

Overview and Legal Analysis of Healthcare Legislation

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1 ■ INTRODUCTION

The aspiration of Georgia to become a leading reformer among the Eastern European states has imparted special dynamism to the processes underway in the country throughout near past. Interchange of reforms and the rapid speed, “formation in action” of the public policy and the search for more effective decisions have led to exclusive challenges in various areas.

Of special interest in given context is the field of healthcare and the assessment of one of the constructions of its system - the legislative segment.

During the working process authors used a “Human Rights in Patient Care” – Practitioner Guide.

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 Georgia, Armenia, 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 in 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

The present analytical paper is a modest attempt of authors, on one hand to look at the healthcare legislation as the foundation of order in the healthcare system and at the same time as the layer of communication between citizens and the healthcare system, and on the other hand to answer the following questions: which technical legal and content flaws does the existing legislation contain? How consistent are the separate sections of legislation with each other? Is it in compliance with the key international legislative standards in the field of healthcare? Further, throughout the study the authors identify problems in the field of healthcare, which are noteworthy for the analysis of legislation, but are complex and extend beyond the legislative dominion.

Within the framework of analysis the authors have worked on various statutes and sub-statutory normative acts.

The laws on:

- Rights of Patient;
- Donation of Blood and Its Components;
- Health Care;
- Medical Activity;
- Public Health;
- Transplantation of Human Organs;
- Medical-Social Expert Examination;
- The Criminal Code with respect to healthcare;
- The Civil Code with respect to healthcare;
- The Code of Administrative Offences with respect to healthcare.

For legislative analysis the group of authors has selected the IRAC (Issue, Rule, Analysis, Conclusion) methodology. This methodology provides a possibility to identify the problems/issues from various sources (experts, court practice, studies, complaints, etc.), examine the norms regulating these problems/issues, assess the adequacy, fairness and effectiveness of such regulation, and to draw the conclusions and recommendations on the need to modify various legislative norms for subsequent better regulation of a problem/issue.

Three working meetings were held within the framework of the study with participation of experts in healthcare legislation, public health policy, bioethics, media and the medical insurance. At the working meetings the group of researchers would present and discuss with experts the implemented work, while the remarks, questions and comments were taken into account at the later stages of the working process.

The authors of the paper wish for the present analysis to meet the three main requirements:

1. **Be impartial, neutral and objective** (not to evaluate the undertaken and pending healthcare reforms from sociological standpoint);
2. **Be available for wide use** (as for experts and law-makers, as well as for other interested persons);
3. **Provide a possibility for finding a link to other analytical papers in the field of healthcare** (not to claim that the research is exhaustive).

The authors of the analytical paper believe that the legislation alone cannot secure the effective functioning of the healthcare system, while it is impossible for the healthcare system with improperly functioning legislation to be effective.

The overview and legal analysis of healthcare legislation has demonstrated that:

- A host of issues is associated with the flaws of legal technique and remedying them does not require additional discussions in the healthcare public policy; offered recommendations are sufficient for amending the respective legislative acts. The first phase of legal analysis of the document - "Is Ready to Act" - has covered these issues.
- There is a rather large group of issues, with respect to which choices have first to be made in the healthcare public policy area, and only afterwards should the policy decisions be accordingly reflected in the legislative sphere. Therefore, recommendations of the legal analysis are not sufficient for directly carrying out the legislative changes; however, they clearly indicate as to which legislative norms must be amended after making this or that policy decision (pursuant to the content of such decisions). This group of issues is examined at the second phase - "Needs to Decide, Then Act".
- The study has identified in addition several topics, with respect to which there are no unambiguous approaches in the healthcare public policy area. These issues require conceptual contemplation, synthesis of approaches and afterwards making the policy decision, which will clearly depict the configuration of respective component of the healthcare system construction. Only afterwards will it be possible to bring the legal segment into compliance with the requirements of healthcare system. Hence, the offered discussion, analysis and recommendations on these issues purport to actualize the topics in the public policy area and the authors believe that there is a longer road ahead before making legislative amendments, as compared to the issues discussed in the previous chapter. These topics are covered by the third phase of the study - "Needs to Think Over, Then the Rest".

2. DESCRIPTION OF NORMATIVE ACTS

Normative acts regulating the field of healthcare as of 1 July 2011 are as follows:

STATUTORY ACTS:

1. Law of Georgia on "Health Care";
2. Law of Georgia on "Public Health";
3. Law of Georgia on the "Rights of Patient";
4. Law of Georgia on "Medical Activity";
5. Law of Georgia on "Medical-Social Expert Examination";
6. Law of Georgia on "Social Protection of Persons with Disabilities";
7. Law of Georgia on "Donation of Blood and Its Components";
8. Law of Georgia on "Transplantation of Human Organs";
9. Law of Georgia on "HIV/AIDS";
10. Law of Georgia on "Licenses and Permits";
11. Law of Georgia on "Medicine and Pharmaceutical Activity";
12. Law of Georgia on "Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance";
13. Law of Georgia on "License and Permit Fees".

SUB-STATUTORY NORMATIVE ACTS:

1. Law of Georgia on Health Care, 10 December 1997

➤ **Respective normative acts:**

- 22 May 2003 Order #119/n of the Minister of Labor, Health and Social Welfare of Georgia on the "Approval of Passport of Medical and Pharmaceutical Institution";
- 25 September 2007 Order #281/n of the Minister of Labor, Health and Social Welfare of Georgia on the "Procedure for Conducting Expert Examination on Temporary Incapacity to Work and Issuing the Medical Absence Excuse";
- 19 June 2008 Order #142/n of the Minister of Labor, Health and Social Welfare of Georgia on the "Procedure for Conducting the Forensic Psychiatric Expert Examination";

- “Procedure for Conducting the Forensic Medical Examination and Rules of Activity of Medical Personnel of Forensic Medical Examination - not adopted (the Ministry of Labor, Health and Social Welfare of Georgia was instructed to develop and approve this procedure within 6 months from enactment of the Law, i.e. until 10 June 1998);
 - 7 December 2010 Order #398/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Form and Rule of Mandatory Notification for Providers of High Risk Medical Activity/Service to be Carried Out in Outpatient/Day Clinic Conditions and the Procedure for Administration of Register”;
 - 22 November 2010 Resolution #359 of the Government of Georgia on the “Approval of Technical Regulations of High Risk Medical Activities”;
 - 10 July 2008 Order #157/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Instruction on Provision of Palliative Care to Persons with Chronic Incurable Diseases”.
2. Law of Georgia on Public Health, 27 June 2007

➤ **Respective normative acts:**

- 21 March 2008 Resolution #69 of the Government of Georgia on the “Approval of Regulations of the Government Commission Managing the Emergencies”;
- 16 February 2008 Joint Order #42/n-#2-22 of the Minister of Labor, Health and Social Welfare of Georgia and the Minister of Agriculture of Georgia on the “Approval of the Rule of Mutual Informing on Disease Outbreaks between the Ministry of Labor, Health and Social Welfare of Georgia and the Ministry of Agriculture of Georgia to Protect the Population from Zoonotic Diseases” - revoked by the 23 February 2010 Resolution #57 of the Government of Georgia;
- 16 February 2010 Joint Order #41/n-#2-23 of the Minister of Labor, Health and Social Welfare of Georgia and the Minister of Agriculture of Georgia on the “Approval of the Rule of Mutual Informing on Disease Outbreaks between the Ministry of Labor, Health and Social Welfare of Georgia and the Ministry of Agriculture of Georgia to Control Diseases Caused by Food and Coordination for Carrying Out Liquidation Measures against Epidemic Outbreak”;
- 15 November 2007 Resolution #252 of the Government of Georgia on the “Approval of Regulations of the Coordination Council of the Integrated Laboratory System for Discovery of Causes of Extremely Dangerous Infections, Epidemic Supervision and Response”;
- “Rules for Importing and Exporting Elements Causing Extremely Dangerous Infections” - not ad-

opted (the Government of Georgia was instructed to adopt these rules within one month from enactment of the Law, i.e. until 27 July 2007);

- The Law on the Management of the Water Reservoir - not adopted (the Government of Georgia was instructed to develop and submit this draft law to the Parliament of Georgia until 1 January 2008).

3. Law of Georgia on the Rights of Patient, 5 May 2000

➤ **Respective normative acts:**

- The Law does not provide for adoption of any additional normative acts.

4. Law of Georgia on Medical Activity, 8 June 2001

➤ **Respective normative acts:**

- 16 May 2008 Order #122/n of the Minister of Labor, Health and Social Welfare of Georgia on the "Creation of Professional Development Council with the Ministry of Labor, Health and Social Welfare of Georgia and Approval of Its Regulations";
- "Rules of Individual Forms of Continuing Medical Education and Professional Rehabilitation", as well as the procedure and criteria of accreditation - not adopted (the Ministry of Labor, Health and Social Welfare of Georgia was instructed to adopt these rules until 1 March 2009);
- 8 April 2009 Order #135/n of the Minister of Labor, Health and Social Welfare of Georgia on the "Approval of Procedure for Participation, Administration and Evaluation of Post-Diploma Education Alternative to Residency (Professional Training), and the Criteria and Rules of Accreditation of Those Medical Institutions and/or Schools, which Offer Post-Diploma Education (Professional Training) Courses";
- 31 December 2008 Order #311/n of the Minister of Labor, Health and Social Welfare of Georgia on the "Approval of the Form of State Certificate Confirming the Undertaking of Post-Diploma Education (Professional Training) Course, the Integrated Residency and the Residency for Alternative Post-Diploma Education (Professional Training)";
- 31 December 2008 Order #312/n of the Minister of Labor, Health and Social Welfare of Georgia on the "Approval of the Form of Sub-Specialty Certificate - Document Confirming the Right to Independent Medical Activity in Sub-Specialty";
- 3 November 2006 Order #295/n of the Minister of Labor, Health and Social Welfare of Georgia on

the “Approval of the Rules and Conditions for Conducting Integrated Post-Diploma Qualification Exam and the Procedure for Enrolling in the Residency”;

- “Rules and Criteria for Accreditation of Post-Diploma Education (Professional Training) Programs” - not adopted (the Minister of Labor, Health and Social Welfare of Georgia and the Minister of Education and Science of Georgia were instructed to adopt these rules and criteria under a joint order until 1 March 2009);
- 17 December 2010 Resolution #385 of the Government of Georgia on the “Approval of Regulations on the Rules and Conditions for Issuing License for Medical Activity and the Permit of Inpatient Institutions”;
- 16 July 2009 Order #244/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the List of Medical Personnel Having the Right to be Employed and Respective Education in the Medical Institution”.

5. Law of Georgia on Medical-Social Expert Examination, 7 December 2001

➤ **Respective normative acts:**

- 2003 Order #1/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Instruction concerning the Procedure for Determination of Disability Status”;
- 17 March 2003 Order #62/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Instruction concerning the Procedure for Determination of a Child with a Disability Status”;
- 2 April 2007 Order #108/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the List of Diseases and Anatomic and Mental Defects, which Allow the Labor of Persons with Disabilities in Special or Individual Conditions”;
- 27 February 2007 Order #64/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Forms Required for the Medical-Social Expert Examination”.

6. Law of Georgia on Social Protection of Persons with Disabilities, 14 June 1995

➤ **Respective normative acts:**

- The Law does not provide for adoption of any additional normative acts, but it obligates the Government to replace the word “invalid” in all sub-statutory acts with the words “person with disability”.

7. Law of Georgia on the Donation of Blood and Its Components, 21 March 1995

➤ **Respective normative acts:**

- Order of the President of Georgia on the “Measures Stimulating the Donation” – not adopted (the Law sets deadline for adoption no later than 1 June 2007);
- Order of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Procedure for the State Control of Quality of Blood Components, Medications, Substitutes and Preservation Solutions” – not adopted (the Law sets deadline for adoption no later than 1 June 2007);
- 27 September 2007 Order #282/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Mandatory Standards for Functioning of Blood Transfusion Institutions”;
- 5 December 2000 Order #241/n of the Minister of Labor, Health and Social Welfare of Georgia on “Determination of Characteristics against Donation of Blood and Its Components”;
- 14 January 2002 Order #14/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Procedure for Preparation, Storage and Use of Blood and Blood Components”;
- 5 December 2000 Order #242/n of the Minister of Labor, Health and Social Welfare of Georgia on “Further Improvement of Pathologoanatomic Service in Georgia”.

8. Law of Georgia on Transplantation of Human Organs, 23 February 2000

➤ **Respective normative acts:**

- 15 March 2001 Order #100 of the President of Georgia on the “Approval of Instruction for Human Cerebral Death Criteria and Clinical Diagnosis of Cerebral Death and Paraclinic Examination”;
- 23 March 2001 Order #108 of the President of Georgia on the “Approval of Rules of Export-Import of Human Organs”;
- 29 November 2001 Order #419/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Rules of Urgency and Duration of Quarantining Human Organs, Criteria Determining Dangerous Infection Risk among Donors, Criteria for Selection and Testing of Donors and Recipients, Standards of Finding, Taking, Storing and Transplanting Human Organs, Standards of Quality Control of Human Organs and Destruction of Human Organs”;
- 25 December 2000 Order #277/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Creation of the Transplantation Council and Approval of Regulations of the Transplantation

Council, Transplantation Bank, Transplantation Information Center, and the Placenta and Navel Blood Cell Bank”;

- 29-30 November 2001 Joint Order #463-#420/n of the Minister of Labor, Health and Social Welfare of Georgia and the Minister of Justice of Georgia on the “Approval of Procedure for Executing the Decision on Organ Transplantation during Lifetime or after Death”;
- 8 May 2003 Order #110/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Procedure concerning the Taking and Transplantation of Organs under the Cross-Donation Principle”;
- 25 December 2000 Order #276/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Regulations of National Bioethics Council”.

NORMATIVE ACTS REGULATING THE HOSPITAL SECTOR:

- 2 February 2010 Resolution #29 of the Government of Georgia on the “Approval of Minimum Service Standards for the Health Care Providers Participating in the State Insurance Programs”;
- 9 December 2009 Resolution #218 of the Government of Georgia on the “Measures for Insuring the Health of Population within the Framework of State Programs and the Terms of an Insurance Voucher”.

Normative acts regulating the post-diploma education (professional training), continuing professional development and certification:

- 18 April 2007 Order #136/n of the Minister of Labor, Health and Social Welfare of Georgia on the “List of Physician’s Specialties, Adjacent Physician Specialties and the Respective Specialties of Sub-Specialties”;
- 3 November 2006 Order #295/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Rules and Conditions for Conducting Integrated Post-Diploma Qualification Exam and the Procedure for Enrolling in the Residency”;
- 8 April 2009 Order #135/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Procedure for Participation, Administration and Evaluation of Post-Diploma Education Alternative to Residency (Professional Training), and the Criteria and Rules of Accreditation of Those Medical Institutions and/or Schools, which Offer Post-Diploma Education (Professional Training) Courses”;

- 14 April 2003 Order #92/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Procedure for Admitting Junior Physicians to the State Certification Exam”;
- 16 May 2008 Order #122/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Creation of Professional Development Council with the Ministry of Labor, Health and Social Welfare of Georgia and Approval of Its Regulations”;
- 23 January 2004 Order #25/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Measures Needed for Ensuring Participation of Physicians in Continuing Medical Education System to Extend the State Certificate for a New Term”;
- 1 November 2005 Order #274/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Number of Points of Continuing Professional Development Required for Extending the State Certificate for a New Term without Passing the Certification Exam by the Individual Components of Continuing Professional Development, and the Number of Points of Continuing Professional Development Corresponding to Various Forms of Medical Education and the Criteria for Granting the Points of Continuing Professional Development Corresponding to Various Forms of Medical Education”;
- 31 December 2008 Order #310/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Form of the State Certificate”;
- 31 December 2008 Order #312/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Form of Sub-Specialty Certificate - Document Confirming the Right to Independent Medical Activity in Sub-Specialty”.

PHARMACEUTICAL REGULATIONS:

- 14 October 2005 Resolution #176 of the Government of Georgia on the “Approval of Regulations of Clinical Examination of Pharmacological Substances, Pharmaceutical Production, Authorized Pharmacy, and Rules and Conditions for Issuing Permits for Import or Export of Medical Substances Subject to Special Control”;
- 1 September 2005 Resolution #153 of the Government of Georgia on the “Approval of Regulations on the Rules and Conditions for Issuing the License for Medical Activity”;
- 22 October 2009 Resolution #188 of the Government of Georgia on the “List of State Bodies Regulating Other Countries’ or Interstate Pharmaceutical Products”;

- 13 October 2009 Order #331/n of the Minister of Labor, Health and Social Welfare of Georgia on the “List of the First and Third Group Pharmaceutical Products for the Advertising and Retail Sale Purposes”;
 - 20 October 2009 Order #338/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Form and Procedure of Notification of the State Agency for Regulation of Medical Activities by the Seller of Pharmaceutical Products about the Commencement and Completion of Wholesale and Retail Sales”;
 - 23 October 2009 Order #344/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Determination of Rules and Conditions for Verifying by the State Regulatory Body of the Validity of Admittance of Other Countries’ or Interstate Pharmaceutical Products to the Markets Subject to the Control of such State Body”;
 - 26 February 2010 Order #53/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the List of Medications Foreseen under the Terms of the Insurance Voucher within the Framework of the Health Insurance State Program and the Format of Provision of these Medications to the Beneficiary under the Physician’s Prescription”;
 - 13 October 2009 Order #325/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Instruction concerning the Procedure in case of Initial Introduction of Pharmaceutical Products under the Recognition and National Regimes of State Registration of Pharmaceutical Products on the Georgian Market, as well as Differently Packed and Labeled Pharmaceutical Product Already Accepted to the Georgian Market”;
 - 13 October 2009 Order #326/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Rules of Removal/Destruction of Pharmaceutical Products Prohibited on the Georgian Market and the Falsified, Flawed, Wasted and Outdated Pharmaceutical Products”;
 - 3 February 2006 Order #32/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Form of License Certificate of Medical Activity”.
- **Rules of circulation of medications subject to special control:**
- 29 November 1999 Order #465/o of the Minister of Health Care of Georgia on the “Temporary Rules for Approval of the Recipe Forms for Prescription of Substances Subject to Special Control, Medication Forms of such Substances, and Combined Medications Containing such Substances, and their Prescription”;
 - 13-15 March 2000 Joint Order #32/o-#102 of the Minister of Labor, Health and Social Welfare of Georgia and the Minister of Internal Affairs of Georgia on the “Approval of Temporary Rules of

Storage, Registration, Prescription, Provision and Intake of Narcotic Drugs Required for the Contingent Being on Semeiotic Treatment by the Narcotic Analgesics”;

- 10 July 2008 Order #157/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Instruction on Provision of Palliative Care to Persons with Chronic Incurable Diseases”.
- **Post-diploma education (professional training), continuing professional development, certification:**
- 18 April 2007 Order #136/n of the Minister of Labor, Health and Social Welfare of Georgia on the “List of Physician’s Specialties, Adjacent Physician Specialties and the Respective Specialties of Sub-Specialties”;
- 3 November 2006 Order #295/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Rules and Conditions for Conducting Integrated Post-Diploma Qualification Exam and the Procedure for Enrolling in the Residency”;
- 8 April 2009 Order #135/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Procedure for Participation, Administration and Evaluation of Post-Diploma Education Alternative to Residency (Professional Training), and the Criteria and Rules of Accreditation of Those Medical Institutions and/or Schools, which Offer Post-Diploma Education (Professional Training) Courses”;
- 14 April 2003 Order #92/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Procedure for Admitting Junior Physicians to the State Certification Exam”;
- 16 May 2008 Order #122/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Creation of Professional Development Council with the Ministry of Labor, Health and Social Welfare of Georgia and Approval of Its Regulations”;
- 23 January 2004 Order #25/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Measures Needed for Ensuring Participation of Physicians in Continuing Medical Education System to Extend the State Certificate for a New Term”;
- 1 November 2005 Order #274/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Number of Points of Continuing Professional Development Required for Extending the State Certificate for a New Term without Passing the Certification Exam by the Individual Components of Continuing Professional Development, and the Number of Points of Continuing Professional Development Corresponding to Various Forms of Medical Education and the Criteria for Granting the Points of Continuing Professional Development Corresponding to Various Forms of Medical Education”;

- 31 December 2008 Order #310/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Form of the State Certificate”;
- 31 December 2008 Order #312/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Form of Sub-Specialty Certificate - Document Confirming the Right to Independent Medical Activity in Sub-Specialty”.

REGULATION OF PERSONNEL:

- 16 July 2009 Order #244/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the List of Medical Personnel Having the Right to be Employed and Respective Education in the Medical Institution”.

➤ **Rules of administering medical documentation and statistical information:**

- 22 August 2006 Order #224/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Forms of Primary Medical Documentation in the Primary Healthcare Institutions, and the Administration and Filling in of such Forms”;
- 19 March 2009 Order #108/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Procedure for Administration of Inpatient Medical Documentation in Medical Institutions”;
- 9 August 2007 Order #338/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Rules for Filling in the Health Status Certificate and the Form of the Health Status Certificate”;
- 10 March 2003 Order #54/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of the Forms of Medical Certificates to be Issued at the Time of Birth or Death of Person, and the Instruction on Filling in and Issuing such Forms”;
- 17 July 2002 Order #198/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Rules of Storage of Medical Records in the Medical Institutions”;
- 5 April 2005 Order #101/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Rules of Administration and Provision of Medical Statistical Information”.

Rights of a patient, issues related to transplantation, HIV/AIDS, bioethics, pathologoanatomic service, blood and blood components, blood transfusion institutions

Regulations of the National Bioethics Council of Georgia	Regulations of the Council are approved by the 25 December 2000 Order #276/n of the Minister of Labor, Health and Social Welfare of Georgia and are updated by the 20 November 2002 Order #326/n of the Minister of Labor, Health and Social Welfare of Georgia.
29 August 2005 Order #224/n of the Minister of Labor, Health and Social Welfare of Georgia	on the “Approval of regulations of the National Bioethics Council”.
“On Bringing Amendments to the 25 December 2000 Order #276/n of the Minister of Labor, Health and Social Welfare of Georgia and Approval of Composition of the National Bioethics Council”	
“On Bringing Amendments to the 20 November 2002 Order #326/n of the Minister of Labor, Health and Social Welfare of Georgia”	
25 April 2007 Order #140/n of the Minister of Labor, Health and Social Welfare of Georgia	on the “Creation of Transplantation Council and Approval of Regulations of the Transplantation Council, Transplantation Bank, Transplantation Information Center”.
“On Bringing Amendments and Supplements to the 25 December 2000 Order #277/n of the Minister of Labor, Health and Social Welfare of Georgia”	
5 December 2000 Order #242/n of the Minister of Labor, Health and Social Welfare of Georgia	on “Further Improvement of Pathologoanatomic Service in Georgia”.
27 September 2007 Order #282/n of the Minister of Labor, Health and Social Welfare of Georgia	on the “Approval of Mandatory Standards for Functioning of Blood Transfusion Institutions”.
14 January 2002 Order #14/n of the Minister of Labor, Health and Social Welfare of Georgia	on the “Approval of Procedure for Preparation, Storage and Use of Blood and Blood Components”.
5 December 2000 Order #241/n of the Minister of Labor, Health and Social Welfare of Georgia	on “Determination of Characteristics against Donation of Blood and Its Components”.

3 ■ IS READY TO ACT

3.1 TERMINOLOGICAL CASE STUDIES, DISCREPANCIES AND OTHER TECHNICAL FLAWS

The legal analysis of the Laws of Georgia on Public Health, Health Care, Medical Activity, and the Rights of Patient has identified various types of terminological problems as follows:

- Terminological conflicts;
- Terminological duplications;
- Terminological gaps in terms of juridical technique.

INFORMED CONSENT

The term “informed consent” is an example of the first group of flaws listed above. The Law on Health Care defines informed consent as the consent of patient or his/her relative or legal representative on conducting medical intervention necessary for the patient, after explaining the risk to his/her health and life related to such intervention.

However, the Law on the Rights of Patient considers a patient’s consent as the informed consent, if s/he had been provided with the information on:

b.a) Essence and need of medical care;

b.b) Expected results of medical care;

b.c) Risk to a patient’s health and life related to such care;

b.d) Other alternative versions of intended medical care and the accompanying risks and possible effectiveness of such alternatives;

b.e) Expected results of refusal of medical care;

b.f) Financial and social issues related to the above-listed Sub-Paragraphs “b.a” - “b.e”.

These two different definitions make it clear that the informed consent under the Law on Health Care is

in compliance with only a small section of definition of informed consent provided in Article 4 of the Law on the Rights of Patient, and that it significantly differs content-wise.

This specific case contains as the terminological conflict, as well as terminological duplication, as the informed consent defined under the Law on Health Care represents only a small section of the informed consent defined in Article 4 of the Law on the Rights of Patient.

PALLIATIVE CARE

Clear example of terminological duplication is the term “palliative care”, which is although defined identically, but is repeated in the Laws of Georgia on the Rights of Patient and Health Care. Both Laws define “palliative care” as medical care, which does not radically improve the condition of a patient and does not change a poor prognosis of the disease, and which aims at temporarily alleviating a patient’s suffering.

Described duplication may be remedied by two means: firstly, one of the Laws can be linked to the definition in the other Law by the referring norm; secondly, and much preferably, the healthcare legislation could be unified/codified in one legal act - the Code, which is further elaborated on in the present study.

PATIENT

Definitions of the term “patient” have different legal connotations in the Laws of Georgia on the Rights of Patient and Health Care. For instance, the Law on the Rights of Patient defines patient as any person, who uses, needs or intends to use the health care services despite of his/her health status, whereas the Law on Health Care considers a patient to be not any person, but only that person who enjoys medical care despite of his/her health status.

In this case the problem lies in the fact that these two Laws provide totally different legal regulation of the patient’s legal institute, which obviously needs adjustment.

Recommendation: this term must be improved, as on one hand a patient cannot qualify as any person because patient is a subject of concrete legal relations, and on the other hand it is necessary to clarify the definition in terms of correct legal technique and, accordingly, to reflect the entry into legal relations with the health care provider.

GENOME

The Law of Georgia on Health Care applies the term “genome”, but does not provide its definition. Definition of “genome” is found in the Law on the Rights of Patient, and the problem arises accordingly – how

adequate and acceptable is it for the Law on the Rights of Patient to define “genome” for the context of the Law on Health Care?! This flaw has to be remedied, in particular, the Law on Health Care must be supplemented with the definition of “genome”, which will be in compliance with the definitions of this term in other laws, and/or this problem will be resolved by codification/unification of healthcare legislation.

PATIENT’S RELATIVE

The term “patient’s relative” is another example of terminological duplication, which is defined as person, who according to the order determined by Georgian legislation enjoys a preferred right to participate in decision-making related to provision of medical care to a patient or patient’s death. This definition is literally repeated in the Laws on the Rights of Patient and Health Care.

In the above specific case additional problem is created by the content flaw and vagueness, as legislation does not fix the order that would have defined which person enjoys the preferred right to participate in decision-making related to provision of medical care to a patient or patient’s death. Hence, definition of the term “patient’s relative” must contain a referring norm, and in particular the priority order of ascending and descending relatives determined under Article 1336 of the Civil Code of Georgia.

LEGAL REPRESENTATIVE

The term “legal representative” is defined only in the Law on the Rights of Patient, but is applied also in the Laws on Health Care and Medical Activity. In this case there is no problem content-wise, but because the above-mentioned laws are not legally unified and contain independent terminology, this term is unknown for the other two laws and requires definition.

Identical setting is found with respect to the term “patient’s relative”: this term is applied in the text of the Law on Medical Activity without any definition.

HEALTH CARE PROVIDER / PERSON RENDERING HEALTH CARE

Another terminological conflict is found between the terms “health care provider” and “person rendering health care”. The first is provided in the Law of Georgia on Public Health, while the other – in the Law of Georgia on the Rights of Patient. Although these two terms are etymologically different in the words “provider”/“person rendering”, they have the same meaning content-wise, and have different formulation in the laws. In the first case the health care provider is defined as a physical person or legal entity providing healthcare, who has the state certificate or respective medical license for performing independent medical activity; while in the other case a person rendering health care is a person, who provides medical services in accordance with the rules set out by legislation of Georgia.

These definitions do not include and leave beyond regulation the physician's assistants and paramedics, who will attempt to provide medical care independently.

On the other hand, existence of two terms having identical meaning is not justified. It would be reasonable to have one term that could be formulated as follows: "Health care provider is a person, who provides medical services in accordance with the rules set out by legislation of Georgia.

MEDICAL CARE

The term "medical care" is defined only in the Law of Georgia on the Rights of Patient, while the other laws such as the Laws on Public Health, Health Care, and Medical Activity do not provide its definition despite of its numerous applications. Further, the above three laws do not even contain a referring norm, which would have indicated the mandatory application of definition of the term "medical care" under the Law on the Rights of Patient for the purposes of these three laws.

MEDICAL RECORDS

The Law on the Rights of Patient defines the term "medical records" as information entered on the paper or in various sources of information including the computer by the health care provider, which is related to the medical care provided to a patient. Legislation of Georgia (namely the Law on Electronic Signature and Electronic Document) provides the definitions of "electronic" and "material" documents. The definitions available in the Law of Georgia on the Rights of Patient must be brought in compliance with the above-mentioned Law. A referring norm could be introduced and the terms "electronic document" and "material document" could be applied.

Another question relates to the completeness of definition of the term "medical records", i.e. how exhaustive is the wording "information related to the medical care provided to a patient" for this definition and specifically which data should this information include? Thus, this term requires legal improvement.

The same term is applied in the Law on Medical Activity, but is not defined therein, which must be remedied.

IMPLIED CONSENT

Clear example of the flawed norm in terms of legal technique is the term "implied consent", which is defined as the situation, when a patient has asked a physician for a medical care, while the physician, despite the absence of a written or verbal agreement, has talked to him/her, examined him/her, etc.

It is unacceptable for the definition of such important legal institute provided in the law, when the definition of a patient's consent is regulated, not to provide its exhaustive and unambiguous definition and to include phrases such as "etc."

Application of the word "situation" is unacceptable in terms of law-making. It is possible to use the word "setting/circumstance" instead, or even the wording "legal relations". In addition, the definition must describe in full the actions taken by a physician towards a patient or a general term denoting such actions must be used, for example - medical care.

Thus, the above-mentioned terminological conflicts, discrepancies and other flaws identified in the healthcare legislation must certainly be amended and remedied.

TERM	CONFLICT	DUPLICATION	TECHNICAL GAP	REMARK/ CLARIFICATION
Informed consent	✓	✓		
Patient	✓	✓	✓	
Genome			✓	
Patient's relative		✓	✓	
Legal representative			✓	
Health care provider	✓	✓	✓	
Medical care			✓	
Medical records			✓	
Implied consent			✓	
Palliative care		✓		

4 ■ NEEDS TO DECIDE, THEN ACT

4.1 MEDICAL MALPRACTICE

The Law on Health Care defines medical malpractice as *unintentional diagnostic and/or therapeutic measures prescribed improperly for a patient's condition by a physician*, which has become a direct cause of inflicted damage. There are several flaws in respect of this legal institute. Firstly, the legal language must be improved. In particular, the word "practice" used in the term includes in itself as action, as well as the act of omission, which is not reflected in the definition of the term. Further, the word "unintentional" is **flawed in terms of legal technique** and requires replacement with a respective legal term, such as "negligence". It is also unclear what kind of damage is implied, i.e. it should be defined what could be meant under the damage.

Apart from the flawed legal technique and legal correctness, the content problem of the above legal institute is of greater importance. It needs to be essentially amended. Namely:

The definition provided in the Law on Health Care implies that a physician is the only responsible person for medical malpractice, and that medical malpractice is in fact equaled to physician's malpractice, which is wrong. Medical malpractice can be caused by medical institution and/or any professional (physician, physician's assistant, technical personnel, etc.) involved in the process of medical care. It is recognized in the US, where this problem is of special concern and there are number of legal regulations resulting from significant medical and court practice, that a vast portion of medical malpractice accounts for the errors of the very institutions and not the physicians or other professionals. Collecting any statistics in this respect in Georgia is impossible, but in the opinion of medical experts the presumable picture should be approximately the same. Therefore, **to solve this content-related legal problem it is necessary, when defining this term, to use the term "health care provider" instead of the word "physician"**, which includes as the professionals involved in health care, as well as the institution. Experience of western states illustrates the same. The term "health care provider" is used when defining the well-known term "medical malpractice".

The words "diagnostic and/or therapeutic measures prescribed improperly for a patient's condition" used in the term also need to be amended, as they provide grounds for vague and diverse interpretations.

The word "damage" needs to be definitely detailed. It should be clear what kind of damage was inflicted to a patient, which could be material - patient's health or life, as well as moral - although not inflicting damage to the life and health of a patient, but having influence on person's emotions, thus causing moral damage.

Based on all of the above, the term “medical malpractice” could be formulated as follows:

“Medical practice shall be an unlawful action or act of omission of a health care provider, which has resulted in patient’s death or disorganization of health, or has inflicted moral and/or material damage to a patient.”

4.2 CONFIDENTIALITY OF INFORMATION

Confidentiality of information on a patient is one of the most crucial issues. According to the international practice, information on a patient is a personal secret, and save strictly defined exceptions, such information is not available to anyone without a patient’s permission.

In the legal reality of Georgia the confidentiality of information on a patient rests on the article concerning the inviolability of private life as recognized by the Constitution of Georgia, in particular: - *Everyone’s private life, place of personal activity, personal records, correspondence, communication by telephone or other technical means, as well as messages received through technical means shall be inviolable.* Restriction of the aforementioned rights shall be permissible by a court decision or also without such decision in the case of urgent necessity provided for by law.

Under the General Administrative Code of Georgia, a private secret, i.e. the information on a person, carries the status of secret information, in particular - information stored in a public institution, as well as information received, processed, created or sent by a public institution or servant in connection with the official activities, which contains a state, commercial or private secret.

Moreover, the personal data are regarded as a private secret by a person, about whom such information exists.

Healthcare legislation of Georgia is not unambiguous towards this issue either. However paradoxical, the Laws of Georgia on Health Care, the Rights of Patient and Medical Activity offer **different interpretations** of protection or non-protection of information on patients.

The Law on Health Care does not ensure the protection of the right of patient to confidentiality, and furthermore, even violates such right. Pursuant to this Law, *“Medical employee and all other employees of a medical institution shall be obligated to preserve medical (doctoral) secret, except cases when the disclosure of confidential information is requested by a relative or legal representative of the deceased person, the court, investigative bodies, or this is necessary for ensuring public security and protection of the rights and freedoms of others.”*

It is implied from the above that if any investigator requests from a patient's physician or medical institution a patient's health record without a court decision, s/he is entitled to receive such information in accordance with this normative act.

The Law on the Rights of Patient contains a separate chapter titled Confidentiality and Inviolability of Private Life. Yet, despite the above title, the mechanism of protection of information on a patient is not evident. To the contrary, the disclosure of confidential information by a health care provider is permitted, if nondisclosure of information endangers the life and/or health of a third person (whose identity is established).

Relatively better mechanism of regulation is available in the Law on Medical Activity, which provides the list of concrete cases when the entity of independent medical activity has the right to disclose confidential information on the health status and private life of a patient, and in particular, if:

- a) A patient authorizes to disclose the information;*
- b) Nondisclosure of information endangers the health and/or life of a third person (whose identity is established);*
- c) There is a reasonable doubt as to the existence of the disease subject to mandatory registration;*
- d) The information is provided to other medical personnel participating in the medical care;*
- e) Disclosure of information is required for the forensic medical examination;*
- f) Disclosure of information is requested by the law-enforcement agencies in accordance with the court decision;*
- g) The information is provided to the state agencies for establishing social privileges to a patient. In such case a patient's consent to disclosure of information is required;*
- h) During the application of information for education/scientific purposes the data are presented so that identifying a person is impossible.*

1. This Article does not ensure the protection of a patient's right to confidentiality either, namely, Sub-Paragraphs (c), (d) and (e) require revision.
2. Sub-Paragraph (c) of this Article does not define "reasonable doubt", and therefore gives ground to wide interpretations, which may infringe upon the constitutional right of inviolability of private secret.

3. It should be definitely specified in Sub-Paragraph (d) that the information is provided to other medical personnel participating in the medical care of this patient and not the personnel participating in the medical care generally. This may also cover the cases when the personnel is invited from the other medical institution for the council of physicians and/or obtaining the second opinion, however, a patient's consent must be required.
4. It is unclear in Sub-Paragraph (e) as to why is it justified to disclose information for the forensic medical examination. We believe in such cases either the court decision or a patient's or his/her legal representative's consent should be required.

Recommendation: In light of the above, the healthcare legislation of Georgia does not ensure the protection of confidentiality of information on a patient. The Code of Administrative Offences of Georgia does not impose responsibility for the breach of confidentiality of information on a patient. Thus, it is necessary to undertake the following legislative amendments:

The Law on Health Care should be amended so that the information on a patient is available to third persons, including the investigative bodies, based on a court decision only;

The following provision - "The disclosure of confidential information by a health care provider is permitted, if nondisclosure of information endangers the life and/or health of a third person (whose identity is established)." - must be clearly formulated in the Law on the Rights of Patient. This provision is rather vague and may become a ground for violating the patient's right to confidentiality.

The following amendments must be made to the Law on Medical Activity, which will:

- Define "reasonable doubt" in Sub-Paragraph (c) of Article 5.1, as under the effective text this term is a subject of wide interpretations, which might breach the constitutional right of inviolability of personal secret;
- Sub-Paragraph (d) of Article 5.2 will necessarily specify that the information is provided to the other medical personnel involved in medical care of this patient and not the personnel involved in medical care generally. This may also cover the cases when the personnel is invited from the other medical institution for the council of physicians and/or obtaining the second opinion, however, a patient's consent must be required;
- It is unclear in Sub-Paragraph (e) of Article 5.3 as to why is it justified to disclose information for the forensic medical examination - either the court decision or a patient's or his/her legal representative's consent should be required for disclosing the information.

4.2.1 Medical Ethics Commission

Setting up, functioning and regulatory framework of the Medical Ethics Commission in Georgia is regulated by the Order of the Minister of Labor, Health and Social Welfare of Georgia, which has approved the internal regulations of the Medical Ethics Commission.

Humanization of medical practice in the country and promotion of the patients' rights, their dignity and personal autonomy through the education of personnel of medical institutions, identification and analysis of ethical aspects of problems arising in the medical care process, and development of relevant recommendations were to be named as an objective of setting up the Medical Ethics Commission.

Pursuant to the Order, the Medical Ethics Commission is set up with the medical institutions, including the medical research institutes and higher medical education institutions, as a consulting body of medical personnel in the ethical issues of medical care.

In accordance with the normative act, each Commission drafts its own charter and detailed description of working procedures in light of the present recommendations and carries out its activities within the framework of the legislation of Georgia and the mentioned charter.

Further on, the Order contains language, which on one hand is flawed in terms of legal technique, and on the other hand contradicts the legal purpose of the Minister's Order as a normative act. In particular, under the Minister's Order setting up of the Ethics Commissions of hospitals is recommended in any medical institution where possible. In other words, the Minister's Order is of a recommendatory nature and its provisions are not subject to mandatory fulfillment.

On the other hand, the Law of Georgia on Normative Acts directly indicates that a normative act is a legal act adopted (issued) by the authorized state or local authority (official) in accordance with the rules established by the legislation of Georgia, which contains a general rule of its permanent or temporary and multiple application and is mandatory for fulfillment.

Hence, the Minister's Order in legal terms contradicts the content and legislative purpose of that very act, for which it had been issued. Georgian legal domain is familiar with the practice of so-called conceptual documents, which are of recommendatory nature and may become the guiding principles for this or that institution, but when the Minister's order is concerned, which is a normative act, it is definitely mandatory for fulfillment.

The said Order is problematic not only in the terms of normative nature, but the legal technique as well. It is flawed in respect of legal terminology and contains analytical-narrative wordings, which are totally unjustified and unacceptable for a normative act.

In addition to the above, the internal regulations of the Medical Ethics Commission approved by the Order need to be revised content-wise in terms of sharing the international practice.

Namely, the composition of the Medical Ethics Commission needs to be revised, according to which the Commission consists of: ethicist (bioethicist), clergyman, lawyer, public representative and there is a clear reservation that the Commission's mandatory member and chairperson is the medical director of a medical institution (chief doctor). Furthermore, according to the referenced commentary - "Setting up of the Medical Ethics Commission "at a high level" and subjecting it to the chief doctor of a medical institution is of special significance. This is important for emphasizing the significance of the Medical Ethics Commission itself and the recommendations developed by it. Establishment of a Medical Ethics Commission as a totally independent body (not accountable before the administrations) undermines its significance. At least, this is the opinion of experts of countries (Netherlands, England, USA) having sufficient experience in this field."

Various aspects are identified in view of the US, European and Australian experience. According to the US practice, the so-called behavior and ethics councils should consist of 5 or more members, including at least one health scientist professional, one health non-scientist professional, and the health professional who is not affiliated with that specific organization where the Medical Ethics Council is set up. Further, this council should include persons well aware of the standards and rules of jurisprudence and professional ethics and behavior. Special membership is possible for the defender of the rights and interests of persons with disabilities.

According to the European forum of successful clinical practice, the Medical Ethics Commission must consist of two practicing physicians, who are experienced in biomedicine and are not affiliated with a medical institution. In addition, there should be one lawyer, one person of free occupation (public representative), and one doctor's assistant or pharmacist.

Pursuant to the recommendations, the Medical Ethics Commission must more or less observe the gender and age balance and take into account the cultural specifics of the society.

In accordance with the 1996 recommendations of the Australian Healthcare Ethics Committee, the chairperson of the Ethics Commission should not be an institution's employee or a person otherwise affiliated to it. Serving as members should be a professional doctor, religious representative, local community leader and a doctor's assistant.

Thus, the Minister's Order should be brought into compliance with international experience and successful practice of the Medical Ethics Commissions.

Unfortunately, in accordance with the internal regulations of the Ethics Commission approved by the Order, the mechanism of setting up the Commission is not determined and the powers and respective procedures are not clearly defined and delimited.

A supervising mechanism should definitely exist, under which the medical institutions will be obligated to really set up and enact the Medical Ethics Commissions, which in itself is a vital foundation for protecting the patients' rights and improving and developing the services in a healthcare sector. As a first priority in this area, the licensing standards of medical institutions should be revised, which in this respect will obligate the management of an institution to set up and promote the proper functioning of the Medical Ethics Commission.

Recommendation: Hence, the above-described Order should be newly formulated for it to clearly define: the mechanism of setting up the Medical Ethics Commission regulated under the Order, composition of the Commission, delimitation of powers.

The mechanism of supervision over the Commission's implementation is rather vague, insufficient and does not meet the best practices of international experience.

4.3 CONTINUING PROFESSIONAL DEVELOPMENT

4.3.1 Notion and brief description of the problem

Continuing Professional Development (CPD) is the subsequent process of the higher medical education and post-diploma education (professional training), which is continuing throughout the entire professional activity of an entity of independent medical activity.

CPD comprises all activities carried out by the physicians formally or informally, pursuant to the requirements of patients and aimed at maintaining, updating, developing and deepening their knowledge, experience and skills.

Physician's activity is based on the principle of autonomy and independence, which means that a physician should act in the best interests of a patient and should be free from any external improper interference in this process.

Caring after CPD is simultaneously a physician's professional duty and a prerequisite of improved quality of medical care. A physician's will - a desire to maintain high level of professional development - is a main driving force of CPD.

4.3.2 The law

a. Global Standards

The analysis of CPD systems in the medical field in various countries worldwide makes it impossible to directly pinpoint specific institutions playing a leading role in the physicians' CPD process. Involved in this

process are various players including the physicians and multinational CPD providers. The volume and interdependence of their obligations varies extensively in different parts of the world and their roles and competence are mostly not clearly defined.

In majority of cases, a key role is played by the medical professional organizations, which carry out the general planning and coordination of CPD activities, including the registration and documentation of these activities. Medical professional organizations are the main initiators, suppliers and supporters of CPD. Physicians themselves also play an important role in the CPD process.

CPD is legally regulated in many states, however, such regulation is mostly flexible and free, even in such countries where the repeated certification of physicians is established.

The World Federation for Medical Education (WFME) existing with the World Health Organization (WHO) has developed in 2003 the global standards of CPD, which represent the action model for each country. In accordance with these standards:

1. Medical professional organizations, through consultations with the relevant state authorities (central and local) and employers should publicly determine the mission and expected results of CPD. The mission and expected results statement should encompass the general and specific issues of national and regional policy in this field and describe the expectations towards the physicians in terms of maintaining and developing their competence.
2. CPD should serve raising the professionalism of physicians and provide them a possibility to act autonomously in the best interests of their patients and the society.
3. CPD must be recognized as an integral part of medical practice and be reflected accordingly in the budgets, as well as in the course of resource management and time planning. It should be applied so that the improvements and achievements in the medical field are introduced in practice.
4. CPD management - physicians should bear overall responsibility for the planning and implementation of their own, individual CPD activities. Medical professional organizations should plan CPD activities and fund and maintain them in accordance with the requirements of their members.
5. CPD providers should be the professional associations and organizations, national and international medical scientific societies, medical schools/universities, institutes providing post-diploma professional education, employers and other providers, such as the state health care institutions.
6. CPD recognition - there should be a system that ensures the recognition of CPD providers or the individual CPD activities. CPD providers must meet the education quality and other criteria determined by the law. They should demonstrate that they apply acceptable education methods and technology. The possibility of conflict of interests must be ruled out to the extent possible. Active

involvement of medical schools in the process of provision of CPD is desirable.

7. The official structure of CPD should be developed and approved by medical professional organizations through consultations with relevant state authorities and should be based on recognized methods and criteria.
8. Funding of CPD should be a constituent part of the health care system. Sources of funding should be selected so as to ensure maximum independence of physicians when selecting the CPD activities. Financial involvement of pharmaceutical companies and companies producing medical technologies in the CPD activities is prohibited because of their conflict of interests. Such organizations can be neither providers nor funders of CPD.

b. Modern Trends of Legislative Regulation of CPD

In the current world there is mainly a twofold attitude towards the CPD. CPD is either voluntary or mandatory. In the countries where CPD is mandatory, it is linked with re-certification or re-licensing of physicians.

In the European states there are national bodies of CPD accreditation, which in the course of accrediting the CPD providers and activities are guided by the European consensus formulated in the charter of the European Union of Medical Specialists (UEMS) on the "Continuing Medical Education" and its annexes, as well as the guidelines developed by the Union. In addition, national bodies of accreditation grant credits, accumulation of which is necessary in the countries where CPD is a mandatory condition of re-certification and re-licensing. Further, the accreditation of international CPD activity providers at the European level is carried out by the CPD Accreditation Council of Europe existing with UEMS, which functions since 2000. Yet, to obtain the final confirmations, this Council addresses the national body of accreditation of a respective country (country, where the specific CPD activity is carried out).

UEMS pursues non-mandatory CPD policy, whereas in numerous European states CPD is mandatory and is related to re-certification or re-licensing of physicians or maintenance of labor contracts with them. In general, there is a trend in the European states that CPD should become mandatory. CPD is mandatory in the majority of US states and Canada.

c. Legislation of Georgia

The Law of Georgia on Health Care defines CPD as a subsequent period of higher medical education and post-graduate professional training, which continues throughout the entire professional activities of an entity of independent medical activity and is an integral part of medical activity.

Pursuant to Article 97 of the same Law, after receiving the higher medical education the professional training of physicians includes post-graduate professional training and CPD. Post-graduate professional

training aims at mastering any of the doctor's specialties, while CPD aims to maintain professional competence of a physician so that his/her theoretic knowledge and practical skills are consistent with the achievements and technologies of contemporary medicine.

According to Article 100 of the Law on Health Care, the components of CPD of a physician, its relevant forms and the criteria and rules of evaluation of physician's participation must be determined by the Law of Georgia on Medical Activity and other legislative acts of Georgia.

The Law of Georgia on Medical Activity, together with the definition of CPD, which slightly differs from the definition provided in the Law on Health Care ("Continuing Professional Development - a subsequent period of higher medical education and post-diploma education (professional training), which continues throughout the entire professional activities of an entity of independent medical activity and is an integral part of medical activity. It aims to ensure the consistency of theoretic knowledge and practical skills of an entity of independent medical activity with the contemporary medical achievements and technologies"), indeed determines the components of CPD.

Pursuant to Article 29¹ of the Law on Medical Activity, CPD components are: (a) continuing medical education; (b) continuing medical practice; (c) professional rehabilitation; and (d) continuing improvement of quality of medical care. The same Law defines each of the listed components. In particular, in accordance with the definitions of the Law:

Continuing medical education	<i>Component of CPD, which includes as self-education, as well as participation in formalized education/training programs, as well as other activities promoting the enhancement and improvement of a physician's professional knowledge and skills (participation in congresses and conferences, publication of works, teaching, etc.);</i>
Continuing medical practice	<i>Component of CPD, which implies continuing practical clinical activities in a concrete specialty and is evaluated under relevant data (number of patients, number of manipulations to be carried out, duration of practice, etc.);</i>
Professional rehabilitation	<i>Component of CPD, which implies undertaking of a relatively long-term (1-5 months) education/training course and aims at restoring a physician's professional competence in a specific medical specialty;</i>
Continuing improvement of quality of medical care	<i>Component of CPD, which implies the periodic evaluation of the quality and results of a physician's clinical activities and a gradual improvement of respective indicators.</i>

In accordance with the same Article 29¹ of the Law on Medical Activity, the separate forms of CPD's first component - continuing medical education - and the professional rehabilitation rules of the third component, as well as the rules and criteria of accreditation are developed by the **Professional Development Council** existing with the Ministry of Labor, Health and Social Welfare of Georgia and are approved by the Ministry. Pursuant to Article 20.7(e) of the same Law, the Professional Development Council in addition carries out the measures of organization, management and monitoring of the continuing medical education and CPD processes.

Internal regulations of the Council approved by the 16 May 2008 Order #122/n of the Minister of Labor, Health and Social Welfare of Georgia provide more specific powers and functions of the Professional Development Council in the CPD process, Article 2 of which stipulates that the Council carries out the following activities:

- Ensures the organization, management and monitoring of the continuing medical education and CPD processes;
- Examines the issues of continuing medical education and CPD, develops relevant recommendations and participates in drafting of normative acts;
- Develops the criteria and rules of accreditation of the continuing medical education programs (including the adjacent physician specialties and sub-specialties), as well as the separate forms of continuing medical education and the rules, accreditation procedure and criteria of professional rehabilitation; accredits these programs and submits them to the Minister for approval in accordance with the requirements of the law;
- Carries out relevant measures and makes respective decisions in relation to the continuing medical education and CPD, unless otherwise provided in the law.

Thus, the Professional Development Council is charged with all important regulatory and supervisory functions in the field of CPD, however, regardless of the requirements of the Laws of Georgia on Health Care and Medical Activity, according to which the Council had to develop until 1 March 2009 the separate forms of continuing medical education and the rules of professional rehabilitation, as well as the accreditation procedure and criteria, the Council thus far has not issued any normative act or carried out any specific activity.

Meanwhile, two normative acts have been adopted in Georgia in relation to CPD, which are still in effect: (a) 23 January 2004 Order #25/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Measures Needed for Ensuring Participation of Physicians in Continuing Medical Education System to Extend the State Certificate for a New Term”; and (b) 1 November 2005 Order #274/n on the “Approval of Number of Points of Continuing Professional Development Required for Extending the State Certificate for a New Term without Passing the Certification Exam by the Individual Components of Continuing Professional Development, and the Number of Points of Continuing Professional Development Corresponding to Various Forms of Medical Education and the Criteria for Granting the Points of Continuing Professional Development Corresponding to Various Forms of Medical Education”.

These acts, in light of their titles, already contradict Article 25 of the Law on Medical Activity, which does not provide for re-certification of entities of independent medical activity. Pursuant to this Article, the state certificate, once granted, is in force for indefinite period of time. Accordingly, meeting the CPD requirements is not the criterion determining the re-certification.

Nevertheless, the law-maker has not revoked the above-mentioned acts, which create certain difficulties for the application of CPD as a mechanism of professional development.

On one hand, the legislator recognizes CPD as an integral part of medical activity and an essential component of professional qualification of physicians and subjects it to the state regulation (charges the state body - Professional Development Council - with the functions of organization, management and monitoring of CPD, determination of the criteria and rules of accreditation of CPD programs, and accreditation of such programs), which almost results in mandatory recognition of CPD; on the other hand, the legislator states that CPD is a physician's right only and not the obligation. Pursuant to Article 29¹ of the Law on Medical Activity, an entity of independent medical activity **may** (i.e. is not obligated) participate in the CPD system, adjust its medical practice to the achievements of contemporary medicine and improve all aspects of this activity.

Thus, a physician in Georgia, who obtains the certificate of independent medical activity for lifetime, participates in the CPD activities only on a voluntary basis. Although the legislator views such participation in activities as an integral part of this physician's activities, overall it is not linked to any specific legal consequences.

Recommendations: Mandatory nature of CPD - any decision with respect to the mandatory nature of the CPD system requires arguments and evidence. In case of recognizing CPD as mandatory, participation in the CPD activities and accumulation of respective points (credits) must be related to certain legal consequences for a physician (maintenance of certificate of independent medical activity, re-certification, extension of labor contract, etc.). Only afterwards should the legislation be brought in compliance with the specific policy area.

Further regulation of CPD - the Ministry/Council should adopt normative acts, which will define the separate forms of continuing medical education and rules of professional rehabilitation, as well as the accreditation procedure and criteria. Preferably the state should also develop certain requirements towards the CPD providers. It should be defined who plays a key role in the CPD process: professional medical organizations, medical schools and universities, employers or the state institutions. A specific procedure of accreditation of providers should be written out. If the legislator aims at voluntariness of CPD, then the main emphasis for regulation may be shifted towards professional organizations, so that they develop the key system and standards of CPD. It is desirable that this process takes into consideration the requirements of global standards and the experience of the European states.

DEFINITION OF TERM - CONTINUING IMPROVEMENT OF QUALITY OF MEDICAL CARE

The law:

The Law on Medical Activity provides the following definition of the term “continuing improvement of quality of medical care”: Component of CPD, which implies the periodic evaluation of the quality and results of a physician’s clinical activities and a gradual improvement of respective indicators.

Analysis: the above definition is improper. The term “medical care” is wider than the “medical activity”; and the continuing improvement of quality of medical care is not the component of CPD. To the contrary, it comprises in itself CPD, as the improvement of quality of medical care implies not only the continuing professional development of a physician, but the continuing development of all components of the medical care process, so that the human health is protected and preserved to a maximum extent. This is an interdisciplinary process, which aims to create, maintain and improve the effective system of protection of individual and public health by raising the standards of preventive, diagnostic, therapeutic and rehabilitation measures.

4.4 INFORMING PATIENTS ABOUT THEIR RIGHTS

Informing patients about their rights is one of the vital and significant rights among that of a patient. Hence, legal reinforcement and monitoring of exercise of this right is essential.

Regulation of this issue under the healthcare legislation of Georgia requires legal improvement and creation of new mechanisms. In particular, although the Law of Georgia on the Rights of Patient contains an independent chapter on the right to receive information, number of gaps has been identified therein.

The Law states that a patient, and in case of his/her consent or legal incapacity, his/her relative or legal representative enjoys the right to:

- Get familiar with medical records and request to amend the existing information on a patient. Medical records store as the pre-amendment information, as well as the new information provided by a patient, his/her relative or legal representative;
- Request copies of any part of medical records.

To receive information on:

- Existing resources of medical care and the types, fees and forms of payment for their receipt;
- The rights and obligations of a patient under the legislation of Georgia and the internal regulations of a medical institution;

- Intended prophylactic, diagnostic, treatment and rehabilitation services, their accompanying risks and possible effectiveness;
- Results of medical examinations;
- Other, alternative versions of intended medical care, their accompanying risks and possible effectiveness;
- Expected results of stated refusal of intended medical care;
- Diagnosis and presumable prognosis, as well as the treatment process;
- Identity and professional experience of person providing medical care.

It is important that the above text provides for the patient's right to receive information on a number of issues, however, several problems are worth noting in this case:

First: - the list of issues, with respect to which a patient enjoys the right to receive information on, is exhaustive, which we believe is a restriction of a patient's right. There should necessarily be introduced the language, according to which a patient will have the right to receive any other medical information related to his/her medical history, treatment procedures and personal identity.

Second: - although on one hand the law grants a patient or his/her legal representative the right to receive information, on the other hand the law is silent on the obligation of a medical institution or medical personnel to provide such information.

The **issue of restriction of provision of medical information on a patient's health status or otherwise related to a patient** is problematic. Pursuant to the Law on the Rights of Patient, "a patient may be denied information on his/her health status or the volume of such information may be reduced, if there is a substantiated assumption that the receipt of full information will cause serious damage to a patient's health. Full information on his/her health status will be provided to a patient if s/he so insists. The decision on non-provision of information or restriction of its volume is confirmed by the Medical Ethics Commission, while in case of absence of the latter in medical institution - by another physician".

Three problems are identified in the above wording:

Substantiated assumption absolutely needs a definition. It may be that the Law does not define this term, but the so-called guidelines approved by the Minister's order should definitely exist.

Insistence - this term is unacceptable in terms of law-making and proper legal technique. It is absolutely sufficient for a demand to exist without any variations.

According to the European experience (e.g. the Finnish Act on the Rights of Patients), medical institutions are obligated to have in the institution the position of Medical Ombudsman, which informs the patients on their rights and monitors the process of provision of information to patients. Should the patients be dissatisfied with medical care or have certain claims against this or that physician, they have the possibility to address the Medical Ombudsman with verbal or written complaints.

Thus, in parallel with remedying a number of legal issues described above, it is crucial to create a legal framework for establishing the institute of Medical Ombudsman, which will be a significant mechanism in terms of informing and protecting the rights of patients on their rights.

4.5 SAFETY OF MEDICAL DEVICES

4.5.1 The law

a. Existing Normative Acts:

The Law of Georgia on “Certification of Production and Service”	
The Law of Georgia on “Standardization”	
The Law of Georgia on “Ensuring Uniformity of Measurements”	
The Civil Code of Georgia	
The Regulations of the Ministry of Labor, Health and Social Welfare of Georgia approved by the 31 December 2005 Resolution #249 of the Government of Georgia	
“Procedure for Registration of Medical Technical Appliances” approved by the 10 December 2003 Order #318/n of the Minister of Labor, Health and Social Welfare of Georgia	
6 January 1999 Order #1/o of the Minister of Health Care of Georgia	<i>on “Urgent Measures for Bringing the Exploitation and Safety of Medical Technical Appliances in the Healthcare System, as well as their Procurement Works into Compliance with the Established Rules”.</i>
4 March 2003 Order #41/n of the Minister of Labor, Health and Social Welfare of Georgia	<i>on the “Approval of Sanitary Norms Ensuring Radiation Protection during the Medical X-Ray Radiological Diagnostic Procedures and Treatment”.</i>
27 September 2007 Order #282/n of the Minister of Labor, Health and Social Welfare of Georgia	<i>on the “Approval of Mandatory Standards for Functioning of Blood Transfusion Institutions”.</i>
2 February 2010 Resolution #29 of the Government of Georgia	<i>on the “Approval of Minimum Service Standards for the Health Care Providers Participating in the State Insurance Programs”.</i>
22 November 2010 Resolution #359 of the Government of Georgia	<i>on the “Approval of technical Regulations of High Risk Medical Activities”.</i>
25 August 2010 Order #1140 of the Government of Georgia	<i>on the “Approval of the Governmental Program for the Legislative Reform in Standardization, Accreditation, Evaluation of Conformity, Technical Regulation and Metrology and the Adoption of Technical Regulations”.</i>

b. Definition

Developed states worldwide pay vast attention to the definition of the term “medical devices”, majority of which has defined this term in domestic legislation. One of the most perfect and exhaustive is the definition used in the European Union, as provided in the 2007/47 EC Directive.

To denote medical devices, the legislation of Georgia applies the term “medical technical appliance”, which is defined in Article 2 of the “Procedure for Registration of Medical Technical Appliances” approved by the 10 December 2003 Order #318/n of the Minister of Labor, Health and Social Welfare of Georgia. Pursuant to this definition, a **medical technical appliance** is a medical technical product used for the prophylactics, diagnostics and treatment of diseases subject to the state registration under the order of the Minister of Labor, Health and Social Welfare of Georgia, and patient care and/or support of these processes (medical technical good): including medical equipment, devices, tools, appliances, installments, sets, instruments, medical optical and prosthetic-orthopedic products, supplemental materials, medical furniture, medical clothing, medical ware, nursing objects, etc.

As it is clear under this definition, a medical technical appliance is a collective term containing in itself other terms denoting medical devices, such as: “medical equipment”, “medical devices and tools”, “medical appliance”, “medical sets”, “medical instruments”, “medical optics”, “prosthetic-orthopedic products”, “supplemental materials”, “medical furniture”, “medical clothing”, “medical ware” and “nursing objects”.

Each of the above-mentioned terms is defined under the same Order.

Order #318/n differentiates two groups of medical technical appliances: medical technical appliances of single use and medical technical appliances of multiple use.

c. Classification

Legislation of Georgia does not contain the requirement of classification of medical devices and none of the laws and sub-statutory acts provides such classification, while to ensure the safety of medical devices, globally it was found necessary to classify the devices by the quality of impact of these devices on human life and health.

Classifications developed by Canada, the United States of America and the European Union are a good example of classification of medical devices. According to these classifications, medical devices in Canada are divided into 4 groups, 3 groups in the US, while the European Union applies the following categories: Class I (Is & Im), Class IIa, Class IIb, Class III.

Under the example of the United States of America, the first class covers medical devices, which are not designed for supporting and preserving the human life functions, and which do not play an essential role in the prevention of health disorder. Accordingly, these devices do not create a potentially high risk

of disease or other injuries (e.g. elastic bandage, examination gloves, wheelchair, etc.). Such devices are subject only to the general control of quality and are often freed from stricter regulation.

Second class comprises devices that create average risk to a patient's life and health. Apart from the general control, such devices are subject to special control (e.g. powered wheelchairs, transfusion pumps). There are certain requirements in respect of majority of such devices: obtaining a permit for appearing on a market, existence of special label, compliance with special standards, and being under post-market-appearance observation.

Third class includes the devices that pose a high risk to human life and health. They require obtaining a permit prior to appearing on the market, and usually are subject to preliminary medical examinations for establishing their safety and efficiency. This class mostly covers the devices that are designed for supporting and preserving the human life functions or play an essential role in the process of prevention of health disorder (e.g. transplant pacemakers, pulse generators, HIV diagnostic tests, automatic external defibrillators, various implants).

Definitions of "safe production" and "unsafe production", as provided in the article on definition of terms of the Law of Georgia on Certification of Production and Service, may be regarded as a certain attempt of classification of production (under production meaning the medical devices as well) in Georgia. Pursuant to Article 3 of this Law, safe production is defined as a good or service, which at the time of normal and reasonable application does not contain risks or contains only a minimum acceptable risk in the conditions of high degree of protection of human safety and health; whereas unsafe production is defined as a good or service, which is not in compliance with the definition of "safe production" provided in this Article.

In accordance with Article 6 of the same Law, when determining the safety of production and high degree of health protection, the following must be taken into account:

- a) Characteristics of production, including the instructions concerning its content, packaging, assembly and protection;
- b) Impact on other production, when its application with such production is presumable;
- c) Presentation and labeling of production, instruction concerning the use and sale of production, any other information or reference provided by a manufacturer;
- d) Category of consumers subject to potential risk at the time of use of the production, and especially children.

Pursuant to Paragraph 2 of Article 1 of the same Law, certain aspects of safety of specific production or separate categories of risk associated with the production are regulated under technical regulations developed by a respective field ministry or other state institution. When developing technical regulations, they should build on the relevant EU directives and other normative acts.

Despite the requirements of the Law, above-mentioned technical regulations concerning the medical devices are not currently developed, while without technical regulations the definitions of safe and unsafe production are quite general, incomplete, and cannot be used for classifying the medical devices.

d. Standardization, Calibration, Establishment of Conformity (Certification)

International Requirements

In effect in the European Union are the 1993 Directive 93/42/EEC concerning Medical Devices, the 1998 Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices, the 1990 Directive 90/385/EEC concerning Active Implantable Medical Devices, and other related directives aimed at harmonizing the laws on medical devices in the European states. The manufacturer must meet the requirements of above-mentioned directives for legally placing its medical devices on the European market.

Pursuant to the Directive 93/42/EEC, a medical device must have a certificate of conformity for it to be used in the EU states. This certificate is issued by a legal entity of public or private law having respective accreditation. Less risky devices belonging to the first class may be certified by the manufacturer itself. Medical devices certified in EU are marked with the sign CE on packaging. They must be accompanied with harmonized pictograms and standardized logos, instructions for use, expiration dates, manufacturer details, references whether the device is sterile or reusable or not, etc.

Apart from the EU directives, widely used worldwide are the standards adopted by the International Organization for Standardization (ISO) and the European Committee for Standardization (CEN). ISO standards for medical devices are given in the ICS 11.100.20 and ICS 11.040 group standards. ISO 13485 and ISO 14971 are used to regulate the quality and risk management system in the area of medical devices. In addition, there are standards for the electric appliances (IEC 60601-1 and IEC 62304) and packaging of medical devices.

Please see below for the list of international standards considered as the standards of Georgia.

Georgia

1. State Registration of Medical Devices

Pursuant to Article 3 of the “Procedure for Registration of Medical Technical Appliances” approved by the 10 December 2003 Order #318/n of the Minister of Labor, Health and Social Welfare of Georgia, the new and modernized medical technical appliances of national and foreign production having potentially malicious impact on the human organism are subject to the state registration.

State registration is carried out by the Ministry of Labor, Health and Social Welfare of Georgia through the Department of Equipment and Technology. The Department issues the registration certificate. Following

the registration, a medical technical appliance is included in the “State Registry of Medical Technical Appliances”, which is administered by the Department.

The list of technical appliances subject to registration is approved by the Minister of Labor, Health and Social Welfare of Georgia, through the submission of the Department of Equipment and Technology.

Procedures of registration of medical technical appliances foreseen under the Order #318/n are not in fact carried out in Georgia. Pursuant to the Regulations of the Ministry of Labor, Health and Social Welfare of Georgia approved by the 31 December 2005 Resolution #249 of the Government of Georgia, there is no Department of Equipment and Technology within the Ministry’s system at all and the Ministry’s competences do not include the registration of medical technical appliances. The list of medical technical appliances subject to registration and the State Registry of Registered Medical Technical Appliances does not exist either.

Moreover, the “Procedure for Registration of Medical Technical Appliances” approved by the Order #318/n contradicts the Law of Georgia on Certification of Production and Service, which, instead of the registration of medical devices by the Ministry of Labor, Health and Social Welfare of Georgia, provides for the certification (i.e. evaluation of conformity with technical regulations) of such devices by the accredited agencies.

2. Technical Regulations on Medical Devices

In accordance with Article 3 of the Law of Georgia on Certification of Production and Service, production means a good or service circulated in Georgia, regardless of whether it is designed directly for consumers, and which is provided or otherwise available for commercial or non-commercial purposes. Accordingly, the definition of production and thus the domain of this Law encompasses medical devices as well.

Pursuant to Article 7 of the same Law, the manufacturer is obligated to place on market only safe products, i.e. safe medical devices.

According to Paragraph 2 of Article 1 of the Law, certain aspects of safety of specific products or separate categories of risk related to the products are regulated by the technical regulations.

Article 3 of the Law stipulates that technical regulation is a document, which defines the characteristics of production or the processes and manufacturing methods related to it including the relevant administrative provisions, observance of which is mandatory. It may also cover or directly relate to the requirements towards terminology, symbols, packaging, marking, labeling, and the production-related process or manufacturing method.

Pursuant to Articles 4 and 5 of the same Law, technical regulations are adopted to protect the safety, life and health of humans and animals, plants, environment and property, in respect of concrete production/goods, and they are developed by a relevant ministry, other state institution or independent

regulatory body in accordance with the procedure established by the Law of Georgia on Normative Acts.

Under Article 30 of the same Law, the list of technical regulations to be adopted in Georgia is developed by the Ministry of Economy and Sustainable Development of Georgia in agreement with the interested agencies.

Pursuant to Paragraph 3 of Article 5 of the Law, based on international agreement, legislative acts of Georgia or decision of the Government of Georgia it is possible to recognize / accept as equivalent the technical regulations of another country and to apply them in Georgia to a full effect.

At the moment the Ministry of Economy and Sustainable Development of Georgia has not developed the list of technical regulations to be adopted in Georgia. In addition, absent also is the technical regulation developed by Georgia or recognized as equivalent concerning the medical devices, except for the 22 November 2010 Resolution #359 of the Government of Georgia on the “Approval of Technical Regulations of High Risk Medical Activities”, which only includes the list of medical devices to be placed in institutions carrying out high risk medical activities.

Certification of Medical Devices

Pursuant to Article 8 of the Law of Georgia on Certification of Production and Service, if the safety of any production is regulated by technical norms, manufacturer is obligated to place on the market such production, which meets the requirements of technical regulations effective or recognized in Georgia and other rules and norms effective in Georgia, which establish mandatory requirements towards the production.

In accordance with Article 13 of the Law, the procedures for evaluation of conformity of production/ goods with technical regulations are established by the same technical regulations.

A conformity is evaluated mainly through the following two ways:

1. By obtaining the declaration of conformity of production with the requirements of technical regulations by a manufacturer;
2. By submitting the production to the accredited certification agency by a manufacturer for evaluating the conformity of specific production with the requirements of technical regulations.

In light of specificities of the goods, its technical complexity and volume of risk, technical regulations must take into account possible versions of procedures for evaluating the conformity prior to placing products on the market.

Pursuant to Article 7 of the Law, placing the production recognized or accepted as equivalent in accordance with technical regulations on the market is possible also based on the submission of document certifying the conformity as foreseen under the procedure for evaluating the conformity existing in the country of manufacture of production.

Apart from the cases foreseen under the legislation of Georgia, evaluation of conformity is voluntary. Such instances, once again, should be defined under the same technical regulations.

Evaluation of conformity (certification) is carried out and the certificate of conformity is issued only by the **accredited body** - a physical person or legal entity, which is accredited by the Center for Accreditation. The Center for Accreditation is a legal entity of public law subject to the control of the Ministry of Economy and Sustainable Development of Georgia. Pursuant to Article 21 of the same Law, the Center administers the Register of Accredited Bodies.

Currently, none of physical persons or legal entities registered in the Register of Accredited Bodies evaluate the conformity of medical devices with the technical regulations, presumably due to the absence of relevant technical regulations. Hence, the certification of medical devices in Georgia is not carried out regardless of the requirement of the Law of Georgia on Certification of Production and Service.

3. Supervision and Control of Medical Devices on the Georgian Market

Pursuant to Article 25 of the Law of Georgia on Certification of Production and Service, a **competent body** exercises supervision and control over the production placed on the Georgian market.

Competent bodies are determined under the legislation of Georgia or technical regulations.

Currently the supervision and control over medical devices placed on the Georgian market is not carried out, as a respective competent body is not determined by any of the laws or technical regulations.

4. Standards on Medical Devices and their Application

The Law of Georgia on Standardization regulates the conformity of medical devices, as production, with the established standards.

Pursuant to Article 2 of this Law, standard is a document registered by an authorized body and designed for universal and multiple application, which establishes rules, general principles and parameters for the production and manufacturing methods related to it. A standard may also include the requirements towards terminology, symbols, packaging, marking, labeling, and the production-related process or manufacturing method.

In accordance with Article 10 of the same Law, **application of standard is mandatory only if foreseen by the technical regulations.**

Registration of standards in Georgia is carried out by the National Agency for Standards, Technical Regulations and Metrology of Georgia - a legal entity of public law, state control over activities of which is exercised by the Ministry of Economy and Sustainable Development of Georgia.

A standard registered by the Agency is considered to be the standard of Georgia.

The Agency administers the Register of Standards and Technical Regulations, as well as the Register of Types of Measurement Means.

The Register of Standards and Technical Regulations includes national standards and international, inter-state standards, which are considered to be the standards of Georgia.

National standards on medical devices indicate the standard registered in 2006 by the Institute of Metrology and the Department for Standards and Technical Regulations of the National Agency for Standards, Technical Regulations and Metrology SST 59:2006 "Devices medical diagnostic ultrasonic. Scanners. Method of certification".

The list of international standards considered as the standards of Georgia in the area of medical devices refers to the following:

ISO 15193:2006, ISO 15193:2007, ISO 15194:2006, ISO 15194:2007, ISO 17511:2007, ISO 18153:2007 in vitro for the diagnostic medical devices, ISO 13485:2006, ISO/TR 14969:2008, ISO 10079-1:2008, ISO 10993-3:2008, ISO 10993-4:2008, ISO 10993-5:2008, ISO 10993-7:2008, ISO 10993-9:2008, ISO 10993-10:2008; ISO 10993-11:2008, ISO 10993-12:2008, ISO 10993-15:2008, ISO 10993-16:2008, ISO 15223:2008;

EN 445-1:2010, EN 556-1:2010, EN 1422:2010+A1, EN 1707:2010, EN 12286:2010, EN 12287:2010, EN 12322:2010, EN 12470-1:2010, EN 12470-2:2010, EN 12470-3:2010, EN 12470-4:2010, EN 20594- 1:2010, EN 27740:2010;

EN ISO 5359:2010, EN ISO 8185:2010, EN ISO 14 160:2010, EN ISO 14602:2010, EN ISO 14937:2010, EN ISO 15002:2010.

However, application of none of the above-listed standards is mandatory in Georgia, as there are no technical regulations providing for the application of these standards.

5. Calibration of Medical Devices

The Law of Georgia on Ensuring Uniformity of Measurements regulates the calibration of measurement means applied in Georgia, however, this Law determines only those legalized measurement means, which are applied for the purposes of administrative fining, taxation and forensics.

Pursuant to Article 10 of the Law, the legalized measurement means are subject to the approval of a type, and initial and periodic certification carried out by the National Agency for Standards, Technical Regulations and Metrology of Georgia or the person accredited by the Agency. Certification takes place based on the technical regulations, which must include the mechanisms of adoption, change and revocation of respective decisions. Based on the international agreement of Georgia the Agency is also obligated to recognize the type and initial certification approved abroad and issue a corresponding certificate.

This Law does not anyhow regulate the certification of measurement means for medical purposes. Accordingly, no certification of a type of medical measurement means and initial and periodic certifications takes place.

In accordance with Article 16 of the same Law, the body determined by the Government of Georgia must exercise the state metrological supervision and control. Pursuant to the 31 July 2003 Order #375 of the President of Georgia, such a body was the State Supervisory Inspection for the Safety of Production and Service functioning within the State Department for Standardization, Metrology and Certification, which is abolished under the 4 November 2004 Order #483 of the President of Georgia.

Thus, a consistent metrological supervision and control over medical devices is also missing in Georgia.

6. Other Laws in the Field of Healthcare

There are several normative acts containing certain requirements with respect to the medical devices.

a) One of them is the 2 February 2010 Resolution #29 of the Government of Georgia on the "Approval of Minimum Service Standards for the Health Care Providers Participating in the State Insurance Programs".

Pursuant to Paragraph 24 of Minimum Standards approved by this Resolution, a hospital must be equipped with devices having international certificate and/or the certificate of calibration of a device issued by the body with respective accreditation; the device must not be manufactured earlier than 1998.

It is unclear who carries out the certification and checks if the device has international certificate and calibration certificate, or if it manufactured before 1998, etc.

Annex #2 of the same Standards includes additional requirements for devices to be installed in hospitals with 50 and more bed wards.

Further, there is the 22 November 2010 Resolution #359 of the Government of Georgia on the "Approval of Technical Regulations of High Risk Medical Activities".

Pursuant to Article 2 of the Regulations, the State Regulatory Agency for Medical Activities exercises supervision over the fulfillment of requirements of the Regulations.

Article 13 of the same Regulations determines what kind of devices should be placed in the institutions carrying out high risk medical activities; nevertheless, there are no concrete requirements with respect to the safety of medical devices.

“A passport of medical and pharmaceutical institution” - the document reflecting the personnel, technical equipment and the volume of work to be carried out - should have been adopted in accordance with the Law on Health Care, which we were unable to identify.

b) The 4 March 2003 Order #41/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Sanitary Norms Ensuring Radiation Protection during the Medical X-Ray Radiological Diagnostic Procedures and Treatment” regulates the safety-related issues of certain types of medical devices to the best possible extent. Under this Order, which is a 100-page voluminous document, the following are approved: (a) hygienic requirements towards X-Ray cabinets, installment of devices, exploitation and conduct of X-Ray examinations (sanitation rules and norms); (b) organization and conduct of radioactive disometric control of radiological departments of medical institutions (methodic instructions); and (c) determination of effective equivalent doses of patient’s radiation during the radiological examinations and the levels of their control (methodic instructions).

c) The 27 September 2007 Order #282/n of the Minister of Labor, Health and Social Welfare of Georgia on the “Approval of Mandatory Standards for Functioning of Blood Transfusion Institutions” also attempts to regulate in detail the issues related to the safety of certain type of medical devices.

7. Purchasing, Exploiting and Ensuring the Safety of Medical Technical Appliances by the General Health and Medical Research Institutions

The 6 January 1999 Order #1/o of the Minister of Health Care of Georgia on “Urgent Measures for Bringing the Exploitation and Safety of Medical Technical Appliances in the Healthcare System, as well as their Procurement Works into Compliance with the Established Rules” regulates the purchasing, exploiting and ensuring the safety of medical technical appliances by the general health and medical research institutions.

Pursuant to this Order, the heads of all general health and medical research institutions operating in Georgia are obligated to purchase medical technical appliances only from the legal entities licensed in accordance with the procedure established by the Ministry of Health Care of Georgia (the license for “wholesale sale of medical technical appliances”). The Ministry of Health Care of Georgia has not adopted the procedure for issuing the license for “wholesale sale of medical technical appliances”. Issuing of this license is not regulated under the Law of Georgia on Licenses and Permits either.

In accordance with the same Order, along with the above-mentioned license a legal entity selling the medical measurement means must possess in addition a respective permit issued by the State Department for Standardization, Metrology and Certification. The State Department for Standardization, Metrology and Certification.

ogy and Certification no longer exists, while the legal entity of public law “National Agency for Standards, Technical Regulations and Metrology of Georgia” does not issue such permits.

The Control Inspection and the Department for Medical Equipment and Technologies of the Ministry of Health Care of Georgia are charged with the control over the fulfillment of this Order. The said agencies do not currently function within the system of the Ministry of Labor, Health and Social Welfare of Georgia.

Thus, none of the provisions of the above-described Order correspond to the reality.

8. Liability

Articles 1009-1016 of the Civil Code of Georgia regulate the liability of the manufacturer of substandard products for the inflicted damages.

According to this Code, any movable thing - even when it is a part of another movable or immovable thing, as well as electric power - is deemed to be a product. While a person who has manufactured a final product, a principal element or part of a product is deemed to be a manufacturer. Any other person who appears as a manufacturer in his/her own name, trademark or other distinguishing mark is also deemed to be a manufacturer.

A person who puts a product out for economic purposes in the form of sale, renting out, leasing or otherwise within the scope of his/her business and by observing the rules prescribed by the Civil Code is also deemed to be a manufacturer.

Pursuant to the Civil Code, a product is deemed substandard if it fails to secure the reliability that was expected from this product having due regard for all the circumstances.

In cases of liability for harm caused by a substandard product, the burden of proof is on the victim.

The obligation to compensate for harm is extended to harm that results from death, bodily injury or disability.

The limitation period on claims is three years from the moment at which the victim became aware or ought to have become aware of the harm, defect or identity of the person liable for compensation of the harm. The claim is extinguished after ten years from the moment at which the product that caused the harm was released for sale by the manufacturer.

The 25 August 2010 Order #1140 of the Government of Georgia foresees bringing amendments to the above articles of the Civil Code, which mainly concern and specify the circumstances excluding the manufacturer’s liability.

9. Measures Established under the Government Program for Legislative Reform in Standardization, Accreditation, Evaluation of Conformity, Technical Regulation and Metrology and the Adoption of Technical Regulations

On 25 August 2010 the Government of Georgia has adopted the Order #1140 on the "Approval of the Governmental Program for the Legislative Reform in Standardization, Accreditation, Evaluation of Conformity, Technical Regulation and Metrology and the Adoption of Technical Regulations". In accordance with the mentioned Program, based on the analysis of legislation on product safety and free turnover (product meaning medical devices also), the state has found it reasonable to adopt the uniform "Code of Product Safety and Free Turnover".

Pursuant to the text of the Order, the work on this Code must have been completed back in October 2010.

The Code must regulate all legal issues concerning the product safety and quality infrastructure. Under the same Order, Georgia wishes to revise and change effective legislation so to create the uniform and effective base for ensuring an adequate level of quality infrastructure.

The Program itself includes general principles and provisions to be stipulated in the Code of Product Safety and Free Turnover.

The same Program provides for gradually bringing the legislation of Georgia in compliance with the EU directives concerning medical devices, in particular: 93/42/EEC concerning Medical Devices, 98/79/EC concerning In Vitro Diagnostic Medical Devices, 90/385/EEC concerning Active Implantable Medical Devices, and other related directives. These Directives are provided in the third group of "Sub-Program on Introduction of New and Global Approach Directives", which envisages their adoption only after full incorporation/adoption of directives in the first group. The first group directives are to be incorporated/adopted within 36 months from adopting the strategy and the Government Program.

Recommendations: Definition - instead of defining numerous terms, it is preferable to introduce one term, which in its content will be similar to the definition of the term "medical devices" applied in the EU Directives. Further, it is recommended that the definition of the term "medical devices" or "medical technical appliances" is provided in the law and not the "Procedure for Registration of Medical Technical Appliances" approved by the 10 December 2003 Order #318/n of the Minister of Labor, Health and Social Welfare of Georgia, which, apart from the definition of terms is a useless document, contradicts other legislative and normative acts regulating this area and is subject to revocation.

Classification - it is desirable that the medical devices are classified in accordance with the classification existing in the European Union. Classification of medical devices is necessary for certification of medical devices in accordance with the procedure established under the Law of Georgia on Certification of Production and Service. Various rules of certification foreseen under the Law

will affect specific medical devices in accordance with the categories that they qualify under. Certification by the manufacturer only will be sufficient for less risky devices. Currently it is implied that the classification of medical devices must be carried out in accordance with the concrete technical regulations. Yet, as the classification of medical devices is a much wider issue, it is desirable that it is regulated by one normative act, be it the law including the definition of medical devices as well or one technical regulation.

State registration of medical devices - it is preferable to revoke the "Procedure for Registration of Medical Technical Appliances" approved by the 10 December 2003 Order #318/n of the Minister of Labor, Health and Social Welfare of Georgia, which is useless and which contradicts the procedures set by other legislative and sub-statutory normative acts regulating this area.

Technical regulations on medical devices - the Ministry of Economy and Sustainable Development of Georgia should develop in agreement with the interested agencies the list of technical regulations to be adopted in Georgia (including those related to medical devices).

Technical regulations related to the medical devices should be adopted.

Certification of medical devices - adoption of technical regulations related to medical devices will give raise to respectively accredited bodies, which will evaluate the conformity of medical devices with technical regulations and issue relevant certificates.

Supervision and control - it is desirable that the law defines a competent body exercising the supervision and control over medical devices placed on the Georgian market.

Standards on medical devices - it is preferable that the technical regulations provide for mandatory application of international standards recognized as the standards of Georgia on medical devices.

Calibration of medical devices - it is recommended that the Law of Georgia on Uniformity of Measurements regulates medical measurement means, determines an institution that will exercise state metrological supervision and control over medical devices, and is amended accordingly.

Purchase and exploitation of medical devices - the 6 January 1999 Order #1/o of the Minister of Health Care of Georgia, which is inactive, should be revoked.

Liability - the amendments to the Civil Code should regulate in greater detail the liability for harm caused by medical devices.

Government Program - it is desirable that the Government Program sets concrete timelines for implementation of measures related to the medical devices, and that the legislative amendments foreseen under the Program are carried out as soon as possible.

4.6 DISABILITY, EVALUATION, DEFINITION OF STATUS

4.6.1 Legislative regulation, existing model and methodology

It is widely recognized that the importance of establishment of the status of disability and identification of needs of persons with disabilities is central in the development of the state policy and selection of strategy in this area.

Currently the rule of establishing the status of disability and evaluation of the status and needs at the legislative level is regulated under the 2001 Law on Medical-Social Expert Examination and four normative acts adopted in 2003-2007. This Law defines the legal, economic and organizational grounds of medical-social expert examination. By its content, the instruction on granting the disability status belongs to the so-called medical model of evaluation of disabilities, which views a disability or temporary loss of health status as a problem caused by health disorder, and which should be mainly solved by treatment, which is well demonstrated also in the definition of disability under the Law.

Pursuant to the Law - **disability is the human health disorder caused as a result of disease, trauma, anatomic or mental defect with solid failure of an organism's functions, which results in temporary or permanent limitation of capability, and which requires its social protection.**

The definition has two main aspects: disability, which is viewed as a health disorder and its result - loss of capability. However, due attention is not paid to the reality that the functionality and disability represent complex interaction between a person's health status and contextual and private factors of environment. As a result, if a problem is not solved through treatment, at the time of medical model the system either does not identify the case at all, or relates all problems arisen in connection with it to the statistical syndrome.

Pursuant to the legislative instruction on establishing the disability status, the Agency for Regulation of Medical Activity chooses those medical institutions, which are given the right for a certain period of time (2 years) to carry out evaluation and expert examination and establish the status of a person with disability for different time spans. Unfortunately, the instruction does not indicate based on which standards or principles does the commission set up under the individual administrative-legal act of the Head of the Agency choose such organizations. The same instruction defines the degree and categories of limited capability, as well as the list of diseases and anatomic and mental defects, which may become the ground for granting the status of disability; however, the instruction does not refer to methods, principles and tools applied at the moment of evaluation, and in fact the competences of human resources involved in the status determination process are not outlined. In turn, the instruction provides in detail the codes of diseases and the list of physician's specialties, which are authorized to carry out evaluation by various nosologies.

As already noted, the rule of status determination in effect is mainly based on the international classification of diseases (ICD-10) adopted by the World Health Organization, which in itself does not contain the

functional status information. It defines the health status and type of disorder and is silent on the limitation of functional activity and problems of participation (socialization). Although the rule of determination also provides the categories of disorder of key functions of an organism, their list is extremely scarce, and the quality of evaluation is very low due to diverse problems in its structure and process. This very methodological choice is behind the fact that the existing system of evaluation identifies the disability during the disorders of the body's functions and/or structure, even less during the disorder of actions, and is virtually "blind" during the evaluation of limitation of person's participation in the social environment.

Owing to the above-described problems, the medical model of evaluation is inadequate in terms of human rights protection and is not cost-effective mainly due to the focus on the social aids and programs. When describing the disability status, due to the absence of standard structure, process and language, the medical model and the nosology-based methodology does not produce that quality and reliable information, which would have enabled the specialists, researchers, politicians and persons with disabilities to analyze a real situation, plan necessary changes, and measure and compare the obtained results.

4.6.2 Recommendation

The so-called social model is considered to be an alternative to the medical model of evaluation of the disability status, which was developed by the persons with disabilities, and the introduction of which with various degrees and frequency has been launched in the US and Europe a decade ago. The actualization of the rights of persons with disabilities worldwide and the unfavorable experience gained with the medical model has been a main driving force of creation of such model.

In accordance with the most radical version of the social model, the disability represents a socially-driven state and not a general sign of capability attributable to humans. It requires political responses, as the problem is created due to the lack of necessary conditions in the surrounding environment, which in itself is triggered by the absence of adequate attitudes, will and other aspects.

Remarkably, such a radical approach characteristic to the social model is not less risky. In fact, incapability is marked with the forms and signs attributable to both models, and when selecting the strategy of changes, decision-makers must certainly take into account this reality. Notwithstanding the fact that international obligations undertaken by the country and the harsh reality clearly illustrate the urgency of changes, as a result of which the medical model will ultimately lose its dominant state, preservation of its components is absolutely essential.

In our opinion, transition to the social model of evaluation, and introduction of modern methodology of determination of the disability status, obviously requires fundamental changes in the existing legislative regulations. Developing a relevant legislative base for a new model will be necessary. At the same time, reforms will be impossible without substantial administrative and financial expenses, which is a huge problem in light of limited financial resources. Therefore, we find it reasonable to plan and implement the changes gradually, as a result of thorough analysis of objectives, priorities and trends.

Prior to drafting the new, adequate legislative base, the first priority task to be implemented we believe is the introduction of new methodology for determination of the disability status; in particular, the introduction of the International Classification of Functionality (ICF), which is regarded as the most effective measuring tool of functionality and incapability related to the health status and is based as on social, as well as on medical models. ICF itself is not a measuring tool of incapability; it defines disability as functioning in various spheres of life and unlike ICD-10, during the evaluation it takes into consideration the surrounding and personal factors. Most importantly, it is neutral in terms of etiology, which enables the interested institutions and professionals to draw non-causal conclusions, and receive and give information in understandable and standard international language.

Transition to the new methodology of evaluation and ensuring the availability requires fundamental changes in the structure and process of existing evaluation system, and namely the introduction of new professional standards and modern evaluation tools and knowledge. As already noted above, changes to be undertaken affect practically all layers of the functioning system, whereas a shift to the new methodology requires radical changes. Hence, the risk of expected losses and complications is rather high, for the avoidance of which it is recommended to develop a new strategy and detailed action plan prior to the launch of the system reform and to consult accordingly with the interested parties.

Overall, we find it necessary to:

- 1) Identify the purpose and volume of ICF in the new model of evaluation of the disability status, determine the priorities.**
- 2) Implement necessary structural and methodological changes for introducing the social model of evaluation and ICF, train the specialists.**
- 3) Develop a new adequate legislative base for the new model of evaluation of the disability status.**

5 ■ NEEDS TO THINK OVER, THEN THE REST

5.1 PATIENT SAFETY

5.1.1 Notion and brief description of the problem

Patient safety means the prevention of errors (hereinafter the “medical error”) and harmful (adverse) impact towards a patient based on and related to health care; as well as the freedom of a patient from unnecessary or potential harm associated with medical care.

Patient safety is a pivotal component of the quality of country’s health care system and one of the key indicators determining this quality.

5.1.2 The law

Regardless of such significance, healthcare legislation of Georgia pays almost no attention to the patient safety as such. Moreover, healthcare legislation is totally silent on this term. The legislation under-regulates the individual components of patient safety as well, such as the safety of medical devices and medical malpractice (definition of which encompasses the components of definition of a medical error, however, there is no clear distinction between these two terms), but there are no provisions in any of the laws that would refer an interested person to the perception of Georgian legislation of patient safety as a conceptual matter.

Meanwhile, patient safety is given increasing importance globally. Since 1990, the World Health Organization has conducted numerous studies and developed many recommendations, under the data of which one out of every ten patients worldwide incurs harm due to the medical error. Owing to this the World Health Organization calls patient safety an endemic problem. In 2002, the World Health Organization member states have adopted the World Health Assembly Resolution on Patient Safety. From the same year, the global alliance on patient safety functions with WHO. Intense activities are carried out also at the level of individual regional organizations.

Especially worth noting from regional initiatives are the regulations adopted by the European Union, in particular: the 9 June 2009 Recommendation of the EU Council of Ministers on Patient Safety, Including the Prevention and Control of Healthcare Associated Infections. The Recommendation states that according to the official data of the EU, it is estimated that in member states between 8% and 12% of patients admitted to hospital suffer from adverse events whilst receiving healthcare. Healthcare associated infections occur in 4,1 million patients a year, and 37,000 deaths are caused every

year as a result of such infections. This document provides 7 general and 2 concrete recommendations on patient safety.

5.1.3 The analysis

Patient safety breaches are mainly associated with the following factors of health care system:

1. Medical equipment (in developing countries, 50% of medical equipment is either useless or partially usable. Often the equipment is not properly used due to lack of relevant knowledge, experience and conditions. As a result, diagnostic procedures and examinations are wrong, leading to erroneous and harmful diagnosis and treatment, thus causing threat to patient's life and health);
2. Prescription, preparation and use of a pharmaceutical product;
3. Surgical error (surgical error is the most evident and easily identifiable form of the medical error, which mostly leads to patient's death or disability);
4. Anesthesia;
5. Healthcare associated infections / hand hygiene (according to the World Health Organization data, healthcare associated infections occur in 1,4 million patients. Hand hygiene is the most necessary measure for reducing the healthcare associated infections and developing the antimicrobial resistance);
6. Unsafe blood products (according to the World Health Organization data, 1,3 million patients die annually because of erroneous infections, which is associated with the spread of blood diseases such as "B" Hepatitis, "C" Hepatitis and HIV/AIDS);
7. Specific factors associated with pregnancy and safety of newborns.

Main types of measures carried out in the area of patient safety are:

- Reporting;
- Analysis;
- Prevention.

Patient safety related measures aim to avoid and remedy those adverse (harmful) results, which emerge from medical care. These results include "error", "deviation from standard" and "accident". Improving only

one of the components in the health care system is not sufficient for achieving the safety. It is not driven only by a human factor, device, or malfunction of one of the system components. Improvement of patient safety in the first place implies the study as to how it is achieved through interrelation of various components.

5.1.4 Patient safety measures

Reporting and Analysis

The United States of America plays one of the leading roles in the development of patient safety measures, which in the course of working on these measures and especially the reporting and analysis related measures has found it effective to introduce in the patient safety area the analogue of the US aviation safety research system. Low incidence in the US aviation system is mostly achieved through the work of two organizations: the National Council for Transport Safety, which carries out mandatory investigations of incidents in aviation, and the Aviation Safety Reporting System, which examines voluntarily provided reports to identify gaps in the aviation system and design ways for remedying them without punishing the actors.

Many similarities have been identified in the activities of the aviation and medical personnel. Representatives of both professions have to work in difficult environment, interact with technology, and face the risk of losing their lives and prestige due to the exhaustion, stress, danger and errors made.

By taking into account the exemplary record of aviation in the prevention of incidents (a human becomes a victim of aviation error in 1 case out of 1 million, whereas the patient safety is breached in 1 out of 300 cases), the United States has found that introduction of the similar reporting system in the medical field would have been effective. In particular, this comprises the mandatory reporting system on grave incidents and the voluntary (non-punitive) reporting, trainings, and institutional approach towards the analysis of reports and generalization of collected information in respect of other incidents. As a result, the US Department of Veterans Affairs jointly with the National Aeronautics and Space Administration (NASA) has developed the Patient Safety Reporting System (PSRS), which similar to the aviation safety reporting system carries out the voluntary and confidential report analysis.

At the same time, there were vigorous debates in the US at federal level concerning the reasonableness of mandatory reporting in the patient safety area. Although by 2005 the mandatory reporting system had been introduced in 23 states, a federal requirement of mandatory reporting was still absent. Finally, in 2005 the US Congress has adopted the "Patient Safety and Quality Improvement Act", which has set up the federal reporting base. Pursuant to this Act, the hospital reports on serious harm inflicted to patients are voluntary and they are drafted by the contracted patient safety organizations, which analyze the errors and develop recommendations. The federal government's function is to coordinate the data

collection process and maintain the national database. Facts provided in the reports are confidential and cannot be used for punitive purposes. Confidentiality of the report results triggers public discontent, however, their publication is still considered as unreasonable.

Since 2008, 35 states have adopted the law allowing the physicians and health care providers to apologize to the victims of patient safety breaches and their families and offer compensation without litigating in courts, which means that the fact of admission of own error by the health care provider should not be used against it for launching litigation in courts and the payment of compensation may as well be established without a court dispute. This practice was widely introduced by prominent medical centers, such as the John Hopkins Medical Center and the Illinois and Stanford Universities, while through the application of this practice the Michigan University has reduced court disputes against it by 75%, thus halving the dispute related costs.

In 2003 the Parliament of Denmark has adopted the Patient Safety Act, pursuant to which since 2004 the mandatory reporting system has been introduced in Denmark. This system obligates the medical personnel to provide to the National Health Council of Denmark a report on all cases of breach of patient safety. Heads of medical institutions are obligated to react to the facts described in the reports, while the National Health Council is obligated to generalize the reports and inform the public. It is prohibited to punish the health care workers or subject them to disciplinary responsibility for facts that they had indicated in their reports.

In the United Kingdom the National Agency for Patient Safety analyzes the reports on medical errors provided on a voluntary basis. Further, confidential investigations are conducted also on certain types of cases. Such cases are: mother and child mortality, mortality of children under 16 years of age, mortality of the mentally ill, peri-operational (occurring during the operation) and unexpected death cases.

Reporting of Near Miss Cases

Near miss is an unplanned event, which has not resulted in anyone's damage or disease but could have resulted. Reporting on near miss cases in aviation, like in other transport areas and fire safety is a widespread type of reporting, which through the analysis of cases helps to identify errors endangering human safety, and which otherwise would have been left unrevealed.

Medical Information Technology

Development of medical information technologies is considered as one of significant measures, which can substantially reduce numerous errors in the field of health care and the costs incurred from these errors. Wide distribution of information technologies is mostly undermined by the necessity to incur costs, regardless of the fact that as a result patients receive better services and the cost of such services is reduced also. Information technologies can also reveal errors that were left unidentified before. Medical

information technologies are equally effective at the time of large-scale natural calamities, when a vast portion of paper documentation is lost.

Instead of hand-written histories of a patient, non-standard abbreviations, etc., the introduction of information technologies includes setting up an on-line history of patients, on-line prescription of drugs and other on-line activities.

The US Medical Institute believes that on-line subscription of drugs is the best means of prevention of probability of making an error during the prescription of a medicine.

Yet, at the same time sample studies demonstrate that the application of medical information technologies contains new type of risks. Namely, the incorrect application of technology, non-verification of trustworthiness of information provided by the technology, a fake alarm put on by the technology, etc. may lead to catastrophic results.

Application of Guidelines

Elaboration and application of guidelines correctly is one of the important patient safety measures. Nevertheless, it also has downsides to it.

Raising the Awareness and Involvement of Patients

Studies conducted in the EU have illustrated that patient safety related cases are often easily avoidable, provided that the correct prevention measures are chosen. Education of patients, as a preventive measure, is given huge importance in the process of patient safety. It is crucial that a patient enjoys the right to be informed and actively participate in the decision-making process. Currently the guideline is being developed in the EU concerning the minimum information that must be provided to a patient by a health care worker on patient safety issues.

The World Health Organization puts special emphasis on the significance of patient's active role in promoting hand hygiene and the process of prevention of healthcare associated infections.

One of the latest documents in the field of patient safety is the "Helsinki Declaration of Patient Safety in Anesthesiology" adopted by the anesthesiologist organizations of Europe in 2010, which covers a majority of above-mentioned measures.

5.1.5 Recommendations

It is recommended that in the field of patient safety Georgia first formulates a state policy and then brings the legislation into compliance with such policy. In our opinion, the approach towards this issue should include at least two areas:

1. Regulation – which means the improvement of legislation with respect to the patient’s rights and patient safety, determination of an authorized agency in this area, and the development of national policy and safety standards;
2. Implementation – which means the implementation of such projects and activities, which are aimed at eliminating specific risks associated with patient safety.

Measures directed at improving the patient safety should preferably foresee the following:

- Creation of the medical care quality and safety monitoring system;
- Development of evidence-based medicine;
- Ensuring the provision of adequate information;
- Enhancement of accountability;
- Introduction of culture, according to which the health care workers and patients freely and in an unrestrained manner report on medical errors;
- Taking into account the patients’ experience and opinions in medical guidelines, legislation, and the policy documents;
- Introduction of the safety culture in medical institutions, which means:
 - Undertaking of responsibility by all medical workers (front line personnel, physicians, administrators) for own safety and the safety of own employees, patients and visitors;
 - Supremacy of safety interests over financial and other goals;
 - Promotion of initiatives of identification, reporting and solving the cases of safety breach;
 - Generalization of incidents and learning from lessons;
 - Creation of relevant resources, structure and reporting system.

Specific recommendations on patient safety provided by us below are based on the 9 June 2009 Recommendation of the EU Council of Ministers on Patient Safety, Including the Prevention and Control of Healthcare Associated Infections, which reflects the measures to be implemented by the state in this area to the best extent. Under these recommendations, all states including Georgia should carry out the following measures:

1. Development of national policy and programs on patient safety, in particular:

- a) Determination or creation of an authorized agency in this area;
- b) Development of national policy and program documents, creation and constant improvement of safety standards;
- c) Encouragement of health care providers at all levels, so that they enhance their role in identification of and reporting on the patient safety cases;

2. Informing citizens in general and patients, namely:

- a) Ensuring the involvement of patient's rights organizations and patients in the process of development of patient safety policy and programs and the patient safety standards;
- b) Public dissemination of information on risks associated with the patient safety, informing patients about their rights and the importance of informed consent;
- c) Introduction of the culture of taking into account a patient's opinion in the process of medical care;

3. Creation and enhancement of non-punitive reporting system, in particular:

- a) Setting up the reporting system, which ensures the provision of information on medical errors, its types and causes, adverse (harmful) impact and the "near miss" cases;
- b) Delimitation of the reporting process from the system of disciplinary and legal responsibility; improvement of the forms of disciplinary and legal responsibility;

4. Education and training of health care workers at all levels in patient safety;

5. Introduction of internationally recognized definitions and terms in the field of patient safety, namely:

- a) Introduction of international classification of patient safety developed by the World Health Organization;

6. Sharing of knowledge, experience and best practices;

7. Development and promotion of researches:

- a) The methodology of research conducted in the area of patient safety should be based on the following 5 components:

- i) Evaluation of damages;
- ii) Identification of cause;
- iii) Development of ways for eradicating the cause;
- iv) Assessment of results;
- v) Elimination of identified cause, creation of safe environment for a patient.

8. Adoption and implementation of the strategy on prevention and control of healthcare associated infections, in particular:

- a) Development of guidelines and recommendations for the purpose of prevention and control of mentioned infections;
- b) Obligating the health care providers – to have the prevention and control program of infections, which will encompass the organizational and structural measures, diagnostic, therapeutic, and patient education and informing procedures;
- c) Education of medical workers;
- d) Development of supervision systems at general and regional levels.

Part of the above recommendations requires relevant legislative amendments.

5.2 THE RIGHTS AND LEGAL STATUS OF MARGINAL GROUPS UNDER THE LEGISLATION OF GEORGIA

Introduction

Present chapter is dedicated to the analysis of the rights and legal status of marginal groups under the healthcare legislation of Georgia. Ambiguous understanding of the term “marginal groups” requires specification as to what is implied under this term for the purposes of the present analysis. The term “marginal groups” in this particular case means the users of psychoactive substances and drug addicts, persons with physical and mental disabilities, HIV/AIDS infected persons and the detainees, assuming that the link and probability of interaction of these groups with the health care system is stronger than that of other marginalized groups (ethnic minorities, sexual minorities, the poor, etc.).

The analysis aims to offer to readers the opinion on the extent of consideration of interests of marginal

groups in the legislation, sufficiency of protection guarantees of their rights and interests in the legislation, and what is the international legal practice like in this regard.

In accordance with the international rights organizations, the rights of marginal groups in the health care system are often violated – medical personnel refuses medical care illegally, ignores the interests, restricts the provision of information, subjects to compulsory treatment, and commits other violations. The risk of violations is even higher, when the interests and rights of marginal groups are deregulated in the legislation or the existing regulation is discriminatory.

Healthcare Legislation of Georgia

To assess the extent to which the healthcare legislation of Georgia takes into account the interests of marginal groups and provides guarantees for their protection, in the first place the legislation must be viewed schematically (see Diagram 1). The legislation of Georgia on human rights in the field of health care consists of the Constitution of Georgia, international treaties and agreements of Georgia, the Law of Georgia on Health Care, the Law of Georgia on the Rights of Patient and other normative acts. As the present analysis does not cover the Constitution and international acts, the Diagram below does not reflect these documents as objects of the analysis.

The Laws on Public Health, Health Care, Medical Activity, and the Rights of Patient are at the helm of healthcare legislation. Special laws in the field of health care concern various categories of marginal groups – the rights of HIV-infected persons are regulated under the Law on HIV/AIDS, the rights of persons with mental disorders – under the Law on Psychiatric Assistance, the rights of drug addicts – under the Law on Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance, and the rights of detainees (including in the field of health care) – under the Detention Code.

Diagram 1.

The below analysis covers the general healthcare legislation with respect to marginal groups.

The Law on Public Health

Scope of application of the law extends to all physical and legal persons in the territory of Georgia. In Chapter 2 the legislator declares human rights in respect of public health, which states that every person in the territory of Georgia is entitled to protection from contagious diseases in the health care provider institutions, as well as to live in the safe health environment. These provisions are significant for the detainees, patients with mental disorders and persons with disabilities (persons staying in institutions for a long period of time). These provisions are often not implemented adequately, which violates the rights of above-mentioned marginal groups – the detained persons and de facto detained persons in institutions are often infected with the very contagious diseases, which is common for the penitentiary, care, and treatment (residential type) institutions. This problem does not indicate that there is a gap in the Law, however, the norm of the same Law, pursuant to which non-fulfillment of requirements is punishable under the legislation of Georgia, is flawed and does not clarify which sanctions or sentence are foreseen for the violation of above conditions.

The Law on Public Health also concerns specific infections and makes a general reservation that in this area the state develops and implements the strategy on prevention and control. Further, the Law contains a general provision on drug addiction and alcoholism.

The Law on Public Health clearly defines the principles of public health, the risks and state obligations. Its general provisions cover marginal groups as well, however, without a special reference to marginal groups. The scope of regulation of the Law (public health) does not require adding special provisions on marginal groups, as the Law equally protects the rights of all citizens in the field of public health.

The Law on Health Care

The Law contains rather strong and declaratory provisions on universal and equal accessibility of medical care for the population, as well as the protection of human rights and freedoms in the field of health care, recognition of a patient's honor, dignity and autonomy, and protection from discrimination of patients in the detention institutions or persons infected with various diseases.

Chapter 2 is dedicated to the rights of citizens in the field of health care, prohibits any kind of discrimination, imposes guarantees for receiving the information, informed consent and the right to select health care provider and to refuse medical intervention, and in addition concerns issues related to persons in detention and incapable patients.

The Law on Health Care includes as the issues of healthcare organization, as well as general regulations on individual areas of healthcare. It in fact "marks" all issues and areas of concern to the field of health care; however, apart from the description of rights in Chapter 2 this Law is silent on the rights of marginal groups. It would be reasonable to introduce in the Law on Health Care the detailed regulations on marginal groups or the rights protection guarantees. Yet, the healthcare legislation of Georgia includes also the special laws, which are tasked to regulate this or that area, and which neutralize the necessity of detailed regulations on marginal groups in the general laws.

On the other hand, the Law on Health Care must include the rights protection guarantees for the marginal groups, as the risks of violation of these groups' rights are greater.

The Law on Medical Activity

The Law on Medical Activity does not contain any regulations on marginal groups. The language of the Law, according to which an entity of medical activity must be only guided by professional standards, principles of humanity, legislation of Georgia and must respect a patient's dignity, religion and traditions, is insufficient for ensuring the protection guarantees for marginal groups.

Unfortunately, it is noteworthy that according to the reports of various organizations, the rights of marginal groups are mostly violated by the medical personnel. In this respect the risks are especially high in the places of detention, mental health institutions, as well as the refugee shelters and child-care institutions. In Georgia, the parliamentary and special reports of the Public Defender describe numerous violations of rights with participation of the medical personnel.

As the Law on Medical Activity is the main law regulating the activities of medical entities, it would be reasonable to supplement this Law with relevant provisions emphasizing the responsibility of medical personnel towards the marginal groups.

The Law on the Rights of Patient

The Law on the Rights of Patient is the key law in the healthcare legislation, direct objective of which is to protect the rights of citizens in the field of health care, and to ensure the inviolability of their honor and dignity. Accordingly, this Law must be viewed as a central document when the protection of the rights of persons including marginal groups in the field of health care is concerned.

The Law prohibits all kinds of discrimination and clearly protects a patient's basic rights to receive information, informed consent, best available standard of treatment and care, inviolability of private life and confidentiality of personal information.

Remarkably, after formulating the provisions on the above rights, the legislator pays separate attention to vulnerable groups – the Law contains special articles on persons in detention, pregnant and breast-feeding women, minors and military servants. It is interesting to realize what were the arguments behind introduction of special articles on listed categories in the Law? If the legislator was guided by the criterion of social vulnerability, then the Law must include also special articles on the elderly, persons with disabilities, and other categories. Whereas if the legislator was guided by the high risk groups of violation of rights, then the Law is silent on the interests of marginal groups such as HIV-infected persons, drug addicts, etc.

Assuming that the Law on the Rights of Patient is a central document on the rights of a patient in the field of health care, it would be reasonable to revise it and supplement it with the rights guarantees for other marginal groups as well. Currently the Law does not put any emphasis on marginal groups (drug addicts, HIV-infected, persons with disabilities), the risk of violation of the rights of which is higher compared to the other groups.

The Law does not impose any specific sanctions or contain any reference to the violations of a patient's rights, such as illegal refusal of medical care, negligence, compulsory treatment, etc.

The rights and legal status of marginal groups in the field of health care are regulated in addition and in greater detail by the special laws.

The Law on HIV/AIDS

The Law on HIV/AIDS is a relatively new law adopted by the Parliament of Georgia in 2009.

The Law introduces a high human rights protection standard and describes the rights of HIV-infected persons with respect to diagnostics, receipt of information, confidentiality, non-discrimination, treatment, care, employment and other rights.

On the other hand, the Law does not contain sanctions for violating these rights, and it is silent on other laws of the legislation of Georgia that might regulate the required sanctions. The Civil and Criminal Codes regulate the legal policy and procedures in cases of violation of rights; however, it is difficult for the reader not keen on jurisprudence to identify these links. Further, such reference is made for the instances when the HIV-infected is dismissed from work. Therefore this is an inconsistent practice. The Law is equally silent on the procedure, which should be resorted to by a citizen (e.g. member of a marginal group) in case of

violation of rights. Such a procedure is defined by the legislation of Georgia, but it would be preferable for the Law to contain a certain reference.

The Law on Psychiatric Assistance

The Law on Psychiatric Assistance aims to ensure the availability of psychiatric assistance to persons with mental disorders and to protect the rights of these persons. This Law was adopted in 2006 and it has replaced the previous act that had failed to protect human rights in the field of psychiatry.

Remarkably, this Law is the only one in healthcare legislation, which, apart from describing in detail and protecting the human rights in the field of psychiatric assistance, also draws its attention to the interests and rights of various groups (persons in detention, unidentified persons, drug addicts, etc.). The Law describes the procedure for placing a person (including involuntarily) in a mental health institution.

The Law on Psychiatric Assistance can serve as a model as for the general laws on health care, as well as for drafting or updating the special laws, because the scope of its regulation is relatively complete and its provisions concern the direct interest groups (patient, potential patient), medical personnel and its interests, describe the procedures (the rules played by the parties), and draw a clear picture of the process (provision of psychiatric assistance).

The Detention Code

The Detention Code regulates the right to health and realization of this right in the places of detention. The Code was adopted by the Parliament of Georgia in 2010.

Articles 24, 119, 120, 121 and 122 regulate the defendant's/convict's right to health care. Pursuant to the Detention Code, a person in detention enjoys the right to undergo health status examination (mandatory), use the required medical care in compliance with the requirements of medical care established in the country in the field of health care, and upon request and permission of the Department Head to invite at his/her own expense a private doctor. The Law contains a special article, which regulates the access of defendant/convict to psychiatric care.

It is important in terms of protection of rights that the Detention Code establishes the guarantee of accessibility to such standard of medical care, which is in compliance with the requirements of medical care established in the country in the field of health care. Realization of this provision in real life becomes complicated and there are human rights violations due to the scarce system resources, lack of qualification by the personnel, and ineffectiveness of the appeal and response mechanisms. The Law also provides scant regulations in these areas.

The Law on Medical-Social Expert Examination

This Law regulates the rights of persons with disabilities. The Law on Medical-Social Expert Examination introduces the medical model of status evaluation, which is outdated and considered as insufficient in terms of human rights protection.

A detailed analysis and recommendations on this particular issue is provided in Chapter 4.6 – Disability, evaluation, determination of status - of the present report, owing to which the present analysis does not provide a repeated examination.

The Law on Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance

Anti-drug legislation aims at promoting the initial prevention of drug use, ensuring the availability of treatment and rehabilitation for the drug addicts, and regulating the reduction of harm caused by the drug use.

Anti-drug legislation of Georgia requires improvement in several areas:

The Law is not brought in compliance with the United Nations anti-drug conventions (bringing the lists and doses of psychoactive substances in compliance with international standards);

Penal regulations against the users of narcotic substances are strict, especially when the utilization and quality of the treatment and rehabilitation services in the country is low;

The Law of Georgia on Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance contains general provisions on narcological assistance.

Although the Law defines drug addiction as the disease, which is characterized with increasing and insurmountable desire towards the narcotic substances due to the mental and/or physical dependence on them, and also introduces the definition of a person ill with drug addiction, the Law does not contain provisions on the rights of drug addicts. The text of the Law makes it clear that there are no rights protection guarantees for the addicted persons and that they are not granted any legal status, based on which the addicted persons would have been “referred” to the health care system and not the criminal system. The criminal and administrative sections of the drug legislation are stronger and much more complete than a corresponding section of the healthcare legislation, owing to which the addicted persons primarily and initially interact with the law-enforcement system. Such imbalance obviously enhances the public safety policy and undermines the public health policy.

It is recommended to undertake a complex reform of anti-drug legislation and within a framework of this reform to introduce more guarantees for the protection of rights of addicted persons.

International Practice

The federal legislation of the United States of America on health care does not contain a special law on marginal groups. The rights of marginal groups are protected as under the US Constitution, as well as by separate laws in the field of health care.

Similar to the US legislation, the healthcare legislation of Great Britain does not contain a special law on marginal groups either; nevertheless, the rights of marginal groups are properly reflected and protected in the health care laws.

Conclusions and Recommendations

The analysis of healthcare legislation of Georgia demonstrates that the rights of marginal groups in general health care laws are not outlined separately. The rights and legal status of marginal groups in the field of health care are regulated by special laws. Provisions of special laws are mostly declaratory, of general nature, and insufficient for preventing the risks of violation of the marginal groups' rights. Special laws are more oriented on creating the legal-organizational framework in the field, rather than the protection of human rights in these areas. Mechanisms of protection of the declared rights of marginal groups in the special laws are vague.

- Provisions on marginal groups must be introduced in general laws on health care (declaratory provisions);
- The rights of marginal groups in the "circle of law" must be more clearly reflected in the special laws on health care, tangible mechanisms must be described or referred to, and the responsible body must be identified.

To support the marginal groups it is recommended to revise and amend the legislation; yet, such amendments should not promote the stigmatization or positive discrimination of these groups.

5.3 THE RIGHTS AND LEGAL STATUS OF HEALTHCARE PROVIDERS UNDER THE LEGISLATION OF GEORGIA AND INTERNATIONAL EXPERIENCE

Present analysis examines the rights of healthcare providers under the legislation of Georgia. In addition, the analysis compares the status quo of the rights of healthcare providers under the US legal framework and the EU member state Czech Republic. At the end of the analysis, provided for the Georgian law-makers as conclusion are the concrete recommendations for undertaking further legislative amendments.

1. Healthcare Legislation of Georgia

The healthcare legislation of Georgia in fact does not regulate the rights of healthcare providers. The legislation only provides meager norms determining the rights of physicians. At a glance there are provisions containing certain rights, but their content is more of obligatory nature than the rights-focused. For instance, under the Law of Georgia on Health Care, a physician has the right to assist a patient if s/he, or in case of his/her incapacity his/her relative or legal representative so requests and allows a physician to provide medical care; further, a physician enjoys the same right in case of implied consent, when a capable patient does not resist in any form in the course of providing medical care.

In addition, there is an article with different content, which allows a physician to refuse medical care, only in certain circumstances –

A physician has the right to refuse medical care to a patient, only if:

- a) There is a possibility of ensuring the continuity of medical care to a patient and no dangerous state for life is evident, or a patient does not require emergency medical care;
- b) A physician's life is put to real threat during the provision of medical care.

The Law on Health Care also includes the right of a physician, to prescribe and/or appoint any medicine and method of treatment in the interests of protecting the health of a patient.

Unfortunately, the other health care laws are silent on the rights of physicians.

2. The US Mechanisms of Legal Regulation

The US legislation regulating public health and health insurance contains key protection mechanisms of healthcare providers in terms of participation in healthcare plans, contractual relations, administration of disputes, and financial accountability vis-a-vis health maintenance organizations (HMO) and insurance companies.

Of equal interest is the regulation of rights of healthcare providers in respect of their faith, consciousness or religion.

2.1 Participation in the Healthcare Plan

In majority of US states the HMOs and insurance companies are obligated to include the healthcare providers in the healthcare plan upon their request. Accordingly, any healthcare provider has the right to request becoming a part of the healthcare plan.

HMOs are obligated to offer to healthcare providers such healthcare plan, which on one hand ensures maximum protection of rights of healthcare providers, and on the other hand provides for maximum realization of patients' rights.

After meeting the minimum qualification requirements, healthcare providers enjoy the right to timely (but no later than 90 days) receive from the HMOs and insurance companies a contract regulating the participation in the approved healthcare plan.

2.2 Contract of Healthcare Provider

2.2.1 Key provisions of the contract of healthcare provider

Under the US legislation, the HMOs and insurance companies are obligated to include the following key provisions in the contract of a healthcare provider:

- Methodology of financial accountability of a healthcare provider, including any planned or unplanned accounting;
- Time allocated for carrying out financial calculations, date of accounting and the concrete volumes of financial liabilities;
- Clear definition of financial calculations for a healthcare provider and availability of such calculations to a healthcare provider;
- Procedures of avoidance/regulation of incorrect or incomplete calculations made as a result of any dispute settlement, remedying of incorrect or incomplete information, and such incorrect or incomplete information;
- The right of a healthcare provider to resolve the dispute concerning any subject matter through the arbitration;
- HMOs and insurance companies do not have the right to hold the healthcare providers liable for any action or error caused by a healthcare plan.

2.2.2 Termination of contract of healthcare provider

HMOs and insurance companies do not have the right to terminate a health contract with healthcare providers. A healthcare plan approved under the contract entitles a healthcare provider to request from HMOs or insurance companies the written grounds of termination of contract, including the mechanisms of possible dispute resolution and appeal.

HMOs and insurance companies are obligated to indicate in the grounds of termination of contract the following:

- Specific grounds for contract termination;
- Reference to the fact that a healthcare provider has the right to request revision of decision before the ad hoc commission provided under a healthcare plan;
- Timelines for appealing a decision and requesting the examination of issue before the ad hoc commission;
- Procedures and requirements for setting up the ad hoc commission:
 - Ad hoc commission must consist of 3 members, who are predetermined under the healthcare plan. At least one commission member must be of the same specialty as the

healthcare provider or of similar specialty. Ad hoc commission may consist of more than three members, but 2/3 must necessarily be of equal profession and qualification with the healthcare provider;

- The commission must make a written decision within reasonable period of time. The decision may concern the restoration/reinstatement of healthcare provider to its initial position, conditional reinstatement, or termination of the contract;
- The decision on termination of a contract enters into force only after 60 days from its delivery.

2.2.3 Non-renewal of contract of healthcare provider

Healthcare provider enjoys the right not to renew the contract concluded with the HMO or insurance company, concerning which the provider must notify the other party 60 days in advance.

2.3 Additional Powers of Healthcare Providers

Healthcare provider has the right to request from HMO or insurance company the following:

- To get familiar with the criteria of evaluation of activities and medical practice of a healthcare provider under the healthcare plan;
- To consult with healthcare specialist prior to formulating the methodology of evaluation of activities of a healthcare provider;
- To evaluate the activities of a healthcare provider under the established criteria and by application of similar approaches of evaluation of other healthcare providers, in view of the categories and numbers of patients of healthcare providers;
- To get familiar with the specific features of own patients by a healthcare provider for the purpose of revision-improvement of a health contract.

In parallel to the above rights, the HMOs or insurance companies do not have the right to terminate or refuse to extend a contract with healthcare providers due to the following circumstances:

- Protection of patient's interests;
- Appeal of a healthcare plan;
- Decision made on the basis of a healthcare plan;

- Provision of information concerning a healthcare plan to relevant state agencies or submission of a complaint with such agencies.

2.4 Treatment of Patients

HMO or insurance company does not enjoy the right to prohibit a healthcare provider from informing its own patient on the following:

- All possible types of treatment corresponding the state of a patient, including the treatment not foreseen under a healthcare plan;
- Provisions and terms of a patient's healthcare plan, which affect his/her health.

HMO or insurance company cannot prohibit a healthcare provider from submitting a complaint with the state authorities concerning the principles of policy and procedures, which in the opinion of a healthcare provider may have an adverse affect on the quality of treatment or access to healthcare.

Further, HMO or insurance company does not have the right to prohibit a healthcare provider from lobbying the interests of own patients for providing a specific treatment, consulting a patient in details about any issues related to his/her treatment including based on a patient's permission, and submitting a complaint on a patient's behalf for protection of a patient's rights.

2.5 Examination of Healthcare Disputes

HMOs and insurance companies are obligated to receive and examine any healthcare complaints submitted by healthcare providers in accordance with the procedures and guiding instructions of the US Medical Association.

HMOs and insurance companies are also obligated to make relevant technical means available to healthcare providers, including special software for quick and effective administration of complaints.

2.6 Timely Compensation with respect to Healthcare Disputes

Healthcare providers have the right to timely receive the complaint-related compensation. HMOs and insurance companies are obligated to compensate to healthcare providers their liabilities arising from the complaints in no later than 45 days from making a decision.

If a liability arising from the complaint is unclear, HMOs and insurance companies are still obligated to compensate to healthcare providers clearly justified costs arising from the complaint, and in no later than 30 days to notify healthcare providers in writing about the need to submit additional information for strengthening unjustified or less justified parts of the complaint.

After a healthcare provider submits required additional information on the dispute, HMOs and insurance companies are obligated to compensate to a healthcare provider the submitted costs within 45 days.

In case of timely non-payment by the HMOs and insurance companies of submitted costs arising from the complaints, healthcare providers enjoy the right to demand extra fines in the amount of annual 12%.

2.7 Realization of the Rights to Faith, Consciousness and Religion of Healthcare Providers

Over last three decades the US Congress has adopted several laws to protect the right of healthcare providers to faith, consciousness and religion. The first one was adopted in 1970s; the so-called “Church Amendments” were approved over different time span to protect the rights of healthcare providers. In particular, they had the right to refuse to provide medical care funded by the state or participate in medical research due to their own religious or consciousness beliefs.

The second law, the Public Health Care Act was adopted in 1996, which banned the federal, state or local self-government authorities receiving state funding from discriminating healthcare providers based on their refusal to undergo abortion-related trainings or deliver such trainings, as well as to carry out the abortion operations and participate in them.

The third, so-called “Weldon Amendments” of 2005 have prohibited the provision of state funding to those federal or state organizations, which had discriminated healthcare providers based on their refusal to conduct abortion operations or fund such operations.

The three above-mentioned laws are upheld by a recently adopted legislative norm, pursuant to which:

- It is clearly recognized that non-discrimination applies to as individual physicians, as well as medical institutions receiving state funding;
- It is foreseen to set up a special office for civil public health rights, which will examine the complaints related to discrimination described above;
- Special office for civil public health rights is authorized to work with federal and state organizations, which may potentially violate the rights of healthcare providers protected under the law, while in case of such violations the office is authorized to apply sanctions provided by the law, including the termination of state funding.

3. Legal Framework of the Czech Republic

Functioning in the Czech Republic is the Health Act of 1997, which regulates the legal status of healthcare providers in terms of their rights and obligations. For the purposes of present analysis, the emphasis will be made only on the rights of healthcare providers. Employment and contractual rights are regulated

under non-specialized legislation and fall within the scope of general labor or civil legal relations. Hence, only the rights-legal framework will be analyzed from medical perspective. In particular, Article 129 of the above-mentioned 1997 Act regulates the right of a physician to choose various types of medical examinations and medical therapies, according to which:

Healthcare provider has the right to independently choose any method of patient's examination and therapy accepted from medical standpoint. Application of this or that method may be based on:

- a) A patient's consent;
- b) Much less probability of risk during the application of chosen method, than during its non-application.

During the conduct of medical examination or therapy a physician has the right to request participation of another physician having different qualification, as well as to receive respective recommendations from healthcare providers.

A physician enjoys important legal powers in terms of refusal to treatment also. Pursuant to Article 131 of the above Act, a patient's doctor has the right to refuse treating a patient, if:

- a) His/her treatment is required by a patient in graver conditions;
- b) Personal relations with a patient are concerned. In such cases a physician must refer a patient to another physician;
- c) A physical condition of a physician does not enable him/her to provide treatment;
- d) After examining a patient a physician considers that a patient does not require treatment;
- e) After examining a patient a physician considers that treatment prescribed to a patient by another physician or requested by a patient is professionally unjustified;
- f) After examining a patient a physician considers that treatment prescribed to a patient by another physician or requested by a patient contradicts the requirements of the law;
- g) A physician considers that s/he is unable to provide relevant treatment to a patient due to lack of necessary qualification;
- h) A patient's condition does not require immediate intervention. In such case a physician has the right to refuse a patient an appointment and conduct the examination at another time.

The legislation of the Czech Republic also protects the physicians' freedom of consciousness and faith, according to which a physician may refuse treating a patient, if:

- Such treatment contradicts a physician's moral, conscientious and religious beliefs.

Moreover, a physician may refuse treating a patient, if:

- a) A patient substantially violates the terms of cooperation during the treatment;
- b) A patient behaves immorally, insults and threatens a physician;
- c) A patient's behavior endangers a physician's life or health.

Conclusion / Recommendations

Based on all of the above, it is recommended to draft a special chapter in the healthcare legislation of Georgia, and particularly in the Law on Health Care, which will regulate the rights of healthcare providers and create relevant guarantees for protection of their rights. To the least, legislative amendments must cover the issues such as:

The rights of healthcare providers in accordance with the requirements of a healthcare plan;

Contractual rights of healthcare providers;

Additional powers of healthcare providers;

The rights of healthcare providers associated with treatment of patients;

The right of healthcare providers to faith, consciousness and religion.

5.4 LEGAL ASPECTS OF TEACHING AND PRACTICE OF STUDENTS AND RESIDENTS OF MEDICAL INSTITUTES

Participation of students and residents of medical universities in the process of medical care

5.4.1 The law

Pursuant to Sub-Paragraph (h) of Article 18.1 of the Law on the Rights of Patient, a patient has the right to receive from a healthcare provider a full, objective, timely and comprehensive information on the identity and professional experience of a healthcare provider. In accordance with Paragraph 4 of the same Article, in case

of a patient's incapacity or inability to make conscious decisions, such information is provided by a healthcare provider to a patient's relative or legal representative. Under Article 20 of the same Law, a patient has the right to refuse to receive information foreseen under Article 18.1 except from cases, when non-acceptability of information can inflict serious harm to the health and/or life of a patient and/or third person.

Under Article 26.1 of the same Law, a patient's informed consent is required for his/her use as a teaching object (what does the use as a teaching object mean?). Informed consent precedes the use of a patient as a teaching object. According to Paragraph 2, the use of incapable patients as teaching objects is regulated by the Law of Georgia on Health Care. Pursuant to Paragraph 3, a patient's consent is not required in cases, when the following is used for teaching purposes: (a) information available in medical documentation on a patient, which does not provide a possibility to establish a patient's identity; (b) materials obtained throughout the treatment and diagnostic process (urine, blood, other tissues), which warrants a patient's anonymity.

In accordance with Article 30 of the same Law, only directly participating persons are allowed to attend the process of providing medical care, except for cases when a patient agrees to or requests the attendance of other persons (who are the persons directly participating in the process?).

Article 42 of the same Law stipulates that using the minor patients under 16 years of age for teaching purposes is allowed only through an informed consent of his/her parent or legal representative. When making a decision, a patient's participation is necessary in light of his/her age and mental capabilities. Using the minor patients over 16 years of age for teaching purposes is allowed only through his/her informed consent. A patient's decision is made known to his/her parent or legal representative.

Pursuant to Paragraph 1 of Article 47 of the Law on Medical Activity, an entity of independent medical activity is obligated to obtain from a patient the verbal informed consent on participation in the medical education process, while for the participation in medical-biological research - a written informed consent.

According to Paragraph 2 of the same Article, if a patient is incapable or has limited legal capacity, and/or is unable to make a conscientious decision, an entity of independent medical activity obtains a written informed consent of a patient's relative or legal representative concerning the involvement of a patient in the medical education or medical-biological research process.

The Law on Health Care

Article 8.3. A verbal informed consent shall be a necessary condition for participation of a patient in the medical education process.

Article 11. In respect of patients who are incapable or are unable to make conscientious decisions, medical intervention or their inclusion in the medical education and scientific research processes shall be allowed only in view of his/her will declared in advance (when s/he was able to make conscientious de-

cisions), while in the absence of the latter - through the informed consent of his/her relative or legal representative.

5.4.2 The analysis

There is no document in Georgia regulating the involvement of students/residents in the treatment process; however, the established competences determine that they must gain clinical skills. Such skills are gained in both the state and private clinics. It is hard to believe that any of these entities strictly observes the principles of confidentiality of information on a patient or applies in practice the process of obtaining preliminary informed consents.

Previously there was a distinction between the definitions of the terms “clinic” and “hospital”, where a clinic was a clinical base of education system, which provided medical care and carried out educational, research and scientific activities, while a hospital was only a healthcare provider institution. Unlike Georgia, these definitions are still maintained abroad. When a patient opts to receive treatment in a clinic, s/he signs the consent in advance, and thus a student or resident is not precluded from participating in the treatment process.

Apart from the obligation to obtain an informed consent, nothing regulates the participation of students and residents in the patient treatment process at the legislative level, even the Law on Higher Education. Pursuant to the law, such a consent from patient is required, but it is not mostly observed, as in Georgia there is neither internal nor international accreditation system of hospitals, which would have evaluated the conformity of formal and informal rules in hospitals with the standards and their mandatory fulfillment. In the West, when selecting the university and education clinics a patient is aware or is notified prior to being served, that residents (private doctor, doctor on duty, etc.) will be involved in his/her treatment process. A patient may refuse this and even ask that his/her private doctor is not a resident but a certified (diploma graduate) specialist. However, in such case a patient will mostly have to bear extra costs to receive such exclusive service. Regardless of such “discomfort”, these clinics have sufficient amount of patients owing to a high demand for specialists and a high quality of medical care.

In case of Georgia, when the status of education and university clinics is not regulated, the hospital hierarchy system is disrupted, and the effective mechanisms of quality control of medical care are absent, it is premature to discuss any extra regulations.

Recommendation: It is necessary to make a decision at the level of policy formation, which will enable the law-makers to define at legislative level the participation of students and residents in the process of medical care, develop relevant sub-statutory acts and reflect this issue properly in the licensing and accreditation process.

7 ■ DISCUSSION

6.1 UNIFICATION/CODIFICATION OF HEALTHCARE LEGISLATION

To avoid the legal conflicts, gaps, duplications, flawed technique and a number of other vague norms in the healthcare legislation as displayed in the present legal analysis, it is crucial to unify and codify a host of laws in the field of health care.

Owing to a significant influence of the continental law system, the Georgian law system is inclined towards unification of legal norms through the codification. The purpose is to include thematically inter-related norms in one law (code), in order to avoid the conflict and duplication of norms, vagueness and other gaps.

The Law of Georgia on Normative Acts allows for the unification and integration of norms in the code, and provides a definition of the code as follows: *“A code is a systematized normative act of legal norms regulating the particular (uniform) social relations.”*

Through the application of the above-mentioned legal mechanism, it is vital to unify and integrate in one code the following laws: the Law of Georgia on Health Care, the Law of Georgia on the Rights of Patient, the Law of Georgia on Medical Activity, and the Law of Georgia on Public Health. For example, the code may be titled the “Code of Health Care”, which will contain the unified terminology and unite the norms regulating each legal institute in sections (books). Such approach will on one hand get rid of different definitions of the same institutes, and on the other hand will provide a possibility to rule out the conflicts, inconsistencies and other gaps both in terms of legal technique and content-wise.

