studies 6.1 and 6.2 in Chapter 6 of this guide – *Patients' Rights and Responsibilities, 6. Right to Privacy and Confidentiality*.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

5. Responsibility to Respect the Patient's Personality and Human Dignity

a. Responsibility as stated in national laws/legislation

The Law on the Protection of Patients' Rights¹⁰⁷ establishes the responsibility of healthcare providers to respect patients' dignity (Article 2 and 5).

The Law on the Protection of Patients' Rights states that the patient has the right to the confidentiality of his personal and medical data, which must be kept confidential even upon his death, in accordance with regulations on personal data protection. However, a patient's data may be revealed if the patient gives his given written consent; if the data are necessary to perform a medical intervention on a patient at another healthcare facility; if the healthcare facility is required by law to process the data; if the data are used for historical, scientific, research, or educational purposes and the patient's identity is not revealed; or if the data must be gathered in accordance with a law that aims to protect the lives, safety, and health of other persons.

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The disclosure of the above-mentioned data must be performed in a manner and to an extent that accomplishes the goal of disclosing the information. However, the confidentiality of the data must still be protected to the maximum possible extent. Patient data must be maintained in compliance with regulations on the protection of classified information and personal data.

Human substances from which the patient can be identified must be kept confidential in compliance with regulations on the protection of personal data.

Unless otherwise stipulated by this Law on the Protection of Patient's Rights, the processing of personal data must be performed in compliance with regulations pertaining to the protection of personal data (Article 25).

The law also states that the personality and dignity of each patient must be respected (Article 5, Para. 4) and that the healthcare facility is responsible for ensure the safety of each person during his admission (Article 33).

The **Law on Mental Health**¹⁰⁸ stipulates the responsibility of healthcare providers to respect the personality, dignity, and privacy of a person suffering from a mental illness (Article 20, Para. 1).

In this manner are the stipulations regarding the conditions under which the patient may be included in scientific research, education etc.

b. Specific supporting laws and regulations

According to the **Law on Mental Health**¹⁰⁹, the healthcare facilities must provide the following options or amenities to patients suffering from mental illness: to be admitted in a room that is separate from patients of the opposite sex; for underage patients, to be admitted in a room that is separate from adult patients; to dispose of clothing, personal hygiene products, and other personal products, in accordance with his mental health status; and to take part in religious activities offered by the healthcare facility (Article 14).

The Law on Blood Safety¹¹⁰ requires the protection and confidentiality of personal, medical, and genetic data that is kept in a donor's medical file. These data are classified information and must be maintained in accordance with regulations for the protection of classified information and personal data (Article 17).

A healthcare facility that offers blood transfusion services must obey the rules and regulations pertaining to the protection of **patients' rights, classified information, and personal data** when handling medical records that contain personal, medical, and genetic data (Article 17, par. 3)

108 Official Gazette of the Republic of Macedonia, no. 71/06

109 Official Gazette of the Republic of Macedonia, no. 71/06

110 Official Gazette of the Republic of Macedonia, no. 110/07

According to the **Law on the Termination of Pregnancy**,¹¹¹ the healthcare provider has the responsibility to maintain professional secrets and respect the dignity of the pregnant woman (Article 4).

c. Relevant Provisions of Providers' Codes of Ethics

The responsibility to respect a patient's dignity is related to the responsibility to maintain professional confidentiality. For information on this topic, see the section titled "Responsibility to Maintain Confidentiality and Keep Professional Secrets."

d. Examples and case studies

1) Examples of compliance

Example 5.1

A healthcare provider informs a patient who suffers from a mental illness about a diagnosis of a cardiovascular illness and the possibilities for treating the illness. Despite the patient's reduced mental ability, the doctor successfully communicates this information to the patient because he uses language that is understandable to the patient.

2) Examples of violations

Example 5.2

A patient insists on changing his healthcare provider because the doctor is not of the same gender as the patient. The patient's issues the request because of a past history of sexual abuse. The healthcare provider does not respect the wishes of the patient and continues to treat the patient.

3) Actual cases

No cases involving the violation of this responsibility have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

111. Official Gazette of the Republic of Macedonia, no. 19/77, 15/95

6. Responsibility for Licensing, Continuing Medical Education, and Re-licensing

a. Responsibility as stated in national laws/legislation

The Law on Healthcare¹¹² defines the responsibilities and conditions for healthcare providers and other medical staff who perform healthcare services, and it sets conditions for internships, proficiency examinations, and the issuance of general licensed and operating licenses (Article 138–145).

“Healthcare services may be rendered only by a healthcare provider who has obtained the appropriate professional education, completed an internship, passed a proficiency examination, and received a basic license and an operating license” (Article 138).

“A healthcare provider with a university education in medicine or dentistry may obtain an operating license if apart from the conditions from Article 153-a, Paragraph 1 of this law, he also has a basic license and has an appropriate specialization or sub-specialization” (Article 153-b, Para. 1).

A healthcare provider who obtained a university education in medicine or dentistry **from a foreign country** may be granted an operating license if apart from the conditions from Article 153-a, Paragraph 2 of this law, also he can provide proof of an accredited, appropriate specialization or sub-specialization; a recommendation from the chamber of medicine of which he is member; and proof of his professional experience in the field for which he wishes to obtain an operating licence (Article 153-b). The license is issued for duration of seven years and it can be renewed in accordance with the conditions stipulated in Article 153-g of the same law.

“A university-trained pharmacist may obtain an operating license if he has obtained proof of a completed internship, passed a proficiency examination, and completed an appropriate specialization or sub-specialization” (Article 153-c).

“A healthcare provider with a university education may renew his license if he continuously upgraded his professional knowledge during the original period of his licensure. The healthcare provider should follow the achievements in medicine, dentistry, or pharmacy and should obtain a certain number of credits in continuing medical education. In addition, the healthcare provider should spend at least 60% of his working hours practicing in the field of medicine for which the license has been issued” (Article 153-g, Para. 1).

The methods for upgrading one’s professional skills and the criteria for accruing credits for the renewal of one’s operating license are determined by the respective professional chambers under an act approved by the Minister of Health (Article 153-g, Para. 3).

¹¹² Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

A university-trained healthcare provider whose operating license has expired may reapply for a license if he obtains additional training and passes an additional proficiency examination within one year of the expiration date of the license (Article 153-i).

b. Specific supporting laws and regulations

There are no specific supporting laws in this field.

c. Relevant Provisions of Providers' Codes of Ethics

The Code of Ethics of the Macedonian Chamber of Medicine¹¹³ establishes the doctor's responsibility for continuously upgrading his professional qualifications and education (Article 4, 59–61).

According to the ***Code of Ethics of the Macedonian Chamber of Medicine***, the doctor shall continuously improve and deepen his professional and scientific knowledge. The doctor is responsible for maintaining and improving his proficiency, morals, and ethics. The doctor must also warn the public about diseases and actively cooperate in the containment and eradication of diseases. The doctor must foster the population's healthcare education and its awareness of good health habits. The doctor must act to mitigate potential harms to human health and must protect the public from physician incompetence and alternative medicine practices (Article 4).

Article 59 of the Code of Ethics of the Macedonian Chamber of Medicine states that every doctor is duty-bound to stay abreast of the latest achievements in medicine and work toward his own professional development. The doctor must pass on his knowledge to his colleagues and other healthcare providers. The development and improvement of the medical profession and science requires the doctor to continuously further his knowledge of medical theory and practice through work with professional associations and in scientific and professional institutions.

Article 60 of the code of ethics states that the doctor must improve his personal knowledge of the humanities and social and natural sciences.

Teaching doctors are responsible for emphasizing the special duty of future doctors to introduce new methods of treatment, for passing along knowledge of the latest developments in scientific and medical research, and for highlighting moral and ethical issues in certain cases. Doctors are responsible for enabling conditions in society and in healthcare facilities that allow for the continuous development of skills in providing emergency medical assistance (Article 61).

According to the ***Code of Ethics of the Dental Chamber of Macedonia***¹¹⁴, the dentist is responsible for continuously improving his professional knowledge and for follow-

113 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

114 Available at: <http://stomatoloskakomora.org/?strana=statut>

ing the regulations of continuing professional education. The dentist is responsible for maintaining the professional skills, morals, and ethics of his co-workers, and he must provide emergency medical care and treatment to persons in danger, in accordance with his proficiency (Article 8).

According to the **Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights**¹¹⁵, every pharmacist is responsible for staying abreast of the latest achievements in medicine and professional education. The pharmacist must share his professional knowledge with his colleagues, especially those who are younger and less experienced (Article 42).

The pharmacist is responsible for expanding his personal knowledge and should develop a strong understanding of the humanities, natural sciences, and social sciences (Article 44).

Other relevant sources

According to Article 153-j of the Law on Healthcare¹¹⁶, the relevant professional chambers **may temporarily or permanently terminate the operating license** of a healthcare provider with a university education.

The temporary termination of a healthcare provider's operating license last up to seven years in cases when the healthcare provider fails to not renew his license within the specified deadline, does not complete additional training within the specified deadline; fails a proficiency examination, is ordered by a judge to temporary terminate his practice, falsified his qualifications for licensure, exceeds the limits of his license, or is found by the relevant chamber's court of honor to have violated the code of ethics of his profession.

When temporarily terminating a healthcare provider's operating license, a professional chamber may require the healthcare provider to perform additional training before submitting a request for the renewal of his license.

A healthcare provider's operating license may be permanently terminated if a court decides that the healthcare provider committed a professional error that caused the permanent disability or death of a patient.

According to Article 153-m of the Law on Healthcare, the Chamber of Medicine and Dental Chamber may determine conditions for issuing general licenses and for issuing, renewing, and terminating operating licenses. The chambers may also determine the form and content of healthcare providers' operating licenses; these decisions must be approved by the Minister of Health.

The Pharmacists' Chamber sets the conditions for issuing basic licenses and for issuing, renewing, and terminating an operating licenses. The form and content of the licenses are also determined by the chamber and are approved by the Minister of Health.

115 Available at: http://www.farmaceutskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

116 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

d. Examples and case studies

1) Examples of compliance

Example 6.1

A healthcare provider's operating license is suspended after he fails to fulfill the requirements for its renewal.

Example 6.2

A patient files a motion with the Court of Honor of the Macedonian Chamber of Medicine claiming that his healthcare provider violated medical and dental ethics. The license of the healthcare provider is terminated following an investigation.

2) Examples of violations

Example 6.3

The Court of Honor of the Macedonian Chamber of Medicine finds a healthcare provider criminally liable for negligence and the infliction of permanent damage to a patient's health. Nevertheless, the chamber does not terminate the healthcare provider's operating license.

3) Actual cases

There is no case of permanent termination of a license due to negligence or malpractice.

There are several cases of temporary terminations of a license, or warning before termination.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

7. Responsibility to Provide Emergency Medical Assistance and Working in Exceptional Conditions

a. Responsibility as stated in national laws/legislation

The responsibility to provide emergency medical assistance is regulated with Article 46 of the **Law on Healthcare**¹¹⁷, where it is stipulated that a healthcare facility, in ac-

¹¹⁷ Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

cordance with its activities, has a responsibility to provide healthcare to each person that asks for healthcare.

The healthcare facility shall provide continuous 24 hour medical assistance, and have all medications and sanitary materials necessary for the provision of emergency medical assistance.

If necessary, the healthcare facility that has provided emergency medical assistance to a patient, must organize proper transportation and medical care of the patient to another relevant healthcare facility.

In order to acquire emergency medical assistance, the patient doesn't need any documents upfront.

In addition, Article 95-e of the same law stipulates that the Center for emergency medical assistance organizes and implements measures and activities for short-term (emergency) healthcare of patients in life threatening condition on the spot, until they are transferred to a relevant healthcare facility.

The Center may also organize home visits and treatment.

The organization and manner of provision of healthcare is regulated by a general act of the healthcare facility, in accordance with its activities (Article 113).

The healthcare facilities have a responsibility to provide emergency medical assistance even in times of protest (Article 171-b).

The provision of emergency medical assistance to foreign citizens is also regulated with this law.

The **Law on Healthcare**¹¹⁸ regulates the provision of healthcare in exceptional conditions, crisis situations and in time of protest with a separate chapter.

In accordance with the **Law on Healthcare**¹¹⁹, the Ministry of Health may form healthcare facilities during certain crises that are enumerated by law. The Ministry of Health has the power to assign special tasks to healthcare facilities and healthcare providers that are outside the scope of their certification and job description (Article 171).

b. Specific supporting laws and regulations

There are no laws in Macedonia that specifically pertain to this right.

118 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

119 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

c. Relevant Provisions of Providers' Codes of Ethics

The Code of Ethics of the Macedonian Chamber of Medicine¹²⁰ and the **Code of Ethics of the Dental Chamber of Macedonia¹²¹** stipulate that the healthcare provider may not abandon his patient in the event of a general emergency unless he is explicitly instructed to do so (Article 33). The doctor may not refuse emergency medical services to those in need, regardless of his speciality, whether he is on duty, or whether he is directly asked to provide medical assistance. In cases of disease epidemics or mass disasters, the doctor must provide priority treatment to the patients who are in most need of medical care (Article 35 and 40). The healthcare provider must provide emergency care despite risks to his own life, health, and safety, except in situations when the healthcare provider's life and health are in immediate danger (Article 36).

The codes of ethics also state that the healthcare provider has special responsibilities and obligations during emergencies (Article 35).

In accordance with the Article 36 of the **Code of Ethics of the Macedonian Chamber of Medicine¹²²**, Article 42 of the **Code of Ethics of the Dental Chamber of Macedonia¹²³**, Article 38 of the **Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights¹²⁴**, and the principles of safety and solidarity, the doctors, dentists, and pharmacists must be ready to immediately report to duty in the event of an emergency, regardless of their position or proficiency. Healthcare providers must be aware of their moral and human responsibilities.

d. Examples and case studies

1) Examples of compliance

Example 7.1

A terminally ill patient is brought to a hospital in an unconscious state. The patient has stated that he does not want doctors to perform any interventions in case his condition deteriorates. However, the patient has provided no written statement of this wish, so the doctor is obligated to perform an emergency medical intervention.

2) Examples of violations

Example 7.2

The denial of emergency medical care to a terminally ill patient is related indirectly to the criminal act of assisting in the performance of euthanasia, which is punishable by law.

120 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

121 Available at: <http://stomatoloskakomora.org/?strana=statut>

122 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

123 Available at: <http://stomatoloskakomora.org/?strana=statut>

124 Available at: http://www.farmaceutskakomora.com//index.php?option=com_content&task=view&id=19&Itemid=34

3) Actual cases

No cases involving the violation of this responsibility have been reported or are otherwise known to the working group responsible for the preparation of this guide.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

8. Responsibility for Equal Treatment and Non-discrimination

a. Responsibility as stated in national laws/legislation

According to the **Law on the Protection of Patients' Rights**¹²⁵, the patient has the right to exercise his rights without any discrimination based on gender, race, language, religion, political or any other affiliation, ethnic or social background, minority status, socio-economic status, status by birth, sexual orientation, or any other identity factor (Article 5, Para. 2). The respect of this right is also a responsibility of the healthcare facility and the whole staff (medical or not). This responsibility is stipulated in Article 32, Para. 4.

The **Law on Mental Health**¹²⁶ in Article 7, Para. 2, forbids healthcare providers to discriminate patients suffering from mental illness on basis of their illness.

In addition, the **Law on Mental Health**¹²⁷ **explicitly forbids the following actions:** any form of torture, inhumane or degrading conduct, or punishment; the performance of clinical or experimental trials on a mentally ill person; the sterilization of a mentally ill person; **discrimination** against a person suffering from a mental illness based on his gender, language, religion, political and other affiliation, ethnic and social background, financial or social status, or any other status; censorship of written documents belonging to a person suffering from a mental illness; the restriction of communication with persons outside of the healthcare facility; and the engagement of a person suffering from a mental illness in performing work for the employees of a healthcare facility (Article 32, Para. 1–8 and Article 20, Points A–F).

b. Specific supporting laws and regulations

The **Law on Mental Health**¹²⁸ forbids healthcare providers from conducting medical or surgical interventions or electro-convulsive therapy without first obtaining the

125 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

126 Official Gazette of the Republic of Macedonia, no. 71/06

127 Official Gazette of the Republic of Macedonia, no. 71/06

128 Official Gazette of the Republic of Macedonia, no. 71/06

consent of the mentally ill person or his legal guardian or, except in cases when interventions or ECT are necessary to save the patient's life or to prevent his condition from deteriorating (Article 20).

c. Relevant Provisions of Providers' Codes of Ethics

According to the Article 97 of the **Code of Ethics of the Macedonian Chamber of Medicine**¹²⁹, Article 70 of the **Code of Ethics of the Dental Chamber of Macedonia**¹³⁰, and Article 56 of **Code of Professional Ethics of Macedonian Pharmacists' Obligations and Rights**¹³¹, the healthcare provider must be impartial and honest in his professional conduct, regardless of his the personal ties to patients.

Other relevant information

Unless there is a need for further treatment as determined by law, convicted and incarcerated persons suffering from mental illnesses have the right to treatment within a healthcare facility if a psychiatrist determines that they are suffering from a mental illness or exhibiting signs of a psychological disorder at the time of their sentencing. This right may be exercised upon the direction of authorities overseeing the sentence (Article 31). Also, a convicted person suffering from a mental illness may request a psychiatric examination at his own expense if it is not approved by the resident doctor of the prison facility (Article 32, Para. 1).

The healthcare facility is also responsible for providing persons who suffer from mental illnesses with legal advice and assistance regarding the protection and exercise of their rights (Article 25).

d. Examples and case studies

1) Examples of compliance

Example 8.1

A healthcare provider recuses himself from the treatment or forensic examination of a person with whom he has close relations. The doctor has a legitimate right, and perhaps even the responsibility, to remove himself from situations in which he cannot guarantee his impartiality.

2) Examples of violations

Example 8.2

The dentist's refusal to provide medical assistance to a patient who willingly declared his Hepatitis B status is not in accordance with the principle of non-discrimination. If the dentist's office is not able to provide proper healthcare to the patient, due to lack

129 Available at: <http://www.lkm.org.mk/akti/kodeks.htm>

130 Available at: <http://stomatoloskakomora.org/?strana=statut>

131 Available at: http://www.farmaceutvskakomora.com/index.php?option=com_content&task=view&id=19&Itemid=34

of finances or other reasons, the patient should be referred to a facility where he will be able to receive proper healthcare.

3) Actual cases

For information on this topic, see case study 2.4 in Chapter 6 of this guide, 2. Right to Access.

4) Practical notes

Administrative, misdemeanor, criminal, and civil protection cases may be opened in response to violations of this responsibility; these procedures are described in detail in Chapter 8 of this guide.

8

National Procedures

In Macedonia, social rights and healthcare rights are guaranteed under the Constitution of the Republic of Macedonia¹ and other laws. According to Article 8 of the Constitution, the founding values of the country's constitutional order are humanism, social justice, solidarity, and the rule of law.

Article 34 of the Constitution guarantees citizens' right to social security and social insurance, which are defined by specific laws and collective agreements.

According to Article 35 of the Constitution, in line with its commitment to the principle of social justice, the state is responsible for the social protection and security of its citizens. The article also establishes the state's responsibility to provide assistance to citizens who are incapable of working and to persons with special needs. The state must create conditions that allow for the inclusion of these citizens in society.

Article 39 of the Constitution guarantees the right to healthcare and states that each citizen has obligation to take care of his own health and the health of others.

8.1 Mechanisms to Protect/Enforce Rights and Responsibilities in Court

In Macedonia, rights and responsibilities may be protected through administrative, civil, criminal, and executive procedures, as well as through alternative mechanisms.

1 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

1. Administrative Procedure

Administrative procedures that are initiated in order to protect human rights in the field of healthcare are subject to the rules governing general administrative procedures.

Contact is made between administrative bodies and citizens when a citizen petitions the bodies to exercise certain rights and interests or when the administrative body requests the fulfillment of certain citizen responsibilities.

The administrative bodies are responsible for enabling the efficient and lawful exercise of citizens' constitutional liberties and rights.

Concept of the administrative procedure

Legislation regarding the administrative procedure contains rules that determine the authority, form, and activities of the procedure. The form and content of actions endorsed as a result of the procedures of state administrative bodies and public authorities are also specified. In other words, the concept of an administrative procedure refers to formal regulations of conduct that differ from specific laws.

There are two types of administrative procedures in Macedonia:

- the **general administrative procedure**, which sets common rules for the establishment and functioning of most state institutions and public organizations, and
- the **special administrative procedure**, which determines the authority, form, and activities of certain bodies operating in specific fields.

Administrative procedures determine the right and responsibility of state bodies to decide on certain administrative issues in specific fields. The authority of such procedures can be divided into two areas:

- **Subject-matter jurisdiction**, which is determined according to the nature of the administrative issue, by a specific law regulating the administrative field, or by a decision-making body in the administrative procedure; and
- **Territorial jurisdiction**, which is determined by territory (i.e.: the internal organizational acts of a decision-making body in the administrative procedure).

Parties involved in the administrative procedure

Parties involved in an administrative procedure may include the person who has requested the initiation of the procedure (the **active party**), the person against whom the procedure has been initiated (the **passive party**), and any person who has the right to take part in the procedure in order to protect his rights or legal interests (the **interested party**).

Any person or legal entity may be a party in an administrative procedure. In order to take part in an administrative procedure, a person or legal entity must meet the following criteria:

- party capability (the ability to carry out one's rights and responsibilities),
- process capability (the ability to individually undertake process actions), and

- party identification (one's right and interest in the specific process).

Communication between administrative bodies and citizens

The basic element of communication between citizens and administrative bodies is the **submission of documents**. These submissions may be requests, automatic data processing forms, proposals, reports, petitions, or other documents that are used by parties to appeal to administrative bodies for the realization or protection of their rights. Submissions must be understandable and must contain all elements necessary for the initiation of an administrative procedure. In particular, the submission must contain the name of the body to which it is submitted; the subject of the request or proposal; the name of the party's legal representative, if one has been retained; and the full name and address of the applicant or his legal representative.

Course of the administrative procedure

The relevant body **initiates** the administrative procedure in accordance with its duties (ex officio) or by the request of an involved party.

The relevant body may initiate the procedure in certain cases that are determined by law or when the procedure is necessary for the protection of the public interest. In other cases, the state body cannot initiate an administrative procedure without receiving a request to do so by one of the involved parties.

After the administrative procedure is initiated, the relevant body must determine **all relevant facts and circumstances** prior to making its final decision on the matter. The administrative body must also allow the parties to exercise and protect their rights and legal interests. This goal may be achieved through a **shortened (urgent) procedure** or through a **special investigation**.

The administrative body may settle the issue directly in a **shortened (urgent) procedure** if the following criteria are met:

- the party has furnished facts or evidence in its request that serve as a basis for determining the actual situation of the issue or whether a position may be determined on the basis of generally accepted facts or information that is known to the relevant body;
- the actual situation may be determined on the basis of official data that are handled by the relevant administrative body, and there is no need for a party to provide special testimony in order to protect his rights or legal interests;
- there are cases, stipulated by regulations, pursuant to which the issue may be solved on the basis of facts or circumstances that are not completely proven or such facts and circumstances may be proven only indirectly, so that the facts and circumstances shall be considered as probable, and all the circumstances lead to the conclusion that the request of the party should be solved positively;
- urgent measures must be undertaken in order to protect the public interest, and the facts that must be considered as a basis for issuing a decision have been already determined or justified.

A special investigation is initiated when certain facts and circumstances must be deemed significant for the resolution of the case. A special investigation may also be initiated in order to give the involved parties the ability to exercise and protect their rights and legal interests.

Parties have the right to participate in the investigation, to provide data that are necessary for the procedure, and to protect their rights and interests.

The relevant body issues a **decision** on the basis of facts that were established during the course of the procedure.

Generally, **the decision is issued in written form**; however, in exceptional cases that are established by law or by special rules pertaining to the law, the decision may be announced verbally. The original document or a certified copy of the decision must be submitted to the party. The written decision must comprise the following elements: an introduction, enacting clause, and statement of reasons; instructions on legal remedies; the name of the relevant administrative body; the number and date of the decision; the signature of the official issuing the decision; and the official stamp of the relevant body.

According to the Law on General Administrative Procedure,² the administrative body is required to make a decision and submit it to the party within a **fixed period**. Unless otherwise defined by law, the period lasts from **15 to 30 days** and begins immediately after the submission of the request. The length of time varies depending on the complexity of the case.

Each party has the right to seek **legal remedies** in the event that they disagree with the decision. Remedies are divided into two types: **regular and extraordinary. Appeal is the only form of regular legal remedy**, whereas **extraordinary legal remedies** may include the following:

- renewal of administrative procedure
- revocation, repeal, and reversal of a decision
- request for the protection of lawfulness
- revocation and repeal by the right of supervision
- repeal or amendment of an effective decision by mutual agreement or upon the request of a party
- extraordinary repeal
- announcement of the invalidity of the decision

Regular legal remedy

A party has the right to **appeal** a decision issued in an administrative procedure. The appeal must be filed within 15 days of the receipt of the decision, unless otherwise stipulated by law. The date of receipt is defined as the date when the decision is delivered to the involved parties.

² Official Gazette of the Republic of Macedonia, no. 38/05, 110/08

During the period reserved for appeal, the original decision cannot be carried out. By exception, a decision may be implemented during the appeal period in certain situations when such action is necessary to prevent irreversible harm to a person. In either case, appropriate safeguarding may be requested by the party whose interests are favored in the decision; this safeguarding is placed as a condition for the implementation of the decision.

The appeal is delivered directly or mailed to the institution that first issued the decision. The appeal is reviewed and considered by a second institution with higher authority. If the higher body chooses to overturn the original decision, it may either issue a new decision or to return the case to the institution that delivered the original decision.

An appeal may be filed even when the original decision **is not endorsed (silence of the administration)**. In such cases, the higher body may require the lower body to endorse a decision within a certain period not to exceed 30 days, or it can issue its own decision on the matter. The decision of the higher body is final.

The decision of an appeal must be issued and delivered to the appellant as quickly as possible. The decision must be delivered no later than two months after the filing of the appeal, unless otherwise determined under a specific law or act.

Extraordinary legal remedies

Renewal of the administrative procedure

A decision in an administrative procedure that cannot be challenged using regular legal remedies may be renewed if one of the following criteria is met:

- new facts are brought to the court, the court discovers relevant evidence from a previous procedure that could lead to a different decision
- the decision was based on misleading data or false testimony from an eyewitness or expert witness, or the decision was issued as a result of criminal activity
- the decision was based on a criminal verdict that was already overturned
- the decision was based on the misleading testimony of one of the involved parties
- the decision was based on an issue that was later resolved in a different manner by the same administrative body
- the procedure was led by an official who was later forced to recuse himself from the case
- the decision was made by an official who was not authorized to make such decisions;
- the composition of the committee of the relevant administrative body failed to meet the required standards or the decision was issued without a quorum of the committee of the relevant administrative body
- one or more of the involved parties was not allowed to participate in the procedure;
- one or more of the parties lacked legal representation as required by law

Renewal of the administrative procedure may be requested by one of the involved parties or initiated by the body that issued the original decision.

The parties may request the renewal of the procedure **within one month** of the original decision. The length of this period is determined according to the reasons given for renewing the procedure.

The involved parties or the relevant administrative body may not seek renewal if five or more years have passed since the decision was issued. Exceptions to this rule include cases when the decision was based on false documents or misleading statements by an eyewitness or expert witness, when the decision was issued in connection with criminal activity, or when the responsible administrative body addressed the same issue in a different case.

A party seeking to renew the procedure may submit its request to either the body that issued the original decision or the body that made the final decision. The proposal for renewal is considered by the body that made the final decision.

Revocation, repeal, and reversal of a decision

The administrative body whose decision is challenged before the Administrative Court through the process of renewal, may repeal or change its decision until the Court reaches the final decision, due to the same reasons that the Court may repeal or change the decision. The administrative body may repeal or change its decision if all of the requests set forth in the appeal are taken into consideration and if the repeal or amendment of the decision does not violate the rights of the involved parties or a third party.

Request for the protection of lawfulness

The Public Prosecutor's Office has the right to request the protection of lawfulness against a decision that was made in a case for which the initiation of an administrative procedure was not possible and court protection outside the administrative procedure is not regulated by law, if there is an opinion that such a decision violates the law.

Requests for the protection of lawfulness may be initiated within one month of the submission of the decision to the Public Prosecutor's Office, or within six months of the delivery of the decision to the party in cases when the decision was not submitted to the Public Prosecutor's Office.

Such requests are reviewed by the body that is responsible for reviewing the original administrative decision.

An administrative body may overturn a decision or refuse a request for the protection of lawfulness.

Appeals of decisions regarding the protection of lawfulness may not be filed.

Revocation and repeal by the right of supervision

A final decision in an administrative procedure may be overturned by the appropriate supervisory body if:

- the decision was issued by a body that does not have subject-matter jurisdiction
- the same kind of issue was settled in a different manner in previous administrative procedure
- the decision was made without the agreement, confirmation, approval, or positive opinion of another competent body, in violation of the law
- the decision was issued by a body that does not have territorial jurisdiction
- the decision was issued as a result of extortion, blackmail, or other unlawful actions

A final decision in an administrative procedure may be overturned by a supervisory body if the decision clearly violates the law. In the event that two or more parties in the case represent different interests, the decision may be overturned only by an agreement concluded between the interested parties.

The decision may be overturned or repealed by a supervisory body. If there is no relevant supervisory body, then the decision may be overturned or repealed by a body that is given the legal authorization to supervise the activities of the body that issued the decision.

The supervisory body may revoke the decision of another body *ex officio*, at the request of a party, the Public Prosecutor's Office, or the Public Attorney. The repeal of a decision may be done *ex officio*, or to be requested officially by the Public Prosecutor's Office or the Public Attorney.

The legal guidelines for revoking or repeal of a decision are enumerated in Article 264 of the Law on General Administrative Procedure.³

Decisions made in accordance with Article 263 of the Law on General Administrative Procedure may not be appealed. The decision may be appealed in an administrative dispute.

Repeal and amendment of an effective decision by mutual agreement or upon the request of a party

If the administrative body that issued the effective decision believes that the relevant law was applied incorrectly, the body may overturn or amend its decision only if the party agrees with the proposed course of action and the proposed activity does not violate the rights of a third party. The party must give its consent to an amended decision that adversely affects a party that has obligations under the original decision.

A decision that is deemed inappropriate for the party may also be repealed or amended. If the competent body finds that there is no need to repeal or amend a decision, then it is obligated to notify the party. Decisions that are amended may not be applied retroactively.

3 Official Gazette of the Republic of Macedonia, no. 38/05, 110/08

The body that issued the original decision is responsible for making any changes to the decision. An appellate body may amend or repeal the decision only in cases where such activity is explicitly allowed under the law. If the appellate body loses its mandate to engage in such activity, the decision may be reviewed by another competent body that is responsible for such activities.

Complaints against amended decisions are allowed only if the amended decision was filed by the body that oversaw the original decision. If the decision was issued by an appellate body, or if the lower body's revised decision was final, then an administrative dispute may be initiated.

Extraordinary repeal

An enforceable decision may be revoked only when it is necessary to eliminate a direct danger to the life or health of a person or people, public security, public order, or public morality. The decision may also be revoked in order to eliminate economic problems that cannot be resolved by other means. The decision may also be revoked partially, to the extent that is necessary to prevent harm or to protect the public interest.

If the decision was issued by a lower administrative body, it may be repealed by a competent appellate body. If no such appellate body exists, then the body that is legally authorized to supervise the activities of the lower administrative body may revoke the decision.

Complaints may be filed against the revocation of a decision if the revocation was ordered by a lower administrative body. Otherwise, administrative proceedings may be initiated to overturn the revocation.

The aggrieved party has the right to seek compensation only for physical damages. According to the Law on Administrative Disputes⁴, the court that is responsible for settling administrative disputes involving revoked decisions is also responsible for issuing decisions on compensation for damages. The court must take into consideration all facts from the case when determining the amount of compensation to provide to the party.

Invalidation of the decision

The law also allows full or partial invalidation of certain procedures. A decision may be overturned or declared invalid at any time at the request of an involved party, ex officio or by a request from the Public Prosecutor's Office.

A decision may be declared invalid if its enforcement would violate the Criminal Code⁵ or other laws.

4 Official Gazette of the Republic of Macedonia, no. 62/06

5 Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

Legal consequences of the revocation or invalidation of a decision

If a decision is declared invalid, the legal consequences of the decision are also invalidated.

The **revocation** of a decision does not overturn legal consequences that have already been enforced, but prevents further consequences.

Execution of a decision

The decision issued as a result of an administrative procedure must be **executed** immediately after one of the following developments:

- the expiration of the period for filing an appeal, if the appeal has not been placed
- the submission of the decision to the losing party, if an appeal cannot be filed or if an appeal would not postpone the implementation of the decision
- the losing party is made aware of a ruling to reject or refuse the appeal

A decision to overturn a lower body's ruling becomes executable upon the delivery of the appellate body's decision to the relevant party.

If a decision must be carried out within a certain period, then it goes into effect upon the expiration of the specified period. If no specific period is stipulated for executing a decision, then it takes effect within 15 days of the date that the decision was made. The 15-day period for implementing a decision begins on the day that the decision goes into effect.

One of the goals of the administrative law is to enable organized, systematic, and judicial control over the lawfulness of an administrative act through a system of **administrative disputes**.

An administrative dispute may be filed for a number of issues; however, it is important to emphasize that in an administrative dispute, the Administrative Court may rule against specific acts of administrative and other government bodies, municipal organizations, and other public authorities when there are no other legal protections stipulating the right to appeal such acts.

A person or legal entity has the right to initiate an administrative dispute if there is reasonable belief that the administrative act violated his rights or interests. The right to initiate administrative proceedings against other entities is stipulated in the Law on Administrative Disputes⁶. Verdicts in administrative disputes are binding and enforceable.

An administrative dispute may be initiated against the final administrative acts of appellate bodies. Disputes may also be initiated against administrative acts of lower courts that cannot be appealed.

An administrative dispute may be filed even in cases when the relevant administra-

⁶ Official Gazette of the Republic of Macedonia, no. 62/06

tive body failed to adopt an adequate act upon the request or appeal of a party. The dispute must be filed in accordance with stipulations of the Law on Administrative Disputes.

An administrative act can be defied in cases when a law is implemented improperly, when an act was imposed by an unauthorized body, or when the procedure for implementing the act was not conducted according to the rules, especially if facts have not been established to an adequate degree or if the evidence led to an incorrect conclusion regarding the facts of the case.

An administrative dispute may be initiated by filing a **lawsuit** within 30 days of the delivery of the administrative act to the relevant party.

If the lawsuit is filed by a person, then the relevant documentation must contain his name and address. If the lawsuit is filed by a legal entity, then court documents must contain the name and address registered with the Central Registry. In both cases, the lawsuit must name the defendant, the grounds for the claim, and arguments for the revocation of the administrative act. The lawsuit must also include a copy of the act under review. If the plaintiff is seeking monetary compensation or the restoration of property, then the suit must also include documentation of those claims. A copy of all documents related to the lawsuit must be provided to the defendant and any other involved parties.

The plaintiff has the right to withdraw his lawsuit at any time before a decision is made. In such case the court will issue a decision to suspend the proceedings.

If the lawsuit is incomplete or ambiguous, it is the responsibility of the president of the court council to call upon the plaintiff to improve the lawsuit within a reasonable period. The president of the court council must also advise the plaintiff and his counsel of the consequences of failing to act upon the court's request. If the plaintiff does not improve the documentation of his claim, the court may dismiss the lawsuit, unless it is determined that the act in question has already been annulled.

A court may dismiss a lawsuit if one of the following criteria is met:

- the legal claim was not submitted in a timely manner;
- the disputed act is not an administrative act;
- the disputed administrative act clearly does not have any effect on the plaintiff's rights and his direct personal interests
- a petition to overturn the disputed administrative act could have been filed but was not registered in a timely manner
- the administrative case cannot be disputed under law
- a court decision has already been issued on an administrative dispute regarding the same matter.

If a court does not dismiss the lawsuit but determines that the disputed administrative act had essential inaccuracies that prevented the assessment of its legality, the

court may move to revoke the act without submitting the legal claim in the procedure for replying to the legal claim.

If the court neither dismisses the lawsuit immediately nor revokes the act, then it must submit a copy of the lawsuit and the supporting documents for a **reply** to the parties. The reply must be issued within a reasonable period determined specifically for each case. This period must be no shorter than eight days and no longer than 30 days. Within the given period, the defendant is responsible for submitting to the court all documents that are related to the case. If the defendant does not submit all the relevant documents after receiving two requests for the information, or if the defendant informs the court that he is unable to provide such information, then the court may issue a ruling in the case without having to consider the documents in question.

As a rule, administrative disputes are decided in a closed court session. However, the court may call for a hearing for the following reasons:

- the administrative dispute is extraordinarily complex
- a better understanding of the case if required in order to issue a decision
- the facts of the case must be determined
- evidence must be presented
- in other situations according to law

Generally, the court issues a decision based on the facts established in the administrative procedure or during the dispute proceedings.

The court may rule to revoke the disputed act if the dispute cannot be decided based on the facts established in the administrative procedure; if there exists a contradiction among various documents; if crucial facts are presented in an ambiguous manner; or if the administrative procedure failed to adhere to rules or procedures, thereby influencing the outcome of the case. The relevant administrative body must adhere to the verdict and adopt a new administrative act.

If the revocation of a disputed administrative act or the renewal of a procedure by the relevant administrative body might cause irreparable harm to the plaintiff, the court may decide upon the facts of the case and issue a verdict or decision based on this interpretation. The court may also undertake similar measures in cases when the examination of public documents or other evidence indicates that the actual facts of the case are different than those established in administrative procedure, or when the administrative act has been revoked and the relevant administrative body has not upheld the decision. In these cases, the facts are determined by a single representative of the court council, by another court, or by another authorized body. Interested parties are called to attend such sessions.

The court is also responsible for investigating the lawfulness of a disputed administrative act within the framework of the lawsuit. The court regards annulments of the administrative act *ex officio*.

The court settles the dispute by issuing a **verdict**.

In its verdict, the court may uphold the lawsuit or dismiss it as an unfounded claim. If the lawsuit is deemed valid, the court revokes the disputed administrative act.

The verdict must contain the following information: the name of the court, the names of the president and other members of the court council, the name of the person who recorded the minutes, the names of the parties in the dispute and their legal representatives, a short description of the case, the date that the verdict was issued and endorsed, dispositive, an explanation and legal advice regarding further actions that are available to the parties (e.g.: filing an appeal). The dispositive must be separated from the explanation. The original copy of the verdict must be signed by the president of the court council and by the person who recorded the minutes.

Each party receives a certified copy of the verdict or court decision. Parties are permitted to appeal the verdict.

Administrative procedure according to the Law on the Protection of Patients' Rights

The Law on the Protection of Patients' Rights⁷ determines the procedure for the protection of patients' rights. The law is based upon the principle of urgency.

Every patient has the right to submit a written complaint to the manager of a healthcare facility within 15 days of a violation of his rights. The patient may also file a complaint within 15 days of learning that his rights were violated. The manager of the healthcare institution is obligated to review the complaint and inform the patient or his legal guardian of his decision on the matter within 15 days of receiving the complaint.

The patient or his parent or legal guardian has the right to submit complaints, proposals, or other messages regarding the care, treatment, or rehabilitation offered by healthcare facilities; these submissions may be addressed to the Ministry of Health or other competent authorities and institutions. The Ministry of Health must examine the facts provided in the submission and issue a response to the patient or his parent or legal guardian within 15 days of receiving the document. Complaints and other submissions are processed through the healthcare institution.

This law also regulates other forms of the promotion and protection of patients' rights. For example, Article 39 states that municipal governments and the city of Skopje must establish the Standing Commission for Advancing Patients' Rights (hereinafter referred to as "the Commission"). The Commission performs the following activities: improving patients' rights and the protection of the rights; monitoring and assessing the condition of the protection of patients' rights; proposing measures for improving

⁷ Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

the protection of patients' rights; cooperating with the relevant authorities; considering patients' complaints and proposing measures to be undertaken by relevant authorities; seeking professional expertise when necessary to determine particular situations; keeping records of complaints from individual patients and measures aimed at protecting patients' rights; preparing and publishing annual reports on the protection of patients' rights; issuing informational, promotional, and other materials for the purpose of improving patients' rights; and performing other activities stipulated by the Law on the Protection of Patient's Rights.

Members of the Commission are required to maintain professional confidentiality and ensure the protection of personal data when performing activities referred to in Article 42 of the law.

The healthcare facility is required to take into consideration the protection of patients' rights. The healthcare facility must provide legal advice and assistance to patients regarding the exercise and protection of their rights.

The Ministry of Health is responsible for appointing a counselor for the protection of patients' rights in all inpatient healthcare facilities. The counselor is charged with the following duties:

- providing legal advice and assistance to patients regarding the exercise and protection of their rights
- reviewing oral and written complaints submitted by patients and providing an opinion for their resolution to the manager of the healthcare facility
- mediating the amicable resolution of patients' verbal complaints against healthcare providers
- maintaining records of patients' verbal and written complaints and other legal procedures that were initiated to protect patients' rights at the healthcare facility (upon completion of the procedure, documentation shall become part of a patient's medical file)
- informing healthcare providers of patients' rights under the law and training them to help patients exercise their rights
- performing other activities for the purpose of protecting the rights of patients admitted to the healthcare facility

The inpatient healthcare facility must provide a workspace for the counselor. The workspace must be located in an easily accessible area and clearly labeled "Office of the Counselor for the Protection of Patients' Rights." The facility must ensure that the counselor has everything necessary to fulfill his duties.

Outpatient healthcare facilities are required to perform the same duties as the Counselor for the Protection of Patients' Rights.

All healthcare facilities are required to post a copy of the Law on the Protection of Patients' Rights in a visible and easily accessible location.

The Minister of Health is also responsible for establishing the State Commission for

Advancing Patients' Rights. Members of the Commission include representatives of patients, nongovernmental organizations, and mass media, as well as experts in the field of patients' rights and employees of the Ministry of Health.

The Commission is responsible for performing the following activities:

- undertaking measures to improve patients' rights and their protection
- monitoring and assessing the situation regarding the protection of patients' rights throughout Macedonia
- following developments worldwide regarding the protection of patients' rights
- proposing measures to the Minister of Health to improve the protection of patients' rights
- cooperating with the Ombudsperson and other authorities in the field of patients' rights
- cooperating with municipal Standing Commissions for Protecting and Promoting Patients' Rights
- providing opinions, recommendations, and proposals to authorities for improving the protection of patients' rights
- requesting professional expertise when necessary to clarify particular situations
- preparing and publishing semi-annual and annual reports on the protection of patients' rights throughout Macedonia
- publishing informational, promotional, and other materials for the purpose of improving the protection of patients' rights
- performing other activities that are important for the promotion and protection of patients' rights.

The Health Insurance Fund is required to ensure that insured patients can properly exercise their rights in accordance with regulations in the field of health insurance. The fund must provide professional assistance to insured patients who seek to protect their rights under the health insurance system. For the purpose of attaining these goals, every regional office of the Health Insurance Fund is required to provide a workspace for counselors specializing in the protection of insured patients' rights. These premises must be located in an easily accessible place and clearly labeled "Office for Expert Assistance to Insured Patients in the Exercise and Protection of Health Insurance Rights." Regional offices of the fund must provide everything that is necessary for the operation of the counselors' offices.

The protection of the rights of patients with mental illnesses is regulated under the Law on Mental Health⁸ in a manner that is similar to the Law for the Protection of Patients' Rights.⁹

The Law on Mental Health and the Law on the Protection of Patients' Rights almost completely replace the relevant stipulations in the Law on Healthcare,¹⁰ which is cur-

8 Official Gazette of the Republic of Macedonia, no. 71/06

9 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

10 Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

rently undergoing substantive changes. The new amendments will include a stipulation referring to the aforementioned laws.

2. Civil Court Protection in the Republic of Macedonia

Generally, relations between persons are established and maintained on a voluntary basis. However, there are also legal mechanisms for resolving disputes between persons. The way that these mechanisms are implemented is determined by special rules in the area of litigation law. Litigation law determines the bodies that are responsible for providing legal protection to persons and establishing the best method for protecting one's subjective rights in cases when these rights cannot be exercised by regular means.

Court-ordered protection is a special form of organized legal protection that is granted by courts in accordance with special rules of conduct stipulated by law. In this procedure, a person or legal entity appears before a court to request appropriate protection after his subjective rights have been violated. The court is charged with determining whether the subjective right that the person or entity seeks to exercise actually exists and how that right may be protected. The court may enforce decisions within the framework of procedural rules established under litigation law. The court must give equal treatment to all subjects participating in the procedure. Court-ordered measures for the legal protection of subjective rights may come from a wide range of civil and legal relations (e.g.: personal, family, labor, property); these measures are imposed through special procedural regulations. In a civil procedure, the court orders protection measures at the request of the entity claiming that his subjective rights were violated.

Court-ordered protection is provided in accordance with regulations on general litigation that are enumerated in the Law on Civil Procedure.¹¹

Grounds for providing court-ordered protection

Legal protection may be provided at request of an authorized subject only when a subjective right cannot be exercised spontaneously and by normal means. The grounds for providing legal protection of patients' rights are usually connected to the right to damages as a result of the violation of their rights.

Authority of courts in indemnity disputes

There exist several types of authority in resolving indemnity disputes; however, our analysis shall be limited to *subject-matter jurisdiction* and *territorial jurisdiction*.

11 Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

Subject-matter jurisdiction refers to the allocation of disputes among courts of the same rank within the court system of a single country. Subject-matter jurisdiction may be based on a number of criteria, including the subject (basis) of disputes (causal criteria), the value of a dispute (value criteria), the person of process entities (subjective criteria), among others.

Territorial jurisdiction refers to the determination of a specific court to hold proceedings and decide a case. Work is allocated among courts with the same subject-matter jurisdiction. The resolution of disputes is divided among courts that are responsible for distinct judicial districts.

The authority of courts is determined by the Law on Courts.¹² Judicial power is exercised by basic courts, the Administrative Court, appellate courts, and the Supreme Court of the Republic of Macedonia.

Basic courts conduct first-level trials in line with their subject matter expertise. These courts have either basic authority or enhanced authority. In indemnity disputes arising from violations of patients' rights, basic courts have the authority to conduct initial trial if the value of the dispute is up to 15 000 Euro. If the value of the dispute is higher than this amount, then the courts with enhanced authority will conduct the trial.

Appellate courts are charged with hearing appeals of basic court decisions. An appellate court oversees a specific judicial circuit that comprises several basic court districts. These courts are located in the cities of Bitola, Gostivar, Skopje, and Stip.

The Administrative court, among other, decides for acts or actions endorsed as a result of the procedures of state administrative bodies, the Government, units of the local self-government and other authorities determined by law, when the law doesn't provide an appellate procedure i.e. other legal protection against such acts or actions.

The Supreme Court of the Republic of Macedonia has subject-matter jurisdiction to consider appeals of decisions made by the lower courts under conditions stipulated by law.

Territorial jurisdiction in court procedures involving **indemnity disputes** is determined according to the Law on Civil Procedure.¹³ The law contains regulations on general territorial jurisdiction and special territorial jurisdiction.

According to the rules of general territorial jurisdiction, a person may file a lawsuit with a court whose jurisdiction includes the address of his permanent residence. If the defendant is a legal entity, general territorial jurisdiction belongs to the court

12 Official Gazette of the Republic of Macedonia, no. 58/06, 35/08

13 Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

whose jurisdiction includes the location of the legal entity's headquarters. Lawsuits regarding a person's property rights are not restricted to courts with general territorial jurisdiction; instead, they may be filed with any court in whose jurisdiction the plaintiff owns property. The lawsuit may also be filed with a court whose jurisdiction includes the disputed property.

The determination of territorial jurisdiction in disputes involving indemnity is considered according to the following rules: For trials involving non-accountable damage liability, authority is granted to a court with general territorial jurisdiction and to a court in whose jurisdiction the harmful action took place. Similarly, territorial jurisdiction may also be given to a court in whose jurisdiction the consequences of the harmful action were registered. If the relationship between a patient and healthcare provider is considered a contractual relation, then authority is granted according to regulations on consensual territorial jurisdiction. Namely, the parties may agree to appear before a first-level court that has no territorial jurisdiction by law, so long as the court has subject-matter jurisdiction. If two or more courts have territorial jurisdiction in a dispute, then the parties may jointly select a first-level court or another court with subject-matter jurisdiction to hear the case. The agreement on territorial jurisdiction must take written form, and it may refer to one or more disputes arising from a legal provision. The agreement may be included in the contract for a legal act (in this case, a service act). This agreement must be submitted to the court in the event of a lawsuit.

The violation of regulations regarding subject-matter and territorial jurisdiction represents an essential violation of the principles of litigation procedure and may be challenged through regular and extraordinary remedies, as determined by law.

Course of the civil procedure

Disputes involving indemnity are resolved according to the regular litigation procedure defined in the Law on Civil Procedure.¹⁴

As with any other litigation procedure, the **litigation procedure for indemnity is initiated by a lawsuit**. The lawsuit, which takes the form of an application, is the initial process action is filed before a court. The lawsuit has the form of the application. The Law on Civil Procedure sets guidelines for the **mandatory content of a lawsuit**. Specifically, the lawsuit must include the following submissions: plaintiff's request, a request for the adoption of a decision in the matter, evidence upon which the request is based, factual evidence, and identifying data (e.g.: the name of court with subject-matter and territorial jurisdiction, the name of the involved parties and their legal representatives, case registration information, and the signature of the applicant). Furthermore, it is sometimes necessary to include information on the value of the dispute and the legal interests of the lawsuit. The lawsuit may also contain **optional submissions**, such as process requests and legal argumentation.

14 Official Gazette of the Republic of Macedonia, no. 33/98

Types of lawsuits

Lawsuits are classified according to the criteria of legal protection sought in each case.

Declaratory lawsuits call for determining the existence of certain rights or legal relationships (e.g.: the veracity of a certain document).

Constitutive lawsuits seek to establish, alter, or terminate legal relationships.

Condemnatory lawsuits seek to punish the defendant.

Lawsuits involving indemnity are considered condemnatory lawsuits.

Types of decisions

Court decisions come in two forms: **verdicts and rulings**. The court issues a **verdict** on the basis of a lawsuit request, while **rulings** are delivered for process issues that do not apply directly to the suit but are presented during the course of the procedure and the decision-making process.

In accordance with the legal protection requested in the lawsuit, the court may issue a **declaratory, constitutive, or condemnatory verdict**. The court is not required to rule on every point of the lawsuit; it may issue a **partial, supplementary, or interim verdict**.

The court may decide on the justification of a lawsuit request based on the pronounced or concluding process acts of the parties regarding the requests stated in the procedure. Therefore, a court may issue a verdict if one of the parties refuses to respond to the lawsuit, does not appear before court, cancels the lawsuit request, or confesses to the allegations stated in the suit. The court may issue a verdict without a hearing in cases when the defendant verifies determinative facts; a defendant's challenge of the lawsuit request has no bearing on the court's ability to issue a verdict without a hearing. The president of the court council may issue a verdict without a hearing in the event that there are no other obstacles to issuing the verdict.

Regular and extraordinary legal remedies

After the conclusion of the initial trial and the submission of a court decision, the procedure may be submitted to a higher court or returned to the court of first instance if the parties submit appropriate legal remedies.

Parties may use all regular and extraordinary legal remedies provided with the rules for regular litigation procedure to challenge a decision issued by the basic courts.

An **appeal** is a regular legal remedy that may be filed by one or more of the parties in response to an initial court decision that has not yet taken effect. A party may

request an appeal within 15 days of receiving a copy of the verdict. The appeal is filed with the court that issued the initial decision and is reviewed by an appellate court, which issues a decision on the justification of the appeal. The appeal delays the implementation of the initial court decision. An appeal may be filed for the following **reasons**: an essential violation of the principles of litigation procedure, the inaccurate or incomplete interpretation of the facts of the case, or the wrongful application of a relevant law. The appeals process is described in detail in the Law on Civil Procedure.

Revision is an extraordinary remedy that may be applied to the decision of an appeals court. In order to seek revision, the party must already have appealed the initial court decision. Revision may be sought due to an essential violation of the principles of litigation procedure or the wrongful application of relevant laws. A request for revision must be filed within 30 days of the receipt of the verdict. The request for revision is filed with the initial trial court that further on though second degree submits the request along with the other documents from the case to the Supreme Court of the Republic of Macedonia. The Supreme Court then issues a decision on the merit of the request. The Law on Civil Procedure regulates the actions of relevant authoritative bodies in the revision procedure and enumerates the types of decisions that may be adopted. The revision doesn't nullify the execution of a court decision that has already taken effect.

Another extraordinary remedy is the **renewal of a procedure**, which may be sought in response to court decisions that have already taken effect. Such requests may be filed regardless of whether the decision took effect at initial trial level or at the appellate level. A request to renew a procedure is filed with the initial trial court, which is obligated to consider the request unless the stated reasons for renewal are connected to a procedure that occurred in a higher court. The renewal of a procedure may be requested due to the following reasons: an essential violation of the principles of litigation procedure, the occurrence of criminal acts, and the introduction of new facts and evidence. The renewal of a procedure may be initiated within 30 days of the discovery of reason(s) for renewal, and with certain exceptions, within five years of the date that the court decision took effect.

Request for renewal may also be submitted when the European Court of Human Rights determines violation of human rights or fundamental freedoms enumerated in the European Convention on Human Rights (and its Protocols) that Macedonia has ratified.

The request may be filed within 30 days from the date when the verdict of the European Court of Human Rights became effective. The request for renewal is submitted to the court that issued the initial verdict that violated the human rights or fundamental freedoms.

In this case the same rules for renewal of a procedure apply.

In case of a renewal of a procedure, the courts in Macedonia must respect the legal

opinions stated in the final verdict of the European Court.

3. Criminal Procedure

Regulations in the Criminal Code¹⁵ regarding the presumption of innocence and the sentencing are based on a legal procedure that is defined explicitly in the **Law on Criminal Procedure**.¹⁶

The criminal procedure is a series of actions that are undertaken in order to identify the perpetrator of the criminal act, collect evidence, and secure a conviction. Actions undertaken by the defendant's legal representative(s) until the final court verdict is reached and sentencing are also included in the procedure.

In criminal cases, courts issue rulings within the framework of their subject-matter jurisdiction as determined by law.

Territorial jurisdiction is held by the court presiding over the district where a crime was committed or attempted. A private lawsuit may be filed with a court whose jurisdiction includes the address of the defendant's permanent or current residence.

The course of a criminal procedure is regulated in detail with the Law on Criminal Procedure¹⁷.

Exercising one's right to an appeal a court verdict is the last phase of the criminal procedure. This phase is also known as the **procedure of judicial remedies**.

Authorized persons may appeal the initial verdict within 15 days of receiving a certified copy of the verdict. An appeal that is submitted by an authorized person within this window postpones the execution of the verdict.

The law stipulates what information must be included in the appeal, and it states that verdicts may be appealed on the following grounds: a substantial violation of the provisions of the criminal procedure; a violation of the Criminal Code; an incorrect or incomplete understanding of the facts of the case; the filing of a decision for criminal sanctions, seizure of property, liability for the expense of conducting the criminal procedure, or lawful property requests; and the public announcement of the verdict in the media.

The appeal is submitted to the court that issued the initial verdict. The appellant must submit a sufficient number of copies for the court, the opposite party, and the

15 Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

16 Official Gazette of the Republic of Macedonia, no. 15/97, 44/02, 74/04, 83/08, 67/09

17 Official Gazette of the Republic of Macedonia, no. 15/97, 44/02, 74/04, 83/08, 67/09

counsel. Appeals that are not filed on time or that are not permitted under law shall be rejected by the council president of the court of first instance.

The initial trial court must submit a copy of the appeal to the opposite party, which then has eight days to file a reply to the appeal with the court. The court of first instance is responsible for submitting the appeal, the reply of the opposite party, and all relevant records to appellate court.

The appellate court may issue a decision at a session of the court council or on the basis of a hearing. The appellate court decides whether to hold a hearing on the appeal.

The court examines the contested verdict and must determine whether the appeal violates the principles of the Law on Criminal Procedure or the regulations of the Criminal Code¹⁸.

The court of second instance may issue the following decisions after examining an appeal:

- dismissal of the appeal as untimely and incorrect;
- dismissal of the appeal as incorrect and conform the verdict of the initial trial court
- repeal of the initial court decision and resubmission of the case to the court of first instance for reconsideration
- alteration of the lower court's verdict

The verdict of the appeals court may be challenged under the following circumstances:

- the appellate court has sentenced a defendant to life imprisonment or has confirmed the verdict of a lower court to sentence the dependent to life in prison
- the appellate court has interpreted the facts of the case in a manner that is different from the interpretation of the initial trial court and has based its verdict on this new interpretation
- the appellate court has overturned the verdict of a first degree court to clear the defendant of charges and has found the defendant guilty.

The court of third instance may issue a decision on the appeal at a session of its court council. The decision must be issued in accordance with the regulations governing the appeals procedure at the second level. No hearings may be held before the court of third instance.

The verdict takes effect once further possibilities for appeal are exhausted. After this point, only **extraordinary legal remedies** may be applied.

¹⁸ Official Gazette of the Republic of Macedonia, no. 37/96, 80/99, 48/01, 04/02, 16/02, 43/03, 19/04, 40/04, 81/05, 50/06, 60/06, 73/06, 7/08, 139/08, 114/09

Renewal of the criminal procedure

A criminal procedure that is closed with a legally valid decision or verdict may be renewed at the request of an authorized person only under certain conditions outlined in the Law on Criminal Procedure¹⁹.

A criminal procedure that results in the issuing of a legally valid verdict may be renewed on behalf of the defendant in cases when:

- it is proven that the verdict was based on the false testimony of an eyewitness, expert witness, or interpreter
- it is proven that the verdict was influenced by the criminal activity of a judge, lay judge, or investigator
- a verdict to clear the defendant of charges was delivered after the prosecutor dropped the case, and it is proven that the prosecutor's actions were based on criminal activity or the abuse of office
- new information or evidence is submitted that would clear the defendant of guilt or subject him to milder punishment under the Criminal Code
- a person is convicted several times for the same crime, or several persons are convicted of a crime that only could have been committed by one person
- the conviction is based on several related charges, and the defendant is cleared of wrongdoing under one of the charges
- the European Court of Human Rights determines that the defendant's human rights or freedoms were violated.

A request to renew a criminal procedure may be submitted by the involved parties or their counsel. A public prosecutor may also renew a criminal procedure if the deceased defendant submitted an appeal before his death or if his spouse or close family member requests an appeal.

A request for the renewal of a criminal procedure may be also submitted after the convicted person serves out his punishment without regard to obsolescence, amnesty, or plea.

Extraordinary mitigation of a sentence

The mitigation of a legally valid sentence is allowed if relevant circumstances that were not present during the consideration of a verdict appear or if the court was unaware of circumstances that existed during their deliberation of the verdict; had the circumstances been known, they would have led to the imposition of a more lenient sentence on the defendant.

A request for the extraordinary mitigation of the sentence may be submitted by a public prosecutor if the procedure was conducted at his request. The defendant and his council, spouse and close relatives may also request this remedy.

¹⁹ Official Gazette of the Republic of Macedonia, no. 15/97, 44/02, 74/04, 83/08, 67/09

Request for the protection of lawfulness

In the event that the Criminal Code or a international agreement that has been ratified in accordance with the Constitution of the Republic of Macedonia²⁰ has been violated during the criminal procedure, the Public Prosecutor's Office may also initiate a request for the protection of lawfulness.

Request for the extraordinary review of an effective verdict

A defendant who is sentenced to imprisonment or juvenile detention may request the extraordinary review of a verdict if there is reason to believe the Criminal Code was violated during the criminal procedure.

The request for extraordinary review of a verdict may be submitted within 30 days of the receipt of the verdict.

A defendant who did not appeal the verdict in his case may not submit such a request unless an appeals court ruled to strengthen his sentence (e.g.: the appeals court sends the defendant to a juvenile detention facility instead of imposing the original sentence of re-education). Requests for the extraordinary review of a verdict may not be submitted in response to decisions of the Supreme Court.

Such request may be submitted by the defendant or his council. The cases in which this request may be submitted are outlined in the Law on Criminal Procedure²¹.

The Law on Criminal Procedure²² also regulates the rules for shortened procedure, alternative mechanisms and procedure against legal entities. The procedure against minors is regulated with the Juvenile Justice Law.²³

4. Executive Procedure

The **Law on Executive Action**²⁴ determines the rules according to which authorities may carry out court orders or decisions. The law also provides stipulations for conducting forced monetary retribution.

Court orders may only be executed upon the issuance of a notarized document from the proper authorities. Administrative decisions are enforced in accordance with regulations established under this law.

20 Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

21 Official Gazette of the Republic of Macedonia, no. 15/97, 44/02, 74/04, 83/08, 67/09

22 Official Gazette of the Republic of Macedonia, no. 15/97, 44/02, 74/04, 83/08, 67/09

23 Official Gazette of the Republic of Macedonia, no. 87/07, 103/08, 161/08

24 Official Gazette of the Republic of Macedonia, no. 35/05, 50/06, 129/06, 8/08, 83/09

Stipulations set forth by the Law on Civil Procedure²⁵ apply to the enforcement of administrative decisions, unless they are otherwise prohibited under the Law on Executive Action or any other law.

Documents that carry the power of enforcement include executive court orders and settlements, executive decisions requiring monetary compensation as a result of an administrative procedure, notarized executive documents; and any documents that are enforceable under other laws.

8.2 Alternative Mechanisms to Protect/ Enforce Rights and Responsibilities

1. Constitutional Court of the Republic of Macedonia

The Constitutional Court of the Republic of Macedonia is established on the basis of the Constitution of the Republic of Macedonia²⁶.

In accordance with Article 50 of the Constitution, every citizen has the right to seek protection of the freedoms and rights that are guaranteed under the Constitution. For this purpose, citizens may appeal to regular courts or the Constitutional Court under a procedure based on the principles of priority and urgency.

According to Article 108 of the Constitution, the Constitutional Court is the state body that is responsible for protecting constitutional stipulations and lawfulness.

The jurisdiction of the Constitutional Court is stipulated in Article 110 of the Constitution. Specifically:

- the constitutionality of laws
- the constitutionality of other acts and collective agreements, and their compliance with other laws
- protects citizens' right to the freedom of belief, consciousness, opinion, public expression, political association, the prevention of the discrimination against citizens on the grounds of gender, race, religion, nationality, or political affiliation
- resolves the conflict of jurisdiction among the holders of legislative, executive, and judicial powers
- resolves the conflict jurisdiction between the local and state authorities
- regulates the responsibilities of the nation's president
- the constitutionality of programs and statutes of political parties and citizens' associations
- other issues, as stipulated by the Constitution.

²⁵ Official Gazette of the Republic of Macedonia, no. 79/05, 110/08, 83/09

²⁶ Official Gazette of the Republic of Macedonia, no. 52/91, 1/92, 31/98, 91/01, 84/03, 107/05, 3/09

The mode of operation of the Constitutional Court and standards of court procedure are defined in the Book of Rules of the Constitutional Court. The Constitutional Court has the authority to make decisions, rulings and conclusions.

The decisions made by the Constitutional Court are effective immediately after their issuance in the Official Gazette of the Republic of Macedonia.

The execution of executive decisions issued under a law or bylaw that was repealed by the Constitutional Court will not be permitted. Ongoing executive procedures will be terminated.

The work of the Constitutional Court is public.

The authorities that issued a document repealed by the Constitutional Court are responsible for the execution of court's decisions and rulings regarding that document.

Practices from the Constitutional Court

Case study 1

After a citizen filed an initiative with the Constitutional Court, the court abolished the a section of the Law on Health Insurance that limited compensation for maternity leave to insured persons who had worked at their present employer for at least six months prior to taking leave. The court ruled that the requirement was unconstitutional because it violated the constitutional principle of equality. In issuing the ruling, the court considered the fact that citizens must pay for health insurance and found that a citizen's health coverage may not be limited as long as the proper payments for insurance have been made. The overturned regulation also stated that insured persons may only receive salary compensation if they have had insurance for at least six months; this principle refers to all types of compensation and is not limited to maternity leave. The court received a separate initiative to overturn this stipulation, but it decided not to initiate a procedure in this case because it concluded that the regulation did not violate the right to equality.

Case study 2

The court issued a decision to overturn a policy of the Health Insurance Fund that restricted coverage of reproductive and hormone medications included in the Positive List of Medications for women over 40 years of age. The court declared the policy unconstitutional because it restricted citizens' constitutional right to healthcare protection. The policy also violated the Law on Health Insurance²⁷ and sections of the Law on Genetically Modified Organisms²⁸ and the Law on Biomedically Assisted Reproduction²⁹.

27 Official Gazette of the Republic of Macedonia, no. 25/00, 34/00, 96/00, 50/01, 11/02, 31/03, 84/05, 37/06, 18/07, 36/07, 82/08, 98/08, 6/09, 67/09

28 Official Gazette of the Republic of Macedonia, no. 35/08

29 Official Gazette of the Republic of Macedonia, no. 37/08

2. The Office of the Ombudsperson

The Ombudsperson is charged with protecting the constitutional and legal rights of Macedonian citizens and other persons in cases when their rights are violated by certain laws or the actions or negligence of state bodies and public institutions. The Ombudsperson takes measures for protection of the rules for nondiscrimination, and for proper and rightful representation of minorities in the public administration and other bodies.

A citizen may file a petition with the Ombudsperson if he believes that his rights have been violated. The law does not stipulate the form of the submission, but it states that the submission must contain the following information: the name and signature of the person submitting the petition, a description of the circumstances, facts, and evidence indicating a violation of the citizen's rights, the state body or public organization that is responsible for the violation, and other legal measures that have been taken prior to filing the petition with the Ombudsperson. The submission may be filed in written or verbal form free of charge at the Ombudsperson's office.

Under certain conditions and upon its own finding, the Ombudsperson may initiate a procedure in response to the allegations contained in the submission.

If the Ombudsperson concludes that a citizen's rights have been violated, he may take the following courses of action:

- issue recommendations, suggestions, opinions, and possible methods of correcting the violation
- recommend the renewal of an already completed procedure according to law
- initiate a disciplinary procedure against the official responsible for the violation
- file a claim with a public prosecutor in order to initiate a criminal procedure against those accused of wrongdoing

Conditions governing the mandate and authority of the Ombudsperson are established by the Law on the Ombudsperson.³⁰

Practices from the Office of the Ombudsperson

Case study 1

Some healthcare facilities had no policies to treat citizens free of charge for certain illnesses whose treatment was sponsored by the government. Following the intervention of the Ombudsperson, healthcare facilities stopped demanding that patients pay for the treatment of these illnesses.

(Source: Office of the Ombudsperson)

³⁰ Official Gazette of the Republic of Macedonia, no. 60/03, 114/09

Case study 2

Patients' right to basic healthcare services covered by the Health Insurance Fund were limited to services performed by facilities that had concluded an agreement with the fund. Considering that previous legislation had not allowed for this situation, the Ombudsperson and the Supreme Court found the practice unlawful. Specifically, they found that the rule violated patients' right to acquire the best available healthcare. The rule also violated citizens' constitutional right to healthcare and citizens' constitutional responsibility to take care of their health and the health of others. After the intervention of the Ombudsperson and verdicts reached by the Supreme Court, the Health Insurance Fund changed its policies to recognize patients' rights. However, after a certain period, both the fund and the Supreme Court changed their stance on the issue: the fund did not accept to cover or reimburse payments from patients at healthcare facilities with which it had not concluded a contract, and the Supreme Court denied the patients' legal motions protesting this practice. The Ombudsperson maintained its position on the issue and continued to intervene when patients' rights were violated by this practice. The Ombudsperson filed a proposal with the Constitutional Court to assess the constitutionality of the fund's actions, which led to a decision by the court (no. 45/2006) to abolish the practice in question. However, this practice still exists in certain facilities, and the Ombudsperson continues to intervene on behalf of patients whose rights are violated.

(Source: Office of the Ombudsperson)

Case study 3

A citizen filed a complaint alleging that the Health Insurance Fund violated his rights by failing to insure the patient and reporting him as unemployed in the Employment Agency. According to the assessment of the Ombudsperson, the actions of the fund were unlawful and violated the citizen's constitutional civil rights. Although the citizen had previously paid healthcare insurance contributions on a regular basis, the Ombudsperson determined that he had outstanding insurance bills and had not received any health insurance coupons. In addition, the citizen was informed by the Regional Chamber of Artisans that his artisan's license was terminated and his shop was removed from the Central Registry. The Ombudsperson found that the citizen had violated the responsibility to pay for health insurance and that the Health Insurance Fund had the right to seek compensation through an executive court procedure.

The Ombudsperson suggested the citizen to register himself as unemployed with the Employment Agency and that the Agency should start paying health insurance contributions towards. The suggestion was accepted.

(Source: Office of the Ombudsperson, case no. 1470/07)

Case study 4

The Health Insurance Fund violated patients' rights by failing to issue health insurance coupons. The Ombudsperson reviewed the relevant documents and concluded that patients' rights were been violated despite the fact that they were paying their insurance bills on a regular basis. The fund's failure to register patients as insured limited their access to free healthcare services, and the patients were forced to pay for healthcare services.

The Law on Health Insurance states that the right to compulsory health insurance may be exercised only by persons who have subscribed to and paid for healthcare coverage. According to the law, an insured person may exercise his right to healthcare services by presenting his healthcare card and providing evidence that he has paid his health insurance contribution (insurance coupons or so called blue coupons).

In this case, the Ombudsperson found that patients' rights were violated, and it requested that the Health Insurance Fund register the citizen as an insured person and issue him insurance coupons. The patient was obliged to pay his outstanding contributions to the Health Insurance Fund according to law, the fund accepted the Ombudsperson's suggestion and the citizen was able to exercise his right to health insurance.

(Source: Office of the Ombudsperson, case no. 470/05; Annual Report of the Ombudsperson, 2005)

Citizens are still experiencing similar problems with the fund in spite of legal regulations. The fund's response to situations similar to the one described above is changing each time new staff and management is hired (2005–2007).

Case study 5

A citizen requested legal protection from the Ombudsperson after his wife was physically abused by a medical technician during her hospitalization.

The Ombudsperson conducted a complete investigation of the case. After determining the facts of the case, the Ombudsperson filed a legal motion against the medical technician and called on healthcare providers to respect the dignity of their patients.

Following the actions of the Ombudsperson, disciplinary measures were filed against the medical technician. *(Source: Office of the Ombudsperson, case no.1828/07)*

Case study 6

The Gynecology and Obstetrics Clinic refused to issue a receipt for medical device purchased by the patient. As a result, the patient was unable to receive reimbursement from the Health Insurance Fund, even though the device was covered under her basic health insurance package.

The Ombudsperson determined that the applicant underwent a surgical intervention and that the medical device was implanted in her body. It was also established that the clinic did not have the medical device in its inventory and that the patient bought the device on her own. After the patient was discharged from the hospital, she requested a receipt for the device, but her doctor refused to issue the document.

The Ombudsperson concluded that the patient's rights were violated in this case, and it appealed to the healthcare facility to issue the receipt so that the patient could be reimbursed for the cost of the medical device. The clinic issued the receipt, and Health Insurance Fund reimbursed the cost of the device.

(Source: Office of the Ombudsperson, case no. 2135/07)

Case study 7

In 2000–2001, after a number of employers were found to have made irregular contributions to the health insurance accounts of their employees, the Law on Health Insurance was changed so that employer contributions to healthcare accounts were discounted by up to 70%. Nonetheless, the Ombudsperson received several complaints that employer contributions to the healthcare accounts of workers who had taken sick leave amounted only to 30% of their salary. The Ombudsperson determined that such actions violated citizens' rights, labor law regulations, and patients' rights, as employees were saddled with additional expenses for treatment.

The Supreme Court has affirmed the decision of the Ombudsperson in this matter.
(Source: *Office of the Ombudsperson*)

Case study 8

Patients requested the protection of their rights for receiving medical treatment abroad and the Health Insurance Fund forced them to sign an agreement under which the fund would reimburse only 20% of the cost of their treatment. However, the patients were entitled to receive reimbursement for 80% of the total cost of medical treatment abroad. By forcing patients to sign the aforementioned agreements, the Health Insurance Fund violated legal regulations pertaining to patients' rights. The Ombudsperson found that patients who refused to sign the agreements were denied clearance to receive medical care abroad. The Ombudsperson determined that this practice constituted a drastic violation of patient's rights, and it appealed to the Health Insurance Fund to stop the practice. After the Ombudsperson repeatedly intervened to protect patients' rights and applied pressure on the Health Insurance Fund, the agreements were revoked and the fund agreed to comply with the applicable laws.

(Source: *Office of the Ombudsperson, case no. 195/01 and other cases; Annual Report of the Ombudsperson, 2001 and 2002*)

Case study 9

An insured patient who paid contributions to his insurance account was treated as a non-insured patient at a clinic. The clinic charged the patient for the entire cost of treatment, even though insured patients cannot be charged more than 20% of the total amount of the cost for healthcare services. The patient was reimbursed after the Ombudsperson intervened on his behalf.

(Source: *Office of the Ombudsperson*)

Case study 10

In 2001, the rights of drug users were violated when the country's only methadone therapy center placed patients on waiting lists for treatment, thus limiting their ability to overcome addiction. Based on research conducted in 2007 by the Office of the Ombudsperson, several methadone therapy centers have opened in recent years, but patients from Skopje are still being placed on waiting lists for treatment.

(Source: *Annual Report of the Ombudsperson, 2007*)

Case study 11

A patient asked the Ombudsperson to protect her right to salary compensation during maternity leave. The Health Insurance Fund refused to recognize this right because the patient's health insurance had been in effect for fewer than six months, even though this regulation had been abolished previously by the Constitutional Court. In addition, the Supreme Court ordered the Health Insurance Fund to recognize patients' right to compensation during maternity leave despite the fact that the patient's health insurance was in effect for fewer than six months before she took leave. The fund refused to accept the Ombudsperson's recommendation, the verdict of the Supreme Court, and a decision of the Constitutional Court; instead, the fund denied the patient's second request for compensation. After the Ombudsperson and Supreme Court both issued new rulings on the matter two years after the patient took maternity leave, at which time the Health Insurance Fund acknowledged the request. The Ombudsperson found that the fund failed to respect patient's rights, court orders, and recommendations of the Ombudsperson. Furthermore, the Ombudsperson found that the Health Insurance Fund violated the rights of newborns who were denied special care due to the lack of compensation for maternity leave, which is required under the Constitution.

(Source: Office of the Ombudsperson, case no. 95/02; Annual Report of the Ombudsperson, 2004)

Case study 12

At the recommendation of the Ombudsperson, a doctor was suspended from work after he sexual harassed a patient.

(Source: Annual Report of the Ombudsperson, 2004)

Case study 13

In 2006–2007, the Ombudsperson received several complaints about unlawful additional charges for healthcare services in certain facilities. The patients were charged for services that should have been provided free of charge or at a discount under the law. The patients were told that they were required to pay for the procedures because the institution did not have the finances necessary to cover their treatment. After the intervention of the Ombudsperson, the healthcare facilities issued new regulations to stop soliciting payments from patients for these procedures.

(Source: Annual Report of the Ombudsperson, 2006 and 2007)

3. Supervision over the Application of Regulations for the Protection of Patients' Rights

Supervision of the application of legal regulations is an effective instrument for the protection of patients' rights. Principles of supervision are included in every regulation. For example, the **Law on Sanitary and Health Inspection**³¹ determines the competence and organization of sanitary and health inspection, the appointment of

31 Official Gazette of the Republic of Macedonia, no. 71/06, 139/08

sanitary and health inspectors, the authority and procedure for conducting inspections. This body supervises the application of regulations that determine patients' rights.

Sanitary and health inspection includes supervision of the implementation of laws and other regulations involving healthcare, health insurance, and healthcare records.

Sanitary and health inspectors may probe facilities, objects, areas, equipment, and activities that may have a harmful effect on people's health. Inspectors may also investigate the health status of other persons.

Sanitary and health inspections are carried out by the State Sanitary and Health Inspectorate, which is a unit of the Ministry of Health.

In the fields of healthcare and health insurance, the State Sanitary and Health Inspectorate, among others, supervises the following activities:

- the exercise and protection of patients' rights and the right to health insurance
- healthcare services, in cases when it has received authorization from the relevant state body
- the maintenance of healthcare and sanitary standards for facilities, equipment, and staff involved in the provision of healthcare, in accordance with regulations on healthcare
- work schedules at the healthcare facilities
- the performance of physicals and preventive medical examinations
- maintaining records in the field of healthcare
- the general acts of healthcare facilities, including the organization and provision of medical care, the usage and maintenance of medical equipment, the admission of patients through primary and specialist physicians and ambulances, the method for conducting supervision over the work of healthcare providers and support staff within the facility, and the type and usage of working garments.

In accordance with the Law on Healthcare³², if sanitary and health inspectors determine that they need to intervene in a situation in order to protect citizens' safety, they may initiate a procedure with the Ministry of Health to exert expert supervision of the healthcare facility.

While conducting inspections, health inspectors are authorized to examine all workspaces and auxiliary premises (e.g.: facilities, documentation and registration, equipment); they also may obtain statements from employees and witnesses, collect samples for analysis, and use the services of legal experts when necessary.

Inspectors are authorized to:

- prohibit the use of workspaces, public premises, devices, and equipment until sanitary and health safety issues are resolved

³² Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

- prohibit the use of public premises that were established without the consent or authorization of the relevant supervisory body
- demand the resolution of errors and irregularities
- demand the implementation of measures to contain and eradicate communicable diseases
- demand the removal of employees whose health condition endangers the life and health of others
- prohibit public gatherings of citizens if there is a danger of spreading communicable diseases at such meetings
- prohibit certain activities that increase the risk of spreading of communicable diseases
- order healthcare facilities and other institutions to bring their disinfection and sterilization mechanisms into compliance with safety standards
- close public swimming pools and spas if necessary safety measures have not been implemented
- order the revision of technological processes that lead to the production of unsafe consumer products
- prohibit the use of equipment that discharges harmful substances or causes harm to the life and health of citizens
- prohibit the provision of healthcare services that violate healthcare protection regulations
- undertake additional measures in accordance with law and other regulations.

The inspector is responsible for safekeeping of confidential information acquired during the course of the health inspection.

If the inspector finds that the subject of the inspection has failed to comply with relevant laws, regulations, and other acts in the field of health safety, he may order the subject to undertake ameliorative measures within a certain period. The inspector is responsible for sending a copy of the report to the subject of the inspection.

If a criminal or misdemeanor violation is uncovered during the course of the inspection, the health inspector is obligated to file an urgent request to initiate a procedure against the subject.

According to Article 31 of the Law on Sanitary and Health Inspection³³ the following fines are applicable for failure to comply with the law or inspector's orders: 1.000 – 5.000 Euros for the legal entity, 500 – 1.500 Euros for the representative of the legal entity.

Law on Healthcare

The Law on Healthcare³⁴ grants the health inspectorate the authority to supervise

³³ Official Gazette of the Republic of Macedonia, no. 71/06, 139/08

³⁴ Official Gazette of the Republic of Macedonia, no. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07, 77/08, 67/09

the implementation of laws and regulations regarding healthcare, as well as the general acts of healthcare facilities.

The law authorizes the Ministry of Health to supervise the legality of work performed at healthcare facilities. Healthcare facilities must organize internal supervision of the work of healthcare providers through a general act.

According to the Law on Healthcare the following fines are applicable: 65 Euros for misdemeanors under Article 191, 1/5 – 15 salaries, as well as temporary or permanent suspension of the license for work.

Law on the Protection of Patients' Rights

The State Sanitary and Health Inspectorate is responsible for supervising the enforcement of the **Law on the Protection of Patients' Rights**³⁵. The inspectorate appoints an inspector for each unit of the local self-government. The inspector must post his working hours on the door of his office for the benefit of patients who seek to protect their rights.

When supervising the enforcement of this law, the State Sanitary and Health Inspectorate has the right and responsibility to prohibit *healthcare facilities and providers* from:

- undertaking any actions that involve the human genome without providing counseling and for any reason other than the prevention, diagnosis, or treatment of a medical condition
- discrimination against patients
- censoring or reading the personal correspondence of patients, or monitoring patients' communications with people outside the healthcare facility
- engaging patients unless such an engagement is part of the patient's rehabilitation and re-socialization
- undertaking medical interventions without the prior consent of the patient or his parent or legal guardian, except in cases when such medical interventions are necessary to prevent death or permanent disability
- intruding or interfering in a patient's private life or family affairs unless the patient has given his consent or the interference is necessary for performing a medical intervention.

When performing supervisory activities, the State Sanitary and Health Inspectorate has the right and responsibility to order a *patient admitted to a healthcare facility* to:

- provide accurate and comprehensive information about his health status
- assist healthcare providers involved in his care, treatment, and rehabilitation
- act upon the advice of healthcare providers on matters regarding his care, treatment and rehabilitation

35 Official Gazette of the Republic of Macedonia, no. 82/08, 12/09

- respect the code of conduct of the healthcare facility
- accept any engagement that is a component of his rehabilitation and re-socialization
- respect the professionalism and human dignity of healthcare providers.

When performing supervisory activities, the State Sanitary and Health Inspectorate has the right and responsibility to order *healthcare facilities* to:

- provide for the personal safety of the patient during his admission to the facility
- inform the patient of his healthcare and health insurance rights and the procedure for exercising these rights
- provide all necessary information to the patient during all stages of healthcare
- provide the patient with all information stipulated by the Law on the Protection of Patients' Rights
- inform the patient of the names, education level, and residency of every healthcare provider involved in the patient's care
- provide all necessary information to the Social Work Center
- give the patient access to his own medical file, clarify data contained in his medical file, and provide copies of medical documents or data contained in his medical record
- allow the persons referred to in Article 23 of the law to exercise the rights stipulated in the article
- maintain the confidentiality of personal and medical data, even upon a patient's death, in compliance with regulations on the protection of personal data
- provide information about a patient's admission to a healthcare facility and his health status
- set up visiting hours during the patient's admission to the hospital or prohibit visits from certain persons, in accordance with the internal guidelines of the healthcare facility
- allow the patient to send and receive mail and make telephone calls at his own expense
- allow the patient to listen to the radio and watch television, insofar as the healthcare facility is able to provide the necessary equipment
- allow the patient to participate in religious activities that are offered by the healthcare facility
- permit the patient to make use of weekend leave time in compliance with his health status
- alert, when necessary, the relevant persons and agencies about the patient's decision to leave the healthcare facility without prior notice
- inform the patient's parent or legal guardian and the Social Work Center about the patient's ability to leave the healthcare facility at will and without prior notice, if the patient is a minor or is otherwise unable to make decisions about his own healthcare
- ensure the privacy of medical check-ups, particularly when providing personal care
- ensure that medical interventions are performed only in the presence of those who are required to carry out the operation, unless the patient has agreed to or has requested otherwise

- allow the patient to be admitted to a room separate from patients of the opposite sex
- allow underage patients to be accommodated in premises that are separated from adult patients
- allow the admitted patient to dispose of unwanted clothing, hygiene products, or other personal items
- inform the patient's parents, legal guardians, or other authorized persons about his admission
- assign a team of doctors for the patient's treatment and rehabilitation upon his admission to the healthcare facility
- ensure that the patient's team of doctors prepares a written, individualized program for treatment and rehabilitation that should anticipate regular follow-up appointments to ensure the stability of his health status
- release the patient immediately if the team of doctors finds that the patient's health status has improved to the degree that he may seek further treatment and care in the community
- upon discharge, inform the patient about his health status and provide advice on how to exercise his rights within the health insurance system at the community level
- inform the patient's parent, legal guardian, or other authorized person about his discharge from the healthcare facility
- establish internal control mechanisms
- undertake other measures stipulated by the Law on the Protection of Patients' Rights.

When performing supervisory activities, the State Sanitary and Health Inspectorate has the right and responsibility to order the healthcare providers who are performing medical intervention on a patient to:

- protect the patient's rights under this law
- perform his duties in compliance with medical ethics and for the purpose of protecting and improving the patient's health
- provide pertinent information to the patient
- provide a second professional opinion in certain cases and under special circumstances
- respect the patient's decision regarding information and medical interventions expressed in compliance with this law
- provide relevant information to the patient in cases when he is participating in a medical study
- maintain the confidentiality of data regarding the patient's health status, medical condition, diagnosis, prognosis, treatment, and other personal issues, even upon the patient's death, in accordance with professional confidentiality regulations and the Law on the Protection of Personal Data
- enclose a written statement in the patient's medical file
- record in the patient's medical file his decision to leave the healthcare facility without prior notice
- inform authorized persons of certain information when stipulated under other regulations (e.g.: inform the relevant authorities of the patient's decision to leave

- the facility without giving prior notice)
- establish humane relations with the patient.

According to Articles 63-65 of the Law on the Protection of Patients' Rights the following fines are applicable: 100 – 500 Euros for the patients, 1.000 – 2.000 Euros for the legal entity, 500 – 1000 Euros for the representative of the legal entity, and 200 – 700 Euros for the person performing the medical intervention.

Law on Mental Health

The State Sanitary and Health Inspectorate is responsible for supervising the enforcement of the Law on Mental Health.³⁶

When performing supervisory activities, the State Sanitary and Health Inspectorate has the following responsibilities:

- to prohibit the unpaid engagement of persons suffering from mental health illnesses if the healthcare facility profits from activities
- to allow admitted patients to be accommodated in rooms that are separate from patients of the opposite sex
- to allow admitted underage patients to be accommodated in rooms that are separate from adult patients
- to prohibit the admission of persons suffering from mental illnesses without their consent, except in certain cases established by this law
- to establish visiting hours during the patient's admission or prohibit visits from certain persons, in accordance with the internal guidelines of the healthcare facility
- to allow the patient to send and receive mail and make telephone calls at his own expense
- to allow the patient to listen to the radio and watch television, insofar as the healthcare facility is able to provide the necessary equipment
- to allow the admitted patient to dispose of unwanted clothing, hygiene products, or other personal items
- to allow the patient to participate in religious activities that are offered by the healthcare facility
- to allow the patient to make use of weekend leave time in compliance with his mental health status, unless the patient is in police custody
- to provide for the safety of the patient during his admission
- to provide all necessary information to the patient
- to order the healthcare facility to notify the patient's parent or legal guardian or other authorized person about his admission and the condition of his mental health (in cases when the patient was admitted without consent, the inspectorate may order the facility to notify the relevant court)
- to assign a team of doctors for the patient's treatment and rehabilitation upon his admission to the healthcare facility

³⁶ Official Gazette of the Republic of Macedonia, no. 71/06

- to ensure that the patient's team of doctors prepares a written, individualized program for treatment and rehabilitation that anticipates regular follow-up appointments to ensure the stability of his mental health status
- to release the patient immediately if the team of doctors finds that the patient's mental health status has improved to the degree that he may seek further treatment and care in the community
- upon discharge, to inform the patient's parent or legal guardian or other authorized person about the patient's mental health status and to provide advice on how to protect his rights within the health insurance system at the community level
- to inform the patient's parent, legal guardian, or other authorized person about his admission discharge from the healthcare facility
- to order the healthcare facility to provide legal advice to the patient suffering from mental illness on how to protect his rights
- to undertake other measures for protecting the rights of persons suffering from mental illnesses, as stipulated by this law.

According to the law on Mental Health the following fines are applicable: 2.500 – 5.000 Euros for the legal entity, 320 – 820 Euros for the representative of the legal entity. The same amount applies to the person stated in Article 40. In addition, there is a possibility for temporary suspension from work.

Law on Blood Safety

The State Sanitary and Health Inspectorate is responsible for supervising the application of the Law on Blood Safety³⁷.

When performing supervisory activities, the State Sanitary and Health Inspectorate is authorized to:

- order the establishment and implementation of procedures for maintenance of records and other regulations based on the Law on Blood Safety
- order the correction of irregularities and errors in accordance with the Law on Blood Safety and other health protection regulations
- order the collection and storage of appropriate data, and enable the protection of data collected through the mandatory analysis of donated blood
- prohibit the distribution and use of blood and blood components that have not been traced or that have not undergone mandatory analysis.

The healthcare facility is responsible for implementing the measures prescribed by the inspector. Appeals of health inspectors' decisions may be submitted to the Minister of Health.

According to Article 63 of the Law on Blood Safety, when performing supervisory activities, the State Sanitary and Health Inspectorate has the following rights and responsibilities:

37 Official Gazette of the Republic of Macedonia, no. 110/07

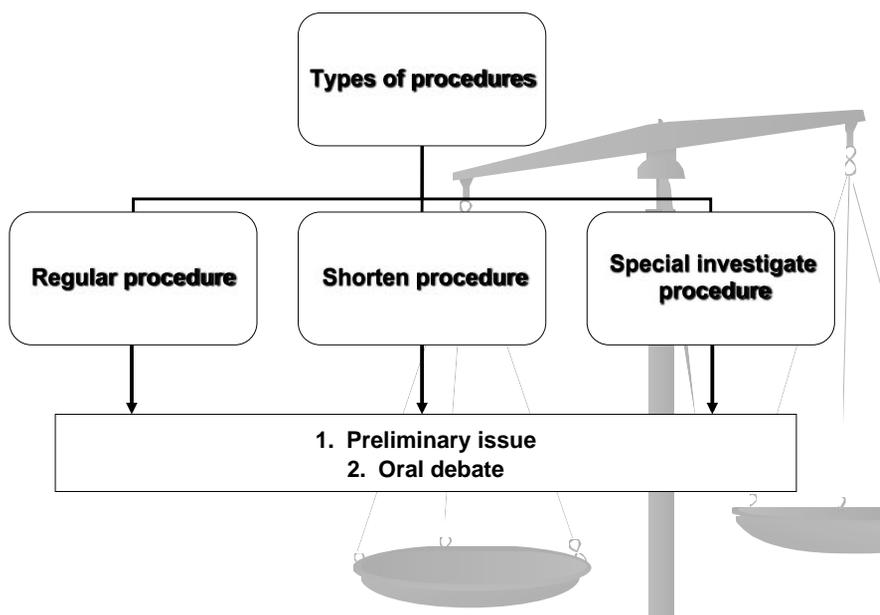
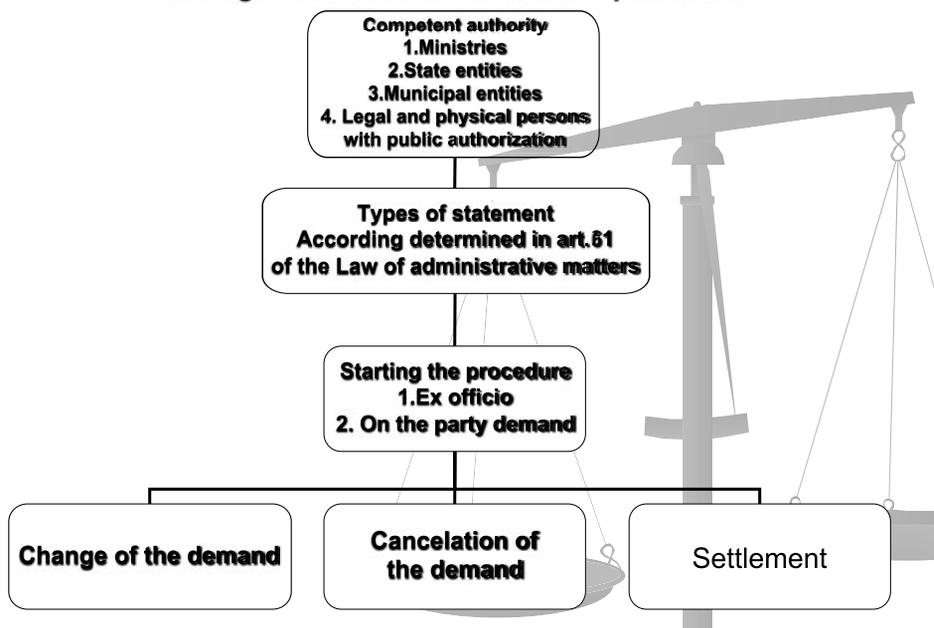
- to prohibit the persons suffering from certain communicable diseases from performing specific tasks that could endanger the health of others
- to limit the movement of persons who are suspected of suffering from certain communicable diseases
- to order disinfection, pest extermination, and other sanitary measures
- to order the quarantine and treatment of the persons suffering from certain communicable diseases
- to suspend the operations of workplaces that have not undergone mandatory health inspections
- to organize check-ups of persons who are suspected of suffering from communicable diseases
- to prohibit the gathering of persons in schools, cinemas, theaters, and other public spaces if there is a risk of an epidemic and if the government has given such an order
- to prohibit legal entities and persons from working if they have not complied with orders to conduct laboratory analysis, disinfection, or pest extermination
- to close down premises that foster the spread of communicable diseases
- to order the implementation of other general and special measures prescribed by the Law on Blood Safety.

According to this law the following fines are applicable: 7.000 – 12.000 Euros for the legal entity, 3.000 – 4.000 Euros for the representative of the legal entity, and 1.500 – 2.500 Euros for the healthcare provider.

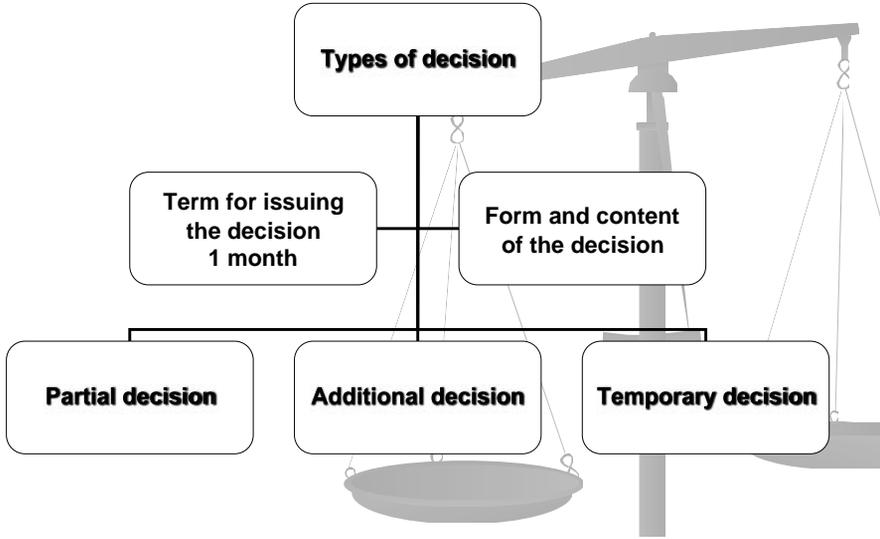
Annex 1

Administrative procedure

Management of the administrative procedure

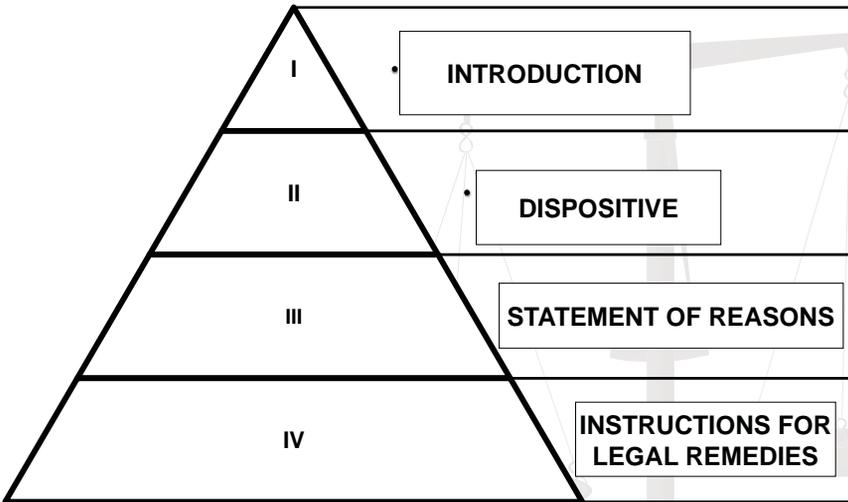


Based on facts determined in the procedure competent authority issues a decision



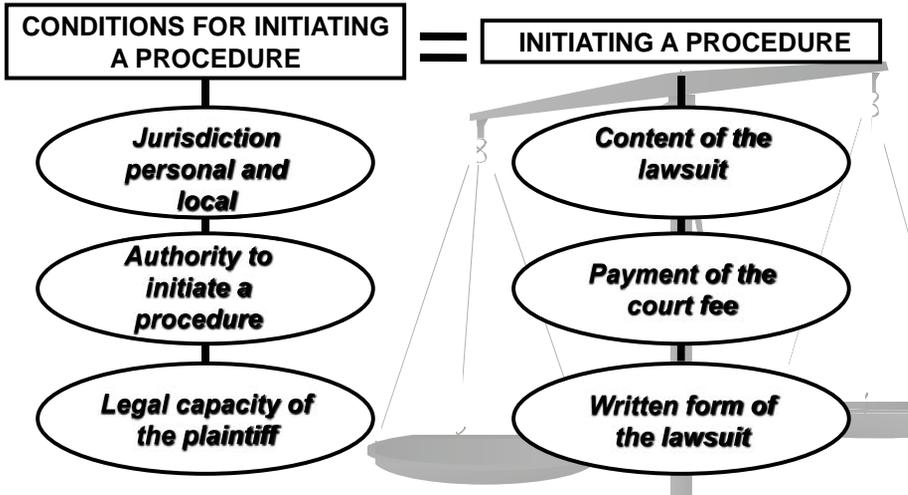
CONTENT AND STRUCTURE OF THE DECISION

Requirements are defined by Article 209 of the Law on Civil Procedure



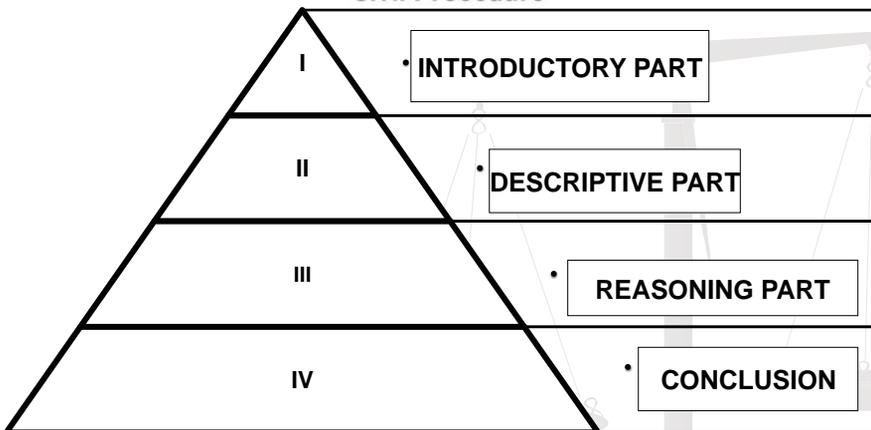
Civil procedure

INITIATING A PROCEDURE

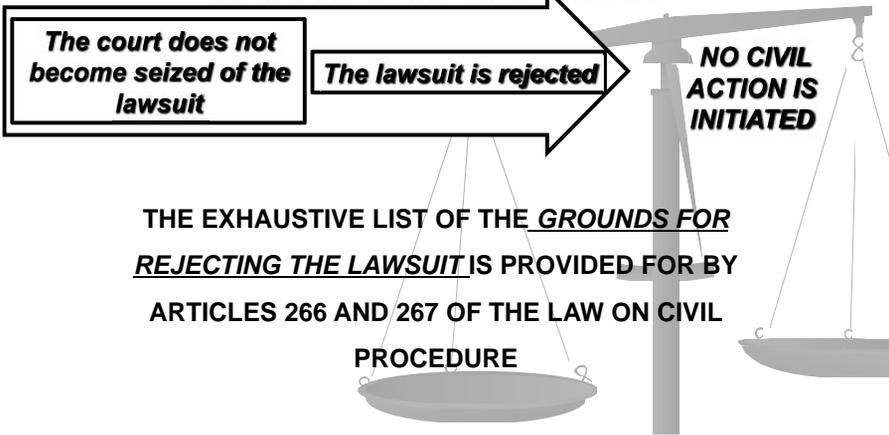


CONTENT AND STRUCTURE OF THE LAWSUIT

Requirements are defined by Articles 98 and 176 of the Law on Civil Procedure



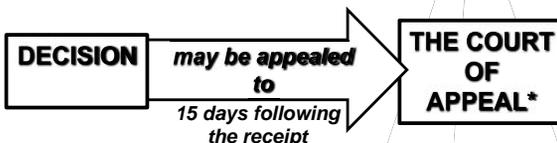
CONSEQUENCES OF NOT COMPLYING WITH THE PROCEDURE FOR INITIATING A LITIGATION PROCEDURE



REJECTION OF THE LAWSUIT

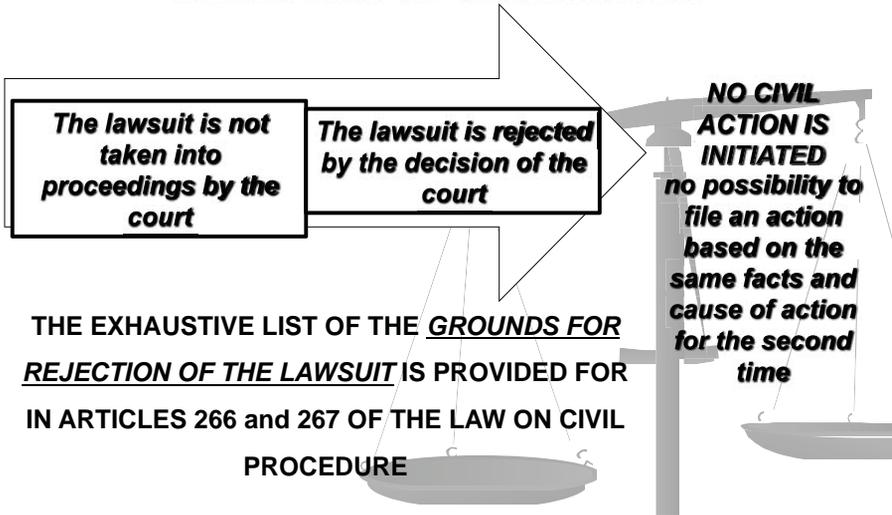


- **Lawsuit**
- Where deficiencies are remedied and the lawsuit is again filed according the instructions by the Court, it is considered accepted as from the date of the initial filing.

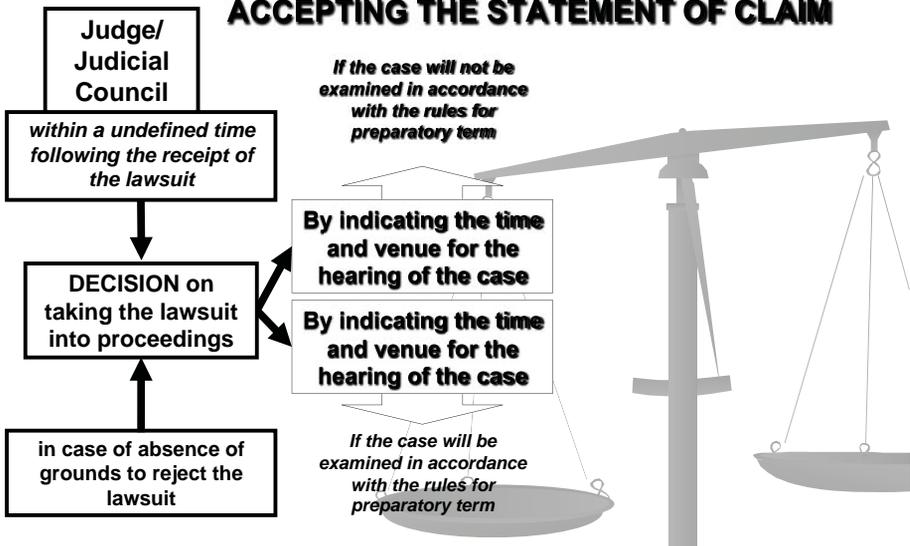


- If the decision is reversed, the lawsuit is considered accepted by the court as from the date of the initial filing

REJECTION OF THE LAWSUIT

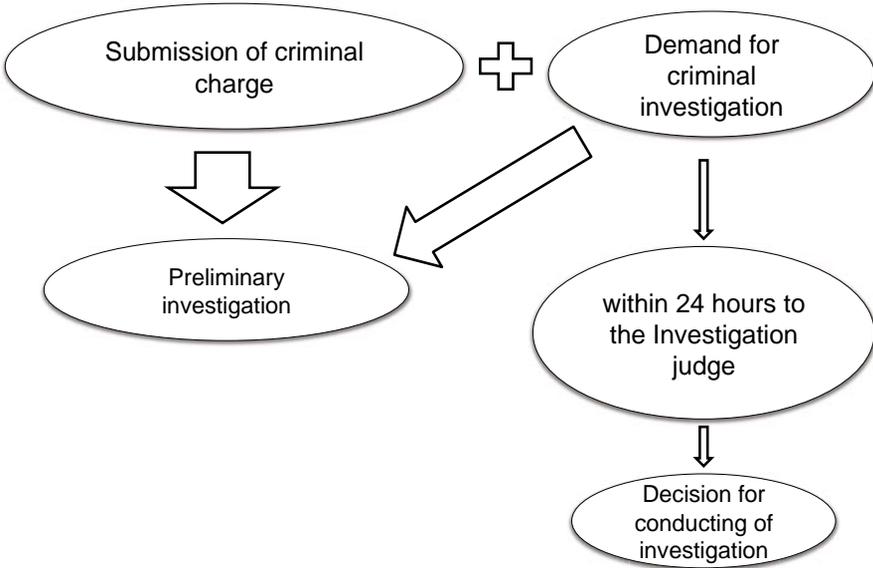


ACCEPTING THE STATEMENT OF CLAIM

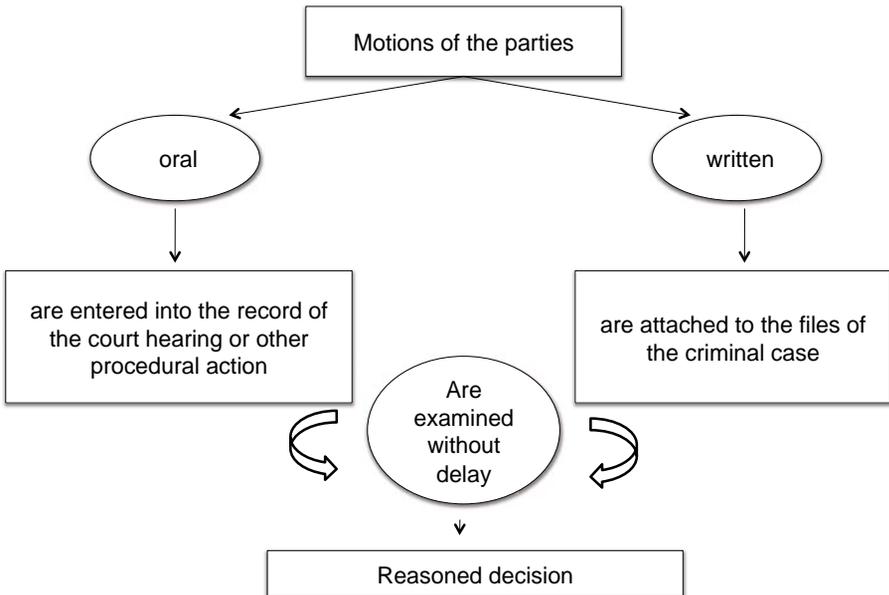


Criminal procedure

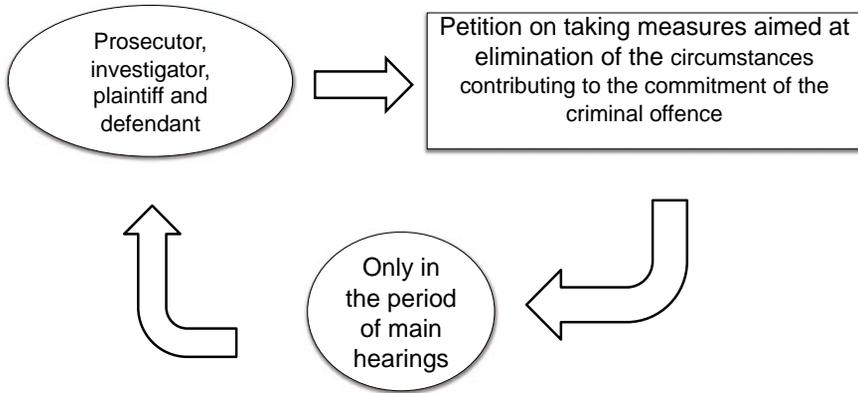
COMMENCEMENT OF THE PRE-TRIAL INVESTIGATION



Mandatory nature of taking motions and claims into examination



The duty to reveal and eliminate circumstances contributing to the commitment of the criminal offence



Freedom to appeal against the actions and decisions of the court conducting the proceedings

- prosecutor – plaintiff – defendant
- written / oral
- time limit to take into examination – without in time frame of 24 hours
- response:
 - by a decision
 - reasoned
 - with notice to the appellant
- right to withdraw the appeal
 - In any time

Glossary of terms

International Glossary

A

Acceptability

One of four criteria set out by Committee on Economic, Social and Cultural Rights by which to evaluate the right to the highest attainable standard of health. **Acceptability:** means that all health facilities, goods and services must be respectful of medical ethics, culturally appropriate, sensitive to gender and life-cycle requirements, as well as designed to respect confidentiality and improve the health status of those concerned (Committee on Economic, Social and Cultural Rights, General Comment 14). See *also* “Accessibility,” “Availability,” and “Quality.”

Accessibility

One of four criteria set out by Committee on Economic, Social and Cultural Rights by which to evaluate the right to the highest attainable standard of health. **Accessibility:** means that health facilities, goods and services have to be accessible to everyone without discrimination. Accessibility has four overlapping dimensions: non-discrimination, physical accessibility, economic feasibility (affordability), and information accessibility (Committee on Economic, Social and Cultural Rights, General Comment 14). See *also* “Acceptability,” “Availability,” and “Quality.”

Accession

The act whereby a state that has not signed a treaty expresses its consent to become a party to that treaty by depositing an “instrument of accession.” Accession has the same legal effect as ratification. Accession is generally employed by States wishing to express their consent to be bound by a treaty where the deadline for signature has passed. However, many modern multilateral treaties provide for accession even during the period that the treaty is open for signature.

Actio Popularis (*public action*)

A legal action brought by any member of a community in vindication of a public interest.

Adoption

The formal act by which negotiating parties establish the form and content of a treaty. The treaty is adopted through a specific act expressing the will of the States and the international organizations participating in the negotiation of that treaty, e.g., by voting on the text, initialing, signing, etc. Adoption may also be the mechanism used to establish the form and content of amendments to a treaty, or regulations under a treaty.

Treaties that are negotiated within an international organization are usually adopted by resolution of the representative organ of that organization. For example, treaties negotiated under the auspices of the United Nations, or any of its bodies, are adopted by a resolution of the General Assembly of the United Nations

Adoption Theory

A theory maintaining that international law becomes an automatic part of domestic law following treaty accession or ratification, without further domestication.

Amicus Curiae (*Friend of the court*)

A legal document filed with the court by a neutral party generally advocating a particular legal position or interpretation. The plural form is amici curiae.

Ambulatory Care

Medical care including diagnosis, observation, treatment and rehabilitation provided on an outpatient basis.

Availability

One of four criteria set out by Committee on Economic, Social and Cultural Rights by which to evaluate the right to the highest attainable standard of health. Availability: means that functioning public health and health care facilities, goods and services, as well as programmes, have to be available in sufficient quantity. This should include the underlying determinants of health, such as safe drinking water, adequate sanitation facilities, clinics and health-related buildings, trained medical personnel, and essential drugs (Committee on Economic, Social and Cultural Rights, General Comment 14). See also "Acceptability," "Accessibility," and "Quality."

B**Basic needs**

Used largely in the development of community to refer to basic health services, education, housing, and other goods necessary for a person to live.

Bioethics

Refers to "the broad terrain of the moral problems of the life sciences, ordinarily taken to encompass medicine, biology, and some important aspects of the environmental, population and social sciences. The traditional domain of medical ethics would be included in this array, accompanied now by many other topics and problems." (Encyclopedia of Bioethics, Warren T. Reich, editor-in-chief, New York: Simon & Schuster Macmillan, 1995, page 250)

Biomedicine

The term unifies fields of clinical medicine and research for health purposes. Broadly it is also defined as the application of the principles of the natural sciences, especially biology and physiology, to clinical medicine.

C**Concluding Observations**

Recommendations by a treaty's enforcement mechanism on the actions a state should take in ensuring compliance with the treaty's obligations. This generally follows both submission of a state's country report and a constructive dialogue with state representatives.

Country Report

A state's report to the enforcement mechanism of a particular treaty on the progress it has made in implementing it.

Convention

This term is used interchangeably with treaty, but it can also have a specific meaning as a treaty binding a broad number of nations. Conventions are normally open for participation by the international community as a whole, or by a large number of States. Usually instruments negotiated under the auspices of an international organization are entitled conventions. The same holds true for instruments adopted by an organ of an international organization.

Customary International Law

One of the sources of international law. It consists of rules of law derived from the consistent conduct of States acting out of the belief that the law required them to act that way. It follows that customary international law can be discerned by a widespread repetition by States of similar international acts over time (State practice). Acts must occur out of a sense of obligation and must be taken by a significant number of States and not be rejected by a significant number of States. A particular category of customary international law, jus cogens refers to a principle of international law so fundamental that no state may opt out by way of treaty or otherwise. Examples might include prohibitions against slavery, genocide, torture and crimes against humanity. Other examples of customary international law include the principle of non-refoulement and, debatably, the right to humanitarian intervention.

D**De Facto** (*In fact, in reality*)

Existing in fact.

De Jure (*By right, lawful*)

A situation or condition that is based on a matter of law, such as those detailed in ratified treaties.

Declaration

An interpretative declaration is a declaration by a State as to its understanding of some matter covered by a treaty or its interpretation of a particular provision. Unlike reservations, declarations merely clarify a State's position and do not purport to exclude or modify the legal effect of a treaty.

Dignity

The quality of being worthy, honored, or esteemed. Human rights are based on inherent human dignity and aim to protect and promote it.

Discrimination

Distinction between persons in similar cases on the basis of race, sex, religion, political opinions, national or social origin, associations with a national minority or personal antipathy (World Health Organization- WHO).

Domestication

The process by which an international treaty is incorporated into domestic legislation.

Dual Loyalty

Role conflict between professional duties to a patient and obligations—express or implied, real or perceived—to the interests of a third party such as an employer, insurer, or the state.

E

Entry into Force

The moment in time when a treaty becomes legally binding on the parties to the treaty. The provisions of the treaty determine the moment of its entry into force. This may be a date specified in the treaty or a date on which a specified number of ratifications, approvals, acceptances or accessions have been deposited with the depositary.

Essential Medicines

Medicines that satisfy the priority health-care needs of the population. Essential medicines are intended to be available at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

Exhaustion of Domestic Remedies

Refers to the process required before submitting a complaint on behalf of a victim to any regional or international tribunal. All available procedures must first be used to seek protection from future human rights violations and to obtain justice for past abuses. There are limited exceptions to the requirement that domestic remedies be exhausted: remedies may be unavailable, ineffective (i.e. a sham proceeding) or unreasonably delayed.

G

General Comments/Recommendations

Interpretive texts issued by a treaty's enforcement mechanism on the content of particular rights. Although these are not legally binding, they are widely regarded as authoritative and have significant legal weight.

H

Health

A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity (WHO).

Health Care

1. 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. This definition and similar ones sometimes are given for "patient care" as well. The World Health Organization states that this embraces all the goods and services designed to promote health, including preventive, curative, and palliative interventions, whether directed to individuals or populations.
2. Any type of services provided by professionals or paraprofessionals with an impact on health status (Online Glossary, European Observatory on Health Systems and Policy).
3. Medical, nursing or allied services dispensed by health care providers and health care establishments (Declaration on the Promotion of Patients' Rights in Europe, WHO, Amsterdam, 1994). See also "Patient Care."

Health Care Establishment

Any health care facility such as a hospital, nursing home, or establishment for disabled persons (Declaration on the Promotion of Patients' Rights in Europe, WHO, Amsterdam, 1994).

Health Care Providers

Physicians, nurses, dentists, or other health professionals (Declaration on the Promotion of Patients' Rights in Europe, WHO, Amsterdam, 1994).

Health Care System

The organized provision of health care services.

Human Rights

Entitlements, freedoms, and privileges which adhere to all human beings regardless of jurisdiction or other factors such as ethnicity, nationality, religion, or sex.

Human Rights are universal legal guarantees protecting individuals and groups from interference with fundamental freedoms and human dignity. Some of the most important characteristics of human rights are that they are:

- guaranteed by international standards
- legally protected
- focus on the dignity of the human being
- oblige states and state actors
- cannot be waived or taken away
- interdependent and interrelated; and
- universal

(The United Nations System and Human Rights: Guidelines and Information for the Resident Coordinator System, Geneva, March 2000).

Human Rights Indicators

Criteria used to measure compliance with international human rights standards.

Human Rights in Patient Care

Concept that refers to the application of basic human rights principles to all stakeholders in the delivery of health care services. It is complementary to bioethics but provides a set of universally accepted norms and procedures for making conclusions about abuses within health care settings and providing remedies. It uses standards contained in the international human rights framework, which are often mirrored in regional treaties and national constitutions. It differs from patients' rights, which codify particular rights that are relevant only to patients rather than applying general human rights standards to all stakeholders in health care service delivery, including providers. It draws on concepts such as dual loyalty, which attributes much human rights abuse in health settings to health care providers simultaneous and often conflicting obligations to their patients and to the State. See also "Dual Loyalty."

|

Interdependent/Indivisible

The term used to describe the relationship between civil and political rights and economic and social rights. Interdependence and indivisibility mean that one set of rights does not take precedence over the other, and that guaranteeing each set of rights is contingent upon guaranteeing the other.

Indirect Discrimination

Descriptive term for a situation in which the effect of certain imposed requirements, conditions or practices has a disproportionately adverse impact on one group or other. It generally occurs when a rule or condition applying to everyone is met by a considerably smaller proportion of people from a particular group, the rule is to their disadvantage, and it cannot be justified on other grounds.

Individual Rights in Patient Care

More readily expressed in absolute terms than are social rights in health care. When made operational, can be made enforceable on behalf of an individual patient (Declaration on the Promotion of Patients' Rights in Europe, WHO Amsterdam, 1994, Guiding Principles). See also "Social Rights in Health Care" and "Patient's Rights."

Informed Consent

A legal condition in which a person can be said to agree to a course of action based upon an appreciation and understanding of the facts and implications. The individual needs to be in possession of relevant facts and the ability to reason.

Informed Consent in the Health Care Context

A process in which a patient participates in health care choices. A patient must be provided with adequate and understandable information on matters such as the treatment's purpose, alternative treatments, risks, and side-effects.

In-patient

A patient whose care requires a stay in hospital or hospice facility for at least one night.

International Human Rights Law

Codifies legal provisions governing human rights in various international and regional human rights instruments.

International Law

The set of rules and legal instruments regarded and accepted as binding agreements between nations. International law is typically divided into public international law and private international law. Sources are (a) custom; (b) treaties; (c) general principles of law and (d) judicial decisions and juristic writings (Article 38(1)(d) of the Statute of the International Court of Justice).

J**Jus Cogens**

Peremptory principle of international law (e.g., prohibition on torture) from which no derogation by treaty is permitted.

M**Maximum Available Resources**

Key provision in Article 2 of International Covenant on Economic, Social and Cultural Rights obliging governments to devote the maximum of available government resources to realizing economic, social and cultural rights.

Medical Intervention

Any examination, treatment, or other act having preventive, diagnostic, therapeutic or rehabilitative aims and which is carried out by a physician or other health care provider (Declaration on the Promotion of Patients' Rights in Europe, WHO, Amsterdam, 1994).

Monitoring/Fact Finding/Investigation

Terms often used interchangeably, generally intended to mean the tracking and/or gathering of information about government practices and actions related to human rights.

N

Negative Rights

Rights under which a State is obliged to refrain from unjustly interfering with a person and/or their attempt to do something.

Neglected Diseases

Diseases affecting almost exclusively poor and powerless people in rural parts of low-income countries that receive less attention and resources.

O

Out-patient

Patient receiving treatment without spending any nights at a health care institution.

P

Party

A State or other entity with treaty-making capacity that has expressed its consent to be bound by that treaty by an act of ratification, acceptance, approval or accession, etc., where that treaty has entered into force for that particular State. This means that the State is bound by the treaty under international law (Article 2(1)(g) of the Vienna Convention, 1969).

Patient

1. User(s) of health care services, whether healthy or sick (Declaration on the Promotion of Patients' Rights in Europe ,WHO, Amsterdam 1994).

2. A person in contact with the health system seeking attention for a health condition (Online Glossary, European Observatory on Health Systems and Policies).

Patient Autonomy

The right of patients to make decisions about their medical care. Providers can educate and inform patients, but cannot make decisions for them.

Patient Care

The services rendered by members of the health professions or non-professionals under their supervision for the benefit of the patient. See also "Health Care."

Patient-Centered Care

Doctrine recognizing the provision of health care services as a partnership among health care providers and patients and their families. Decisions about medical treatments must respect patients' wants, needs, preferences, and values.

Patient Confidentiality

Doctrine that holds that the physician has the duty to maintain patient confidences. This is to allow patients to make full and frank disclosure to their physician, enabling appropriate treatment and diagnosis.

Patient Mobility

Concept describing patient movement beyond their catchment area or area of residence to access health care; mobility can take place within the same country or between countries.

Patient Responsibility

Doctrine recognizing the doctor/patient relationship as a partnership with each side assuming certain obligations. Patient responsibilities include communicating openly with the physician or provider, participating in decisions about diagnostic and treatment recommendations, and complying with the agreed-upon treatment program.

Patients' Rights

1. A set of rights calling for government and health care provider accountability in the provision of quality health services. Associated with a movement that has emerged out of increasing concern about human rights abuses in health care settings, particularly in countries where patients are assuming a greater share of health care costs and thus expect to have their rights as “consumers” respected.
2. A set of rights, responsibilities and duties under which individuals seek and receive health care services (Online Glossary, European Observatory on Health Systems and Policies).
3. What is owed to the patient as a human being by physicians and the State.

Patient Safety

Freedom from accidental injury due to medical care or medical errors (Institute of Medicine).

Positive Rights

Rights under which a State is obliged to do something for someone.

Primary Health Care

1. General health services that are available in a community, located near the places where people live and work.
2. First level of contact that individuals and families have with the health system.

Progressive Realization

The requirement in Article 2 of the International Covenant on Economic, Social and Cultural Rights that governments move as expeditiously and effectively as possible toward the goal of realizing economic, social and cultural rights, and to ensure there are no regressive developments.

Protocol

Refers to a section in a treaty that clarifies terms, adds additional text as amendments, or establishes new obligations. These new obligations can be quantitative targets for nations to achieve.

Public Health

Collective actions of a society to ensure conditions in which people can be healthy

(Institute of Medicine).

Public International Law

Establishes the framework and the criteria for identifying states as the principal actors in the international legal system. Deals with the acquisition of territory, state immunity and the legal responsibility of states in their conduct with each other. Also concerned with the treatment of individuals within state boundaries including human rights, the treatment of aliens, the rights of refugees, international crimes and nationality. It further includes the maintenance of international peace and security, arms control, the pacific settlement of disputes and the regulation of the use of force in international relations. Branches, therefore, include international human rights law, international humanitarian law, refugee law and international criminal law.

Q

Quality

One of four criteria set out by the Committee on Economic, Social, and Cultural Rights by which to evaluate the right to the highest attainable standard of health. Quality: means that health facilities, goods, and services must be scientifically and medically appropriate and of good quality. This requires skilled medical personnel, scientifically-approved and unexpired drugs, and hospital equipment (Committee on Economic, Social and Cultural Rights, General Comment 14). See also “Acceptability,” “Accountability,” and “Availability.”

R

Ratification

The formal acceptance of the rights and obligations of a treaty. If the treaty has entered into force, the treaty thereafter becomes legally binding to parties that have ratified the treaty. Requires two steps: (a) the execution of an instrument of ratification, acceptance or approval by the Head of State, Head of Government or Minister for Foreign Affairs, expressing the intent of the State to be bound by the relevant treaty; and (b) for multilateral treaties, the deposit of the instrument with the depositary; and for bilateral treaties, the exchange of the instruments between parties.

Reservation

A statement made by a State by which it purports to exclude or alter the legal effect of certain provisions of a treaty in their application to that State. A reservation may enable a State to participate in a multilateral treaty that it would otherwise be unable or unwilling to participate in. States can make reservations to a treaty when they sign, ratify, accept, approve or accede to it. When a State makes a reservation upon signing, it must confirm the reservation upon ratification, acceptance or approval. Since a reservation purports to modify the legal obligations of a State, it must be signed by the Head of State, Head of Government or Minister for Foreign Affairs. Reservations cannot be contrary to the object and purpose of the treaty. Some treaties prohibit reservations or only permit specified reservations.

Respect, Protect and Fulfill

Governments' obligations with respect to rights. **Respect:** Government must not act directly counter to the human rights standard. **Protect:** Government must act to stop others from violating the human rights standard. **Fulfill:** Government has an affirmative duty to take appropriate measures to ensure that the human rights standard is attained.

Right to Health

Right to the enjoyment of a variety of facilities, goods, services, and conditions necessary for the realization of the highest attainable standard of physical and mental health (Committee on Economic, Social and Cultural Rights, General Comment 14).

S**Secondary Health Care**

General health services available in hospitals

Social Rights in Health Care

Category of rights that relate to the societal obligation undertaken or otherwise enforced by government and other public or private bodies to make reasonable provision of health care for the whole population. They also relate to equal access to health care for all those living in a country or other geopolitical area and the elimination of unjustified discriminatory barriers, whether financial, geographical, cultural or social and psychological. They are enjoyed collectively (Declaration on the Promotion of Patients' Rights in Europe, WHO, Amsterdam, 1994, Guiding Principles). See also "Individual Rights in Patient Care."

Self-Executing Treaty

A treaty that does not require implementing legislation for its provisions to have effect in domestic law.

Shadow Report

An independent NGO submission to a treaty enforcement mechanism to help it assess a state's compliance with that treaty.

Signatory

A party that has signed an agreement. In regards to a treaty, a signatory is not yet legally bound by the treaty. Instead, a signatory agrees to an obligation not to defeat the object and purpose of a signed treaty. See *also* "Ratification."

Special Rapporteurs

Individuals appointed by the Human Rights Council to investigate human rights violations and present an annual report with recommendations for action. There are both country-specific and thematic special rapporteurs, including one on the right to the highest attainable standard of health.

T

Terminal Care

Care given to a patient when it is no longer possible to improve the fatal prognosis of his or her illness/condition with available treatment methods, as well as care at the approach of death (Declaration on the Promotion of Patients' Rights in Europe, WHO, Amsterdam, 1994).

Tertiary Health Care

Specialized health services available in hospitals.

Transformation Theory

A theory maintaining that international law only becomes part of domestic law after domestication and the incorporation of treaty provisions into domestic legislation.

Treaty

A formal agreement entered into by two or more nations which is binding upon them. A bilateral treaty is a treaty between two parties. A multilateral treaty is a treaty between more than two parties.

W

Working Groups

Small committees appointed by the Human Rights Council on a particular human rights issue. Working groups write governments about urgent cases and help prevent future violations by developing clarifying criteria on what constitutes a violation.

Glossary of terms

Country-Specific Glossary

Autolog transfusion is a transfusion in which the blood donor and the blood recipient are the same person, and in which the blood or blood components taken previously are donated to the same person. (LBS)

Autolog donors are persons who can donate blood for their own use, if the blood need can be previously predicted for a planned intervention, after the predetermined blood donation plan. (LBS)

Active substance is a pharmacologically active substance given in a pharmaceutical dosage form. (LDMD)

Common name is an International Non-proprietary Name (INN), recommended by the World Health Organization, or if such name does not exist, it is the usually used name. (LDMD)

Harassment is any inappropriate, immoral or indecent behavior, attack to personal dignity, causing fear, repulsion, degradation, and humiliation or insulting behavior. (LEOWM) **Sexual harassment** is every verbal, non-verbal or physical behavior of sexual type that represents insulting of the personal dignity, especially when it causes fear, repulsion, degradation, humiliation or insulting behavior. (LEOWM)

Genetic data is data from any type that are related to the hereditary characteristics of the patient or are related to the inheriting matrix of those characteristics in an interrelated group of individuals in which the patient belongs. (LBS)

Blood donor is person in good health condition and with good medical history, which voluntarily donates blood or plasma for therapeutic purposes. (LBS) *Multiple blood donor* is a person, which donated blood before, but not in the last two years preceding the current blood donation, in the same blood donation centre (LBS). **Regular blood donor** is a person that routinely donates blood or plasma in the last two years, in accordance with the minimum required time intervals – minimum two times per year, in the same blood donation centre. (LBS)

Blood donation is collection of blood and blood components from one person (blood donor) for transfusion to another person (blood recipient), or for medical use or as source for production of other blood components and products. (LBS)

Discrimination – 1. Any type of isolation, exclusion, distancing or other treatment with effect of violation of equality of enjoyment of rights, except in the cases determined with this law (LMH). 2. **Discrimination** is every distinction, utilization or limitation based on gender that endangers or impairs the implementation or protection of the human rights and freedoms. (LEOWM) **Direct Discrimination means** unequal treatment created through the legislation or actions of particular entities based on gender in same or similar situations in the implementation, respect and protection of the human rights and freedoms (LEOWM). **Indirect discrimination** means creation of unequal treatment of persons of different gender with legislation, standards or behaviors that formally provide for equal treatment and are seemingly neutral, but are applied inconsistently based on gender, unless that is in the interest or necessary for providing special protection, or is caused by objective conditions and circumstances that are not related to the gender. (LEOWM)

Distribution is supply with blood and blood components to other healthcare facilities and producers of blood products from plasma. The distribution does not include dispensing of blood and blood components for transfusion purposes. (LBS)

Good practices

Good manufacturing practice (GMP) is a system of quality of organization, supervision and control of quality of in all aspects of medicine production. (LDMD)

Good control Laboratory Practice (GcLP) is part of the good manufacturing practice (GMP) related to the control of the quality of medicines. (LDMD)

Good Laboratory Practice (GLP) is a system of quality of organization processes and conditions for planning, implementation, control, recording (protocol) and reporting about the preclinical laboratory studies. (LDMD)

Good Distribution Practice (GDP) is a system of quality related to the organization, implementation and supervision of the storage of medicines and medical devices in accordance with the sequence of operations and conditions, before further use or distribution and transport of the medicines from the producer to the end user. (LDMD)

Good Clinical Practice in Clinical Trials (GCP) is internationally recognized ethical and scientific system for the quality of the planning and implementation, recording, control and reporting for the clinical trials on human subjects and provides reliability and quality of the data obtained with the trials, as well as protection of rights, safety and good condition of the involved subjects, in accordance with the Helsinki Declaration of WHO for biomedical research in humans. (LDMD)

Good Pharmaceutical Practice (GPhP) is a set of internationally accepted standards for health promotion through supply with medicines and medical devices, information sharing about medicines, improvement of the patients care, prescription in accordance with the recommended use of the medicine and other related activities. (LDMD)

Equal opportunities of women and men by dignity and right means promotion of the principle of equal participation of women and men in all areas of public and private sector, equal status and treatment for implementation of all rights and in the development of their individual potentials through which they contribute in the societal development, as well as equal benefits from the results of that societal development. (LEOWM)

Equal treatment means absence of direct or indirect discrimination based on gender, in accordance with this or other laws. (LEOWM) See also Discrimination

Epidemics is an increase of number of affected persons from a particular communicable disease which by time and place surpasses the usual number of cases of that disease in the previous period, as well as unusual increase of the number of affected persons with complications or death outcome. (LPPCD)

Essential medicines are basic medicines intended for treatment of the most common diseases of the major part of the population and as such are defined by a responsible authority. (LDMD)

Communicable disease is a disease caused by a biological agent (bacteria, viruses, parasites, fungi) or their toxins, which in direct or indirect way can be transmitted, to humans. (LPPCD)

Protection of persons with mental disease is a set of activities undertaken by the health, social and penitentiary system in accordance with this law or other law in related area through inter-sectoral or interdisciplinary system of measures. (LMH)

Protection from communicable diseases is achieved through planning, organization, continued epidemiological surveillance and implementation of measures determined in this law, as well as supervision and control of the measures implemented. (LPPCD)

Health care comprises of measures, activities and procedures for protection and promotion of health and natural and working environment, the rights and responsibilities of the health insurance, as well as measures, activities and procedures that are undertaken by healthcare organizations for protection and promotion of human health, prevention and alleviation of diseases and health conditions, timely and effective treatment and rehabilitation with professional medical measures, activities and procedures. (LH)

Health care of terminally ill persons is protection provided to a patient whose health condition is no longer possible to be improved with the available methods of treatment, as well as care in the period before occurrence of death. (LPPR)

Healthcare institution is institution established and working in accordance with the health-related regulations. (LPPR)

Health insurance is established for provision of health services; it can be obligatory and voluntary. Obligatory health insurance is established for all citizens of the Republic of Macedonia, for provision of health services and monetary compensations based on the principles of comprehensiveness, solidarity, equality and effective use of resources, under conditions determined in this law and its subordinated bylaws. Voluntary health insurance is established for provision of health services that are not covered under the obligatory health insurance. (LHI)

Medicine name is the name that can be innovative that is not causing confusion with the common non-proprietary name, or is the common (non-proprietary) name or scientific name followed by trademark or the name of the producer/bearer of the approval for distribution. (LDMD)

Intrahospital (nosocomial) infection is infection for which the transmission, which in terms of time occurrence, is related to a treatment or stay in healthcare facility. (LPPCD)

Infection is penetration of a biological agent in the human organism and the reproduction and maintenance of that agent in the organism. (LPPCD)

Quarantine is isolation that consists of limitation of movement of sick persons or suspected sick persons or limitation of contacts of sick persons with particular diseases of high transmission risk, in specially determined space, where the risk of spread of the disease is decreased to minimal level, with presence of health-care staff that uses appropriate protection means, and has special movement regime and behavior. (LPPCD)

Controller of set of personal data is physical or legal entity, state body or other body that independently or with other entities determines the goals and way of processing of the personal data (in further text: the Controller). When goals and ways of processing of the personal data are determined by law or other legal document, the controller and the special criteria are set by that respective law or legal document. (LPPD)

Blood is full blood, collected from one blood donor and processed either for transfusion or for further production of blood derivatives. (LBS). Blood component are therapeutic components of the blood (erythrocytes, leukocytes, trombocytes and plasma) that can be prepared with different methods. (LBS). Blood and blood components are preparations obtained from blood; they are not considered as medicines in the sense of this law and are used as raw material for industrially

produced medicines. For them, in accordance with this law, permission for distribution shall not be necessary. (LDMD).

Medicine is every substance or combination of substances formulated in a way that can treat or prevent diseases in humans. Medicine is also, every substance or combination of substances that can be used or can be given to humans for regeneration, correction or modification of physiological functions by causing pharmacological, immunological or metabolic activity, or for establishing a medical diagnosis. (LDMD)

Person with mental disease is a person that has been diagnosed with mental illness by specialist doctor-psychiatrist, in accordance with the diagnostic criteria of the evidence-based medicine. (LMH)

Personal data is every information that is related to the identified physical entity or physical entity that can be identified, and a person that can be identified is a person whose identity can be determined directly or indirectly especially based on a unique personal number of the citizen, or based on one of more characteristics specific for his/her physical, mental, economic, cultural or social identity. (LPPD)

Collection of personal data is a structured set of data, which is available in accordance to certain criteria, regardless whether it is centralized, decentralized or dispersed on a functional or geographic basis. (LPPD). **Processing of personal data** is every operation or set of operations that are performed on the personal data in automatic or other way, such as: collection, recording, organizing, storage, adaptation or change, underlining, consultation, use, disclosure through transfer, publication or in other way making the personal data available, equalization, combination, blocking, deletion or destruction. (LPPD)

Medical intervention is every examination, treatment or other activity with preventive, diagnostic, therapeutic or rehabilitation purpose that is undertaken by licensed medical professional. (LPPR)

Medical data - 1. Data related to the health of the patient. Medical data includes the data related to the anamnesis, prognosis and treatment of the patient, as well as data that has clear and close connection to the health of the patient. (LPPR). 2. **Medical data** is personal data related to the health of the patient. These are data that has clear and close connection to the health of the patient, as well as genetic information about the patient. (LBS). 3. **Special category of personal data** is personal data that disclose racial or ethnic origin, political, religious or other beliefs, membership in syndicates and data that are related to the health condition or sexual life. (LPPD)

Medical record - 1. Medical record of the patient is the record in which all data and documents about the health status of the patient are stored and kept, the medical or clinical condition, diagnosis, prognosis and treatment and other personal data, and which medical record is kept in accordance with the regulations for medical evidence and statistics and with this law. (LPPR). 2. **Medical record** of

the patient is the record in which all data and documents about the health status of the patient are stored and kept, the medical or clinical condition, diagnosis, prognosis and treatment and other personal data, and which medical record is kept in accordance with the regulations for medical evidence and statistics, protection of patients' rights and with this law. (LBS)

Medical device is every instrument, apparatus, device, material or other product that is used in human medicine, which has no pharmacological, immunological or metabolic effect, and is used independently or in combination, including the necessary software for appropriate use of the device, for the purposes of: diagnosis, prevention, monitoring, treatment or alleviation of a disease; diagnosis, monitoring and surveillance, treatment or compensation of injury or disability; examination or modification of anatomic or physiological process and control of conception. (LDMD)

Authorized healthcare facility is healthcare facility for occupational medicine that performs its activities in accordance with the health-related regulation, and is engaged by the employer for implementation of the healthcare protection at workplace. (LSHW)

Patient is a person, sick or healthy, which will seek medical intervention or to which medical intervention will be performed, for the purpose of protection or promotion of health, prevention of disease or other health conditions, treatment, care or rehabilitation. (LPPR)

Preventive measures are all measures that are undertaken or are planned to be undertaken on all levels with the employer, for prevention or reduction of the health and safety risks at workplace. (LSHW)

Working relationship is a contractual relationship between the employee and the employer in which the employer at his/her own will is involved in the organized process of work with of the employer, for personal income and other benefits, personally and without interruptions is performing its work according to the guidelines and under the supervision of the employer. (LRA)

Employee is every physical person who is in contractual working relationship based on concluded agreement for employment. (LRA). **Employee** is a person employed based on a permanent or temporary contract, on any legal grounds, is self-employed, professional farmer or person that performs other work as part of the training programme. (LSHW).

Workplace is every place intended for performing work and located in the space of the employer or in temporary or mobile working location and to which the employee has access during his/her work and which is under direct or indirect control of the employer. (LSHW)

Working environment is a space in which the work is performed, a workplace, work-

ing conditions, working processes, social relationships and other influencing factors from the external environment. (LSHW)

Employer is legal or physical entity, as well as other entity (state body, local self-government unit, affiliation of foreign company, diplomatic core), that employs employees based on employment contract. (LRA)

Employer is physical or legal entity that uses the services of an employee in accordance with the employment contract or on other legal grounds, farmer or physical person who independently or with other member of his/her family performs agricultural or other activity, as his/her main profession, and who does not employ other persons. (LSHW)

Serious adverse event - 1. Every event connected with collection, testing, processing, storage or distribution of blood or blood component that can lead to death, endangerment of life or incapacitation of the patient or that prolongs the clinical treatment or morbidity. (LBS). 2. **Seriously adverse event** is every unwanted event related to procurement, testing, processing, storage or distribution of tissues and cells, that can lead to transmission of communicable disease, death or threat to life, to disability or incapacitation of patients or can lead to or prolong the hospital treatment or disease. (LBAR)

Serious adverse reaction – 1. Unintentional response of the blood donor or patient related to collection and transfusion of blood or blood components that can lead to death, threat to life or incapacitation of patients, or that prolongs the hospital treatment or morbidity. (LBS). 2. **Serious adverse reaction** is unintentional reaction that includes also communicable disease, in donors or recipients related to procurement or human use of tissues and cells that is fatal, represents threat to life, leads to disability or incapacitation or that can prolongs the hospital stay or the disease. (LBAR)

Screening is epidemiological method for understanding the actual situation of the population with regards to particular communicable disease, its causing agent, immune response or similar, with use of particular sample. (LPPCD)

Consent is a freely and without any force expressed will of a person with mental disease that has a judgment capacity, based on previously obtained information about the care, treatment and rehabilitation, as well as about the rights that this person has and the ways of enjoyment of these rights. (LMH). **Consent of the entity of personal data** is free and finally expressed will of the entity of that personal data with which this entity agrees with the processing, of his/her personal data for predetermined purposes. (LPPD)

Entity of personal data is every physical person to whom the processed data is related. (LPPD)

Substance is every matter regardless of origin, that can be: human, e.g.: human

blood and blood products, animal, e.g.: microorganisms, whole animals, parts of organs; animal excretions, toxins, extracts, blood products; herbal, e.g.: microorganisms, plants, parts of plants, extracts and excretions of plants; chemical, e.g.: elements, chemical matters that are found in the nature or chemical compounds that are prepared with chemical change or synthesis; and obtained by biotechnological processes. (LDMD)

Patient information is information for the user, in written form provided with the medicine, and contains basic information about the medicine and its proper use, and has to be written in a language understandable to the patient-user. (LDMD)

Facility for transfusion medicine is healthcare facility responsible for any aspect of collection and testing of blood and blood components, regardless of the purpose, processing, storage and distribution when they are intended for transfusion. This does not include the units of transfusion medicine within the hospital healthcare settings. (LBS)

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“Human Rights in Patient Care: A Practitioner Guide” is a practical, “how-to” manual for lawyers taking human rights cases in health care settings. Each volume in the series contains information on both patient and provider rights and responsibilities, as well as procedures for ensuring that these rights are protected and enforced at the international, European and national levels. This is the first compilation of diverse constitutional provisions, statutes and regulations organized by right and responsibility, paired with practical examples of compliance, violation and enforcement. The guide explores litigation and alternate forms for resolving claims, such as ombudspersons and ethics review committees. The Practitioner Guide is a useful reference for lawyers and other professionals working in a region where the legal landscape is often in flux. The full series is available at www.health-rights.org.

Human rights in health care is a legal area that in Republic of Macedonia is fully regulated with the national legislation, as well as with the signed and ratified international instruments. Since gaining its independence, in Republic of Macedonia the right to health and the responsibility for one's health and the health of others is incorporated into the Constitution of the Republic of Macedonia and into the current legislation, and since then it evolved with patients' rights and responsibilities, as well as with rights and responsibilities of the health workers and the health care facilities.

This Guide, in which the compulsory international and regional legal framework and the national legislation of Republic of Macedonia in this field are processed, is a useful tool for lawyers, health care workers, health care facilities managers, and other practitioners that come face to face with these issues in their professional daily routines.

(from the Preface to the Macedonian edition)



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