USAID
FROM THE AMERICAN PEOPLE

CoReform
HEALTH SYSTEMS TRANSFORMATION

REGULATION OF HEALTH PROFESSIONALS

OPTIONS AND RECOMMENDATIONS

Sepetember 2008
This publication was produced for review by the United States Agency for International Development. It was prepared under the auspices of CoReform

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This document was prepared with financial assistance from USAID
Contract No. GHS-1-00-03-00039-00 Task Order 800

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REGULATION OF HEALTH PROFESSIONALS

OPTIONS AND RECOMMENDATIONS

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INTRODUCTION

The ongoing healthcare reform in Georgia is ambitious and associated with risks. At this stage, priorities of the reform are finalizing privatization of medical service provision and changing the model of public financing. Now modifying field regulations reflecting new relationships in the emerging new environment is becoming an important factor for the success of the reform.

The goal of the paper is to discuss options for aligning regulatory environment with the principles of the ongoing reform.

It is worth noticing that in spite of focusing on professional education the main issue to be discussed is how to manage the process to facilitate development of the optimal model of regulation. In addition, regulations themselves will have a development potential. Elaboration or modification of rules of regulation should be carried out according to the needs of a sector development.

MOTIVATION AND APPLICATION AREA OF REGULATION

A motivation to regulate is mainly linked with an attempt to reduce the problems in terms of safety, quality and pricing of services.

1. **Safety of services**
2. **Quality of services**
3. **Prices of services**

The listed areas of regulation are overlapping. Setting a mandatory requirement for one of them will indirectly influence two other factors. The problem of elaborating adequate regulations is mainly associated with the difficulty of estimating a magnitude of this indirect influence.

E.g., it is quite difficult to draw a clear line where the regulation of specialist's competencies ends and where the responsibility of an organized healthcare provider to ensure adequate environment enabling a physician to practice required skills starts. In other words, ideally, skills required from a physician, requirements defined for a hospital administration in terms of equipment, infrastructure or management quality should be concordant, and it is obviously a difficult goal to achieve.

As an example of extreme policy scope let's assume, disregarding the context, that the aim of service quality regulation is to achieve the same level of medical education and service provision in Georgia as in Belgium and that this level has already achieved - i.e. a capacity of professional human resources to produce services of such quality that are close to those of provided in Belgium is ensured. It can be expected then that in such a situation a massive emigration of Georgian medical personnel to the Western countries will become then a main issue for Georgia. Therefore, it will be optimal to balance quality requirements and investments for implementing these requirements with the investments in other components of the sector while the total amount of investments will be dependent on a market demand. A central planning and effective management of human resources is a

paramount problem in the developed countries with a high culture of public administration. Such a goal probably should not be considered for Georgia.

Despite the difficulties of such kind for the reason of simplicity, we will try to group the instruments used in a regulatory practice by their content. To reduce the amount of material to be discussed it is enough to **review** the process **on the example of regulating health professional education**.

REGULATION OF EDUCATION

Organizationally, medical education is regulated at three main stages.

1. **Regulation of higher medical education**
   - 1.1. Regulation of the number of individuals willing to get higher medical education
     - 1.1.1. Quota (the number defined by the accreditation center)
     - 1.1.2. Number of publicly funded students (study grants);
   - 1.2. Regulation of the process of higher education
     - 1.2.1. Accreditation of the program (curriculum) of higher education
     - 1.2.2. Length of higher education
       - 1.2.2.1. Mandatory volume (length) of theoretical education
       - 1.2.2.2. Mandatory volume (length) of training practice
     - 1.2.3. Completion of higher education
       - 1.2.3.1. Unified post diploma qualifying examination – certification examination (external)[1]
   - 1.3. Quality assessment of higher education (accreditation of an institution of higher education)
2. **Regulation of specialty training**
   - 2.1. Policy on specialty training
     - 2.1.1. Requirement to have specialty training
   - 2.2. Obtaining the right to undergo specialty training by an applicant
     - 2.2.1. Based on assessing of an individual by the regulating authority
   - 2.3. Regulation of a provision of specialty training
     - 2.3.1. Unclear requirements for provision of specialty education, difficulties in administration, limited competition among providers to attract residents
   - 2.4. Regulation of the process of specialty training
     - 2.4.1. Defining required duration of specialty training;
     - 2.4.2. Defining required curriculums for specialty training;
     - 2.4.3. The right to provide specialty training.
   - 2.5. Recognition of the results of specialty training
     - 2.5.1. One-stage assessment (examination) carried out by the regulating authority
3. **Continued education and professional development**
   - 3.1. Deregulated

[1] Law of Georgia on Higher Education:

Article 76. Regulated Professions

1. Only Law of Georgia shall define the list of regulated professions requiring higher academic education and passing certification examinations (28.03.2007. N4529)

The obligation for a periodical renewal of a right to practice no longer exists.

Stage I – Higher Education

There are no serious barriers to start medical education. A number of private medical schools prepare human resources for healthcare sector along with university medical education provided by the state. Quality of medical education is under the control of the Ministry of Education and Science by means of the mandatory requirements for accreditation defined for any institution of higher education. These requirements are quite general and do not aim directly at assuring the quality of medical education. Their role can be viewed as being a tool for ensuring minimum study environment where higher education should take place.

Objective criteria are not used for determining a minimum duration of higher education. In principle, educational programs and study methods used by different higher institutions to define a minimum duration of higher education should be comparable with each other. It is desirable if one considers variety of new methods of education used by medical schools and great discrepancies in the quality of their final output.

At the end of higher education, a graduate student gets a diploma and becomes eligible to work **as a junior doctor** under supervision. **The right to work as a junior doctor** is similar by its content with a license used in the Western countries, giving an individual a legal right to start practicing as a physician.

Note #1
In Georgia, the right to practice medicine under supervision is defined by a diploma of a higher accredited medical school.

As we can see from the table below, at the first stage of education all regulatory instruments are legalized in Georgia and the level of their application and influence on the overall situation is in hands of respective administrative bodies.

Note #2
It can be said that administrative bodies will obtain legal capacity to impose restrictions at every stage of education as they increase their technical competencies.

Table #1

	Stage of Higher Education	Regulatory Instrument	Competent Body
1	Defining the number of students	Rule used for defining the number of students	MES[2] - At the proposal of the LEPL National Center of Education Accreditation
2	Public funding	Public educational grant	MES
3	Private funding	Deregulated	
4	Selection of individuals	Unified national	MES - LEPL National Center of

[2] Law of Georgia on Higher Education, Article 7, Paragraph 1, Subparagraph "f".

	willing to get education	examination	Education Accreditation
5	Study course	Program accreditation	MES - of the LEPL National Center of Education Accreditation
6	Length of education	Credits	Defined by law
7	Quality control of the process of education	Institutional accreditation	MES - of the LEPL National Center of Education Accreditation
8	Certifying the fact of completing education	Diploma	Institution of higher education

Stage II – Specialty Training

A fact of completing education is certified by a diploma issued by a higher educational institution. Pursuant to the Law of Georgia on Education, "a medic who has got a diploma" is eligible to pursue his or her studies in a MA or a residency program. However, it should be noted that this condition is not enough to continue study due to the somewhat contradictory provision of the Law on Medical Activity stipulating that passing a unified qualifying examination is a mandatory requirement to obtain the right to proceed to specialty training – i.e. to move to the stage of specialization it is required to overcome an examination barrier. A special feature of this barrier is that it is a first attempt to substitute a regulatory competence of the education authority for that of the healthcare authority.

Healthcare authority has a leading role in regulating specialty training. However, pursuant to the paragraph 5, article 47[1] of the Law on Higher Education accreditation of a residency program (program accreditation) is carried out jointly by the MoLHSA and the MES.

Table #2

	Stage of specialty training	Regulatory Instrument	Competent Body
1	Obtaining the right to undergo specialty training	Unified qualifying examination	MoLHSA – Council – LEPL Agency for Regulating Medical Activity
2	List of specialties	Normative act of the Minister of Labour, Health and Social Affairs	MoLHSA
3	Study course and its duration	Accreditation of a residency program	A joint competence of the MoLHSA and the MES
4	Quality control of the process of education	Institutional accreditation	MoLHSA – Council – LEPL Agency for Regulating Medical Activity
5	Right for independent medical practice	Unified state certification examination	MoLHSA – Council – LEPL Agency for Regulating Medical Activity

To obtain the right for independent medical practice a graduate of a higher education institution (a junior physician) having state accreditation should acquire a medical specialty. The right to undergo specialty training is linked with passing a unified post diploma qualifying examination. After the examination, there are two options to acquire practical skills and theoretical knowledge in a desired specialty:

1. Residency;
2. Post diploma education alternative to residency.

A principal difference between the two is a source of funding. The first one is exclusively financed by the state (except dentistry) while the second one is funded privately. As for technical differences, the most important distinction is that alternative education is more flexible being manifested by a possibility to extend twofold the length of training compared with the residency program in the same specialty.

The right for independent medical practice is gained by passing a unified certification examination upon completion of a residency or alternative post diploma education. After passing the examination successfully, a certificate in a given medical specialty is given to a physician enabling him to work as a medical specialist at the same time defining the limits of his or her competencies as an independent medical practitioner.

Stage III – Continued Professional Development

Pursuant to the amendments to the Law of Georgia on Medical Activity as of May 2008, continued professional development is transformed to a voluntary process. However, many questions need to be answered. Why a voluntary process is left defined in the law? Who is responsible for developing this process? What benefits will entail participating in this process?

Regulatory Bodies

Regulatory authorities are:

1. **Ministry of Education and Science of Georgia;**

Competencies of the Ministry of Education and Science are limited to regulating higher (university level) medical education.

2. **Ministry of Labour, Health and Social Affairs of Georgia;**

Competencies of the Ministry of Health start from administering a post diploma qualifying examination extend to managing a process of post diploma specialty training and end with conducting a state certification examination.

3. **State Agency for Regulating Medical Activity;**

The agency is a lower organization in the system of the Ministry of Health and its major function is implementation of policies defined by the Ministry. The agency ensures administration of examinations a formal supervision of professional activities. The agency gathers information on disputes arising while performing professional activities and submits collected information to the respective council of the Ministry for decision-making.

4. **Professional Development Council;**

The council in itself is a union of bureaucratic and professional organizations. Like the European countries, a dominant role of professional groups is apparent in the council. The council provides advice to officials enabling them to make decisions on issues of professional regulation.

Options for Implementing Technical Changes

Possible Changes at the Stage of Education

Recommendation #1
Abolish a defined mandatory length of medical education

Recommendation #2
Abolish mandatory program accreditation

Recommendation #3
Retain mandatory institutional accreditation

As it becomes clear from the analysis of current situation, the role of two stakeholders – a "provider of education" and a competent public body responsible for education policy – is apparent at this stage. Organized private employers and purchasers of services appeared as direct stakeholders of the system in connection with the essence of the ongoing reform.

Instruments used in the Western countries to regulate the stage of education (duration of practical and theoretical training, study curriculums, educational institutions recognized by the state based on an assessment) exist in Georgia as well. The difference is that institutional players do not participate in decision-making or are involved in decision-making only formally.

Table #2 – Interests of involved parties

Existing and new stakeholders	Individuals interested in getting education	Providers of medical education	Users of human resources (Health care providers)	Organized payers (Insurance industry, the state) + payers	The state + taxpayers
Number of staff	Market demand	The number optimal for profit maximization	Interested in having options to choose from	Indifferent	Interested
Quality of education	Interested	Indifferent	The most interested	Interested	Interested in the result of cooperation

Organized employers of medical personnel are most interested in the quality of education as well as in having options to choose from on the market. Organized payers (insurance industry) are directly interested in average qualification of medical staff as a whole. Disregarding the role of these two new stakeholders in the process of supervising higher education should not be considered a correct approach.

Consequently, it is possible to consider the following options:

Table #3: Commencement of medical education

	Existing practice	Option I	Option II
Obligatory requirement for education institution – a right for operation	• Is granted through the process of accreditation	• Is granted through the process of accreditation (content of a license)	• Licensing
Way of public funding	• Universal subsidies (through grants)	• Selective subsidies (e.g. deficient professions or professions associated with increased public interest / risk)	• No subsidies

Table #4: Length of medical education

	Existing practice	Option I	Option II
Public policy on a mandatory length of theoretical and practical education	• Universal overall length of theoretical and practical education is defined	• Competencies of defining the length of education are delegated	• Setting the mandatory length of education is prohibited

Table #5: Educational program

	Existing practice	Option I	Option II
Public policy on a program of education	• Elaboration of a mandatory theoretical and practical education program is defined	• Courses of theoretical and practical education are segregated • Curriculums of theoretical courses are defined on the basis of and according to their international analogues • A curriculum of a practical course for the educational sector is defined based on the demand of industry representatives	• Not regulated • Introduction of mandatory programs are prohibited

Supervision of the process of education	• Ministry of Education and Science (with the elements of a self-regulation)	• By means of intermediary and licensing exams organized and held by the industry	• By means of intermediary and licensing exams held by a representative body

Analysis of the Stage II and Possible Options

According to the legislation in force, upon completion of the first stage of education a diploma of a higher education institution is issued giving the right to work as a junior doctor. The diploma, by its content, is similar to the license used in the Western countries that gives a holder the right to work under supervision. At the same time, competencies of a junior doctor are not defined clearly and if such a doctor works in a respective environment under supervision (factually, acquiring practical experience and knowledge) he or she is deprived of the opportunity that such an activity be regarded as a commencement of specialty training; we do not consider that it is a practical approach.

Note #3
It is important, that a status of a junior doctor will not be a legal impasse in a physician's professional development.

Recommendation #4
Abolish a mandatory unified qualifying examination required for commencing specialty training.

Recommendation #5
A diploma and a physician's license should be issued simultaneously.

Certification in Georgia includes a main function of certification (right to work) and certain functions of licensing – i.e. it certifies competencies of various kinds and at the same time gives the right to practice.

For example, if a person completes specialty training (a residency program) in anesthesiology-resuscitation- one of the longest course of specialization, then pursuant to the existing regulations he or she cannot work as a family physician unless he or she undergoes specialty training in a given field. Regulations in force concerning the stage of specialty training have a strong impact on the effectiveness of a labour market by limiting seriously a labour mobility.

Different public policy options of can be considered in this regard:

		Specialty training
1	The role of the state in specialty training	1. Abolishing legal obligation of regulating medical specialties by the state; 2. Limiting the area of regulation by seriously reducing the number of specialties; 3. Delegating powers of a mandatory regulation of specialty training; 4. Delegating powers of a voluntary regulation of specialty training;
2	The basis of giving	• Period of practice, certified by a medical facility or a trainer physician

	the status of a specialist	• Checking the acquired knowledge (examination)
3	The body giving the status of a specialist	• State body • Delegating to the association of service providers • Delegating to the multilateral representative body (the state, providers, financial intermediaries, professional groups)
4	Administrative sanctions	• Suspending a certificate • Cancelling a certificate

At the stage of specialty education, it is critical to take into account demands of emerging private healthcare providers in knowledge and practical skills of human resources. These providers assume the role of a major stakeholder and a leading party in developing educational programs for specialty training. The issue in what form and in what period they should get involved in the process where they do not play a role in these days is to be discussed.

A special role of PHC doctors within the new institutional arrangement has to be noted. The insurance industry will be vitally interested in the professionalism and prioritization of the role of PHC. Therefore, involvement of the insurance industry in raising professionalism of PHCs will be a matter of priority.

Providing Specialty Training

It is critical for the circles interested financially in the competencies of a professional staff to create opportunity for involving these groups not only in setting the rules of regulation but also in implementing a training process. A clear need in deregulating the rule and criteria of accreditation of medical facilities where provision of a post diploma education (professional training) is possible becomes apparent[3]. In addition, providers of specialty training should have a capacity for setting requirements for individuals applying for residency training instead of a unified post diploma qualifying examination administered by the state.

Options for institutional change

It is desirable to change the institutional arrangement in parallel with correcting obvious inconsistencies in the existing regulatory frame.

Delegate competencies of making decisions and elaborating rules of regulation to a representative body under legislation.

Provide for the opportunity to involve employers in the representative body notwithstanding the fact that they may not consider themselves to be able or feel unprepared to get involved in the process of regulation and decision-making.

[3] Order of the Minister of Labout, Health and Social Affairs N 135/n as of 18.04.2007 – on approval of the rule for participating, managing and assessing post diploma education alternative to a residency training (professional training) and the rule and criteria of accrediting medical facilities where provision of a post diploma education (professional training) is possible.

It is desirable that the organizational structure and functions of the representative body be set out in compliance with a respective international standard (e.g. ISO standard on arrangement, competencies and rights and responsibilities of a certifying authority).

Legal framework

It will be important to get answers on principal issues, which in turn are preferable to be formulated in the result of a consensus, before starting the work on the model.

What should be defined by law?

- Competences of resolving disputes and debates which will be entrusted to the "body" - i.e. scope of powers within which the "body" will operate;
- Stakeholder rights which cannot be restricted by the "body" (e.g. right of a doctor to participate in the process of certification, to appeal against any decision made by the "body" or any defined procedure);
- Cases when the "body" will be held responsible and sanctions:
    - Financial;
    - Other

Participants

It can be defined that at least the following participants should be present to make a decision:[4]

1. The state – a ministry;
2. Organized providers of health services;
3. Organized purchasers of medical services;
4. Professional organizations;
5. Providers of education;

Define the competence to organize structures needed for certain issues on their own.

Competencies and responsibilities

- The competence to agree on rules and conditions of decision-making by the "body";
- Should there be decisions that have to be made by the "body" and should there be a party who will make such decisions instead of the "body" if the latter fails to do so?
- Source of funding needed for operating the system of certification and covering liabilities.
- Other activities performed by the "body" should not compromise the process of certification.

Transparency

- Is it needed to ensure transparency of work performed by the "body" founded on a voluntary basis?

[4] It will also be of interest to involve representatives of the independent medical practitioners' association.

- If yes, how should the transparency is ensured?
- Will the parties not involved in the work of the “body” (e.g. independent practitioners) be responsible for providing information to the consumers about compliance of their services with the “voluntary” standard developed by the “body”?

Instruments

- Should the regulatory instruments used by the “body” be defined by law?
- How should we imagine the ways of administering decisions being made and their funding?

ATTACHMENT # 1: RECOMMENDATIONS ON AMENDMENTS TO THE REGULATING LEGISLATION FOR ACTIVITIES OF MEDICAL PERSONNEL

PROFESSIONAL MEDICAL ACTIVITIES

1. Introduction

The present Report drafted under the CoReform Project has been reviewed with the wide group of stackholders. By considering their ideas and the new suggestions shared during the discussions the document specifies recommendations on professional regulation provided by the consultant in the Major Report.

The document summarizes Final Report's conclusions based on the grounds of the ideas shared by interested parties along with the short corrected description of the proposed scheme.

Formal meetings with participation of the commissioning organization (MoLHSS) have been held with:

1. Representatives of insurance industry;
2. Representatives of new management teams of hospitals acquired by investors;
3. Rector of the largest educational institution (Tbilisi State Medical University) responsible for provision of profesional training.

2. Description of New Regulations and Conditions

The suggested regulation scheme of professional medical operation envisages sharp deregulation of legislation, introduction of the efficient mechanism for protection of patietients' rights and facilitation of the establishment of the environment for resolution of disputs between the providers and consumers.

2.1. Principles

Service provider and consumer relations should be based on the following principles:

1. **Everybody** has right to provide medical services, **except the following:**
   1.1. Medical interventions declared under the legislation as explicitly risky manipulations for life and health.
2. Launch of medical service implementation **implies** service provision by recongnized professional standards, if no other provision is envisaged in the specific terms and conditions of the agreement;
3. The state protects the right of the professional sector representative in applying his/her formal title, which is granted through special (theoretical and/or pratical) education;
4. Compensation of material and immaterial damage caused in the process of medical service to the patient whould occur by applying financial mechanism rather than administrative charges;
5. Possibility of consideration and dispute resolution between the service provider and consumer with a competitive principle is ensured;
6. In cases when the fault of service provider is confirmed in the damage caused to the consumer, financial resources should be made available to provide an adequate compensation to the damaged consumer;
7. State, ensures the implementation of the rules agreed through negotiation of the private sector via the judiciary.

2.2. Adjustments in Motivation Trends

In line with these principles several technical issues of fundamental importance need to be explained for facilitation of relations between the parties.

Models applied for regulation of professional operation are based on **two pre-conditions**, which are essential for attainment of positive results. The first pre-condition may be characterized as the *ability* of the service provider *to render* it, while the second pre-condition is the practical implementation of the ability itself in individual cases. The first pre-condition is ensured if qualifications through relevant education and the second – *the motivation to operate* for the best implementation of the ability *notwithstanding* the essence of the motivation.

If the acclaimed mechanism of the “ability” generation is the adequate education and practice, there is no unified idea established on the implementation system of the ability.

The fact remains that the existing regulation system focuses on protection of formal signs of the ability generation. While discussing the introduction of adjustments on the policy level the main task was to conceptualize a scheme, which would have an impact on the formalized criteria of ability generation on the level of the motivation system rather than the contrary.

The essence of the work conducted by the consultant was to conceptualize and present such a framework, which will enable provision of professional service quality adequate to the demand. The author believes the definition of rules for bilateral legal relationship of the parties and introduction of practical mechanisms of their execution. This idea has been more solidified after the meeting with health sector representatives.

2.3. Scheme Participants

2.3.1. Medical Service Providing Physical Entities

Everybody has the right to provide medical services, provided:

- Not everybody has the right to provide full spectrum of medical services. Implementation of medical manipulations, which are prohibited for entities without the relevant authority thereby restricted with the list promulgated in the law;
- Implementation of the prohibited manipulations on a regular bases of even once (except wht cases when they are required for saving life when other means are not available). Violation of this rule is a criminal offence and charged under the law;
- The list of prohibited manipulations is formulated by a representative body as a recommendation to the Minister.

2.3.2. Entities Granted Professional Authority

1. An entity has right to apply the professional authority provided s/he has been granted a state license;
2. It is desirable to set two major medical professions under the law:
   2.1. Doctor;
   2.2. Nurse.

3. A license holder is obliged to make the information open and easily accessible to the consumer (patient) about personal qualification and service responsibility type;
4. Application of professional authority by the state may be protected in narrow medical specialisations as well (with pre-defined rules and conditions).

2.3.3. Core Medical Specializations

As mentioned above, it is recommended to declare doctor and nurce as core medical specialisations. To get a license in these specializations it is essential to hold relevant education. It is desirable that medical education is not regulated with obligatory criteria of least time.

Medical education enables an entity to exercise legal application of the relevant authority and carry out the exceptional procedures defined in the law.

2.3.4. Narrow Specialization

- The state does not get involved in the formation of narrow specialisation.

At the same time the state believes the narrow specialisation as a significant message indicating about the competence of the entity at the professional labour market and its provision to the consumer conditions the reduction of information on the market. By taking into consideration the pre-conditions[5] for the efficient operation of the market the state stands ready to spend resources for the provision of correctness of the message in cases when its conditions need to be protected.

Without the demand of state acknowledgement, definition of narrow specialization, award of the authority as a result of the certification process are voluntary and may be enforced by under any conditions and by any entity.

2.3.4.1. Requirements for the Recognized Certification Body

It is important for the regulation scheme to establish conditions which will enable the establishment of voluntary narrow specialization within its scopes.

It is logical that the definition of narrow specializations and application of the authority by the narrow specialist under the protection of the state may have practical importance, provided:

1. Competencies of the specialist are clearly defined (*or the foreign equivalent is acknowledged*);
2. Operational standards of narrow specialisation service are clearly defined (*or the foreign equivalent is acknowledged*) (recommendations and guidelines for clynical practice);
3. In addition it is possible that rules and conditions for training of the specialists may be justified;
4. There is an interested party, which conducts the qualification acknowledgement procedure (certification) and is materially *liable* for its quality;

Expenditure of state resources for protection of authority application will be justified provided the above conditions are met.

[5] Controversial issue. This form has been developed as a more acceptable form to parties after the consultations of the author with the interested parties.

At the same time, certifying body (responsible for the assessment of professional qualification) may be any legal or physical entity, whose operation are related to the definition of professional qualifications and responsibility over them under the rules as defined on the ground of their assessments. Certifying body may be a professional union.

2.3.4.2. Responsibility of the Recognized Certifying Body

Acclaimed certifying body is obliged to:

1. Consider the disputes on harm caused to consumers by its certified members through violations of the professional ethics and medical operation;
2. Make its decisions publicly accessible on the behaviour and operation of the member;
3. In cases on harm caused by the member to consumers present the interests of the member at the arbitration/court of law (if agrees to the corectness of the member's actions).
   3.1. If the member acknowledges its fault the certifyin body enforces measures towards the member as defined in the internal circular and does not participate in protection of its professional interests at the court of law/arbitration.

2.3.5. State

For the execution of the principles presented above the state competence implies the application of following measures:

1. Licensing of physical entities;
   - Licensing is the obligatory pre-condition of the state application of professional authority;
2. Acknowledgement of the certifying body:
   - By acknowledging the certifying body the state provides for protection of the members' application of the granted authority;

The state maintains a registry of licensed and certified personnel, along with ensuring their public disclosure.

The state is authorized to acknowledge the medical service standards declared by international professional organizations or foreign countries. In line with the declared standards, the rendered service if proven harmful to patients will be the legal mechanism for the service provider.

2.4. Professional Responsibility and Mechanism for Its Implementation

2.4.1. Principle of Responsibility

Free expression of will by parties is associated with implementation of relevant obligations. It is recommended that the responsibility is funded under the following principle[6]:

- **It is prohibited for the industry representative to render service which is beyond its competence.**

In other words the service provider has legal right to render only the adequate service within its competense. A competent body has the right to grant the right of service under its sole decision or to

[6] Similar to the principle used in the Netherlands.

allow some part of the service to an entity which has no relevant qualification provided the responsibility over such service does not shift to another entity.

2.4.2. Realization of Responsibility

Pre-condition for the realisation of the responsibility is to ensure competent and unbiased consideration of the consumer's complaint.

Initiation of relationship between the parties should be considered as a legal contract envisaged under the law for the provision of service by the provider in line with the standards acknowledged in the country. In addition, the list of fundamentally important issues implies the definition of **"services complying with the quality standards acknowledged in the country".**

Prior to the development of national standards or the adaptation of foreign ones it is desirable that the state legalizes the clinic practice standards used by international organizations specialized in development of affirmative medical standards or clinic practice standards applied in the developed countries. This action will give the adequate sense to the term which is frequently used in the current legislation without any particular content.

Despite this solution of standard-related problems it should be noted that this action is not sufficient. In contrast with the technical standards it will be rather hard if not impossible to take decisions without expertise studies and specific situation analysis on the basis of clinic practice guidelines and protocols.

The next step is the availability of an unbiased decision by competent entities in the conditions of formally acknowledged standards by competition principle. Right to apply to the court of law is a constitution right granted to every individual and legislative provision for exercising it will be declarative and a true waste of time. At the same time it is clear that qualification and procedures of the judiciary will most probably be insufficiently flexible and user-friendly, accessible and forthcoming.

We believe that as it was suggested in the Main Report, professional arbitration mechanism may be used with the following observation:
Service initiation face by the service provider under the professional arbitration should occur under the law for consideration of the consumer complaints.

The following logical step if the accesability to financial resources, which may be assessed adequately for the compensation of the damage caused to the consumer by the service provider through arbitration/court of law. Adequate application of this mechanism without the accessible financial resources is rather impossible to imagine. Also, the Main Report deemed inappropriate to include the award of an obligatory license as one of the pre-conditions for safeguarding the incurred damage. In this particular case it is clear that the incurred damage is being safeguarded.

For operating medical practice (with the applicable restrictions) in the conditions of sharp reduction of the impediment or claim to get the adequate financial guarantee is the obligatory pre-condition for getting the professional authority.

2.4.3. Consumer

The legislative amendments should incorporate the following conditions and rights:

1. Consumer is authorized to request the following information before service is rendered:
   1.1. On the professional authority of the service provider;
   1.2. On the Financial Responsibility Form for possible damage caused as a result of the medical service;
2. Within three years from the moment of initiation of the service the consumer is entitled to file a dispute and claim compensation of the damage;
3. If the consumer dies his/her legal representative may claim compensation for the damage within a year, provided they did not refuse to the pathologic-anatomy extraction of the corp;
4. Consumer is entitled to file a complaing on the activity of medical service provider through a competent representative even in those cases when no national or international standards have been developed in relation to the rendered service.

2.4.4. Arbitration

(See Main Report)

2.4.5. Representative Body

Representative body (except the rights and responsibilities elaborated in the Main Report) is desirable to be added the following:

1. Development of the list of exceptional medical procedures and authority to make recommendations to the Minister;
2. Authority to acknowledge the certification body;
3. Authority to acknowledge the roadmaps and guidelines for clinical practice applied in foreign countries;
4. Develop an adequate financial guarantee volumes and possible form[7].

3. Process Conducted Under the Proposed Sceme

1. Towards deregulation trend the following should be done at pre-diploma stage:
   1.1. Invalidation of obligatory time (credit hours) for getting higher medical education;
   1.2. Invalidation of accreditation of study programmes.
2. Graduates of higher educational institutions shall be awarded relevant diplomas;
3. To get the legal application right for professional authority – the license a diplomised graduate shall:
   3.1. Show the relevant diploma;
   Procurement of insurance for the damage caused by professional mistake, or
   3.2. Present financial guarantee.
4. Licence is issued with open-date.;
5. Control over the protection of license terms and conditions (the only changeable component of which is the insurance) shall be conducted by the license issuing body;

[7] Verified with competent officials (Author's note)

Despite the fact that confirmation of the doctor’s qualification as a formal obligation goes beyond the direct responsibility of the state, the presented scheme provides direct insentives for the definition of specialty formation and qualifications of individual doctors for insurance purposes.