

APPROVED  
by Decree of the State Committee of Ukraine  
for Regulatory Policy and Entrepreneurship,  
of the Ministry of Health of Ukraine  
of 16 February 2001 p. # 38/63

Registered with  
the Ministry of Justice of Ukraine  
on 2 March 2001 p. # 189/5380

## **LICENSING CONDITIONS of Conducting Business Activity Related to Health Care Practice**

### **1. General Provisions**

1.1. These Licensing Conditions of Conducting Business Activity Related to Health Care Practice (hereafter referred to as Licensing Conditions) have been developed in conformance with the Basics of Laws of Ukraine On Health Care, Laws of Ukraine On Pharmaceuticals, On Enterprises in Ukraine, On Licensing of Individual Types of Economic Activities and other legislative acts, and determine the licensing conditions of conducting business activity related to health care.

The effect hereof shall apply to all business entities duly registered as legal persons irrespective of their organizational and legal form and type of ownership, and conducting activities related to health care practice, as well as to natural persons being business entities performing activities in the said sector.

Pursuant to Article 9 of the Law of Ukraine On Licensing Individual Types of Business Activities, health care practice as a type of business activity is subject to licensing.

1.2. Terms defined herein shall be used in the following meanings:

**Health care practice** – activities associated with a package of social measures aimed at promoting public health improvement, raising sanitary culture, diseases and disabilities prevention, at diagnostics, aid to persons suffering from acute and chronic diseases, as well as at rehabilitation of patients performed by persons having special education and qualification.

**License to performing health care practice** – a document conformant with a state-approved form attesting to the right of a licensee to perform health care-related activities indicated therein during the specified period and conditional on the licensee's compliance with licensing conditions.

1.3. The acceptance of documents filed for obtaining a license, license issuance, re-issuance and annulment, issuance of license duplicates, maintaining of licensing files and registers, oversight, within respective competence, of licensee's compliance with licensing conditions, issue of instructions on remedying Licensing conditions violations shall be a responsibility of the Ministry of Health of Ukraine.

1.4. The permitted types of health care practice shall include activities as per medical specialties as listed in an Annex attached hereto.

## **2. Licensing Conditions of Performing Business Activities Related to Health Care Practice**

### **2.1. General Organizational Conditions**

2.1.1. Business activities related to health care practice must be performed by the Licensee in observance of requirements of the following acts:

*1) Laws of Ukraine:*

On Consumers Rights Protection;

On Enterprises in Ukraine;

On Licensing Individual Types of Business Activities;

Basics of Laws of Ukraine On Health Care;

On Ensuring Public Sanitary and Epidemiological Well-being;

On Protection of Citizens Against Infectious Diseases;

On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and Social Protection of the Population;

On Pharmaceuticals;

On Circulation in Ukraine of Drug Substances, Psychotropic Agents, Their Analogs and Precursors;

On Measures of Countering Illicit Circulation of Drug Substances, Psychotropic Agents and Their Abuses;

On Psychiatric Care;

On Transplantation of Organs and Other Anatomical Materials to Humans;

*2) Orders of the Ministry of Health of Ukraine On Organization and Provision of Medical and Sanitary Care to Citizens, as registered with the Ministry of Justice of Ukraine;*

*3) Resolutions of the Cabinet of Ministers of Ukraine dated 15.07.97 N 765 On Approving the procedure of State Accreditation of a Health Care Institution.*

2.1.2. Health care practice shall be performed by business entities subject to a license authorizing individual types of health care practice conditional on their meeting qualification, organizational and other special conditions established hereunder.

2.1.3. Business activities relating to individual types of health care practice shall be performed by business entities subject to a license and subject to the availability of:

premises meeting set sanitary standards and rules; conformity of premises to said rules and standards shall be attested to by a conclusion of a State Sanitary and Epidemiological Service institution having a jurisdiction over the place of business;

instruments, equipment, apparatus equipped in accordance with the Table of Medical Equipment of Treatment and Diagnostic Wards, Outpatient Clinics, Inpatient Hospitals (hereafter referred to as the "Equipment Table") as approved by the Ministry of Health of Ukraine.

All measurement instruments and equipment must have passed metrology testing.

The conformity of the material assets with the Equipment Table, availability of legal and regulatory framework governing individual types of health care practice shall be confirmed by a conclusion of the Ministry of Health of Ukraine or an agency empowered by it.

2.1.4. Privately owned business entities, as well as natural persons being business entities engaged in health care practice shall not be entitled to issue medical certificates.

The issue of prescriptions and receipt of medications and medical-purpose items by patients free of charge or on preferential terms, as well as issue of prescriptions for drug substances, psychotropic agents and precursors permitted for use in Ukraine and contained in respective Tables of the List of Drug Substances, Psychotropic Agents and Precursors as approved by the Resolution of the Cabinet of Ministers of Ukraine dated 06.05.2000 N 770, shall be performed by business entities in accordance with the Rules of Issuing Prescriptions for Medications and Medical Purpose Products as approved by the Order of the Ministry of Health of Ukraine dated 30.06.94 N 117 and registered with the Ministry of Justice on 28.07.94 under N 171/380.

## **2.2. Qualification Requirements to Business Entities Engaged in Health Care Practice**

2.2.1. Conducting health care practice shall be allowed to persons having adequate special education and meeting qualification requirements.

The conformance with qualification requirements shall be attested to by:

- 1) a diploma on medical education as per the state-approved form;
- 2) certificate of a specialist doctor as issued by a higher medical education institution and by III – IV accreditation levels post-graduate education institutions in accordance with a Regulation On Doctors Assessment as approved by the Order of the Ministry of Health of Ukraine dated 19.12.97 N 359 and registered with the Ministry of Justice on 14.01.98 under N 14/2454;
- 3) certificate of awarding (confirmation) of a respective qualification category in the specialty as issued in accordance with a Regulation On Doctors Assessment as approved by the Order of the Ministry of Health of Ukraine dated 19.12.97 N 359 and registered with the Ministry of Justice on 14.01.98 under N 14/2454;
- 4) certificate of completion of professional upgrade and retraining of paramedical personnel and pharmaceutical workers as issued by I – III accreditation levels higher medical education institutions (post-graduate education) in accordance with the Regulation On Issuing Certificates of Completion of Professional Upgrade and Retraining of Paramedical Personnel and Pharmaceutical Workers, as approved by the Order of the Ministry of Health of Ukraine dated 07.09.93 N 198 and registered with the Ministry of Justice of Ukraine on 31.12.93 under N 208;
- 5) document certifying the duration of working experience in line of specialty as at the time of filing an application (copy of employment record containing data for the past years or an excerpt therefrom).

2.2.2. Persons without special education seeking a license authorizing health care practice in the field of traditional and alternative medicine must meet qualification requirements as set by the Ministry of Health of Ukraine as per the Order of the Ministry of Health of Ukraine dated 10.08.2000 N 195 On Issuing Special Permits to Health Care Practicing in the Field of Traditional and Alternative Medicine, as registered with the Ministry of Justice of Ukraine on 20.02.2001 under N 150/5341.

2.2.3. Doctors having not worked for over three years in line with a concrete doctor's specialty shall be permitted to engage in health care practice upon having passed internship in accordance with the Order of the Ministry of Health of Ukraine dated 17.03.93 N 48 On the Procedure of Referrals of Doctors for Internship and Their Subsequent Admission to Medical Activity as registered with the Ministry of Justice on 01.04.93 under N 19.

2.2.4. License to health care practice to young specialists having graduated from higher medical education establishments who had studied under the state procurement procedure shall be issued upon their completion of a working term as envisaged by the Regulation On Employment of Graduates of Higher Education Establishments

Having Studied Subject to Conditions of State Contracts Under Educational and Vocational Curriculums of Training of Masters of Public Administration as approved by the Resolution of the Cabinet of Ministers of Ukraine of 1 September 1997 N 949, and upon their being awarded with a qualification category in a medical specialty.

2.2.5. Specialists having undergone medical training at medical education institutions of foreign countries shall be permitted to engage in professional activities in Ukraine upon the verification of their qualification in accordance with the Procedure of Admission to Health Care and Pharmaceutical Activity in Ukraine of Citizens Having Passed Medical or Pharmaceutical Training at Educational Establishments Abroad, as approved by the Order of the Ministry of Health of Ukraine dated 19.08.94 N 118-c (as amended and added), and registered with the Ministry of Justice of Ukraine on 12.09.94 under N 218/428.

2.2.6. Business entities shall be prohibited from admitting to performing health care practice by persons failing to meet qualification requirements as set under paragraphs 2.2.1 - 2.2.5 hereof.

### **2.3. Special Conditions to Business Entities Engaged in Health Care Practice**

2.3.1. Business entities engaged in health care practice must:

adhere to applicable sanitary and hygienic standards and rules, as well as to asepsis and antisepsis rules;

observe requirements attached to the operation and use of medical purpose products and materials in compliance with user's manuals and specifications;

adhere to requirements to maintaining medical documentation (bookkeeping and accounting) conformant with state statistics forms as approved by the Order of the Ministry of Health and the State Committee for Statistics dated 31.07.2000 N 256/184 On Approval of Forms of State Statistics in Regard of Health Care and Guidelines Concerning Filling Them Out, registered with the Ministry of Justice of Ukraine on 22.09.2000 under N 635/4856, and to file reports to zonal medical statistics agencies and regional medical statistics centers within set deadlines;

provide emergency medical assistance to patients being a critical condition, as well as in cases of accidents or in acute diseases;

abide by professional ethics and deontology principles, keep doctor's secret except for cases when otherwise is required under applicable laws.

2.3.2. Medical intervention (application of diagnostics, prophylactics or treatment techniques capable of affecting human body) shall comply with the procedure envisaged by Articles 42 – 44 of the Basics of Laws of Ukraine On Health Care.

2.3.3. The right to conducting medical examination and issue of official conclusions in connection therewith with the view of identifying HIV-infected patients and provision of health care aid to them and medical monitoring shall only be vested in state and communally-owned health care establishments having adequately equipped special laboratories accredited in accordance with the procedure established by the Cabinet of Ministers of Ukraine.

### **2.4. Special Conditions to Business Entities Engaged in Health Care Practice**

2.4.1. At performing health care practice, business entities shall comply with requirements of the procedure and conditions of compulsory insurance of medical personnel and other persons in cases of person's being infected with a human immune deficiency virus in line of duty, as well as in cases of disability or death caused by diseases resulting from HIV-infection development, as approved by the Resolution of the Cabinet of Ministers of Ukraine of 16.10.98 N 1642.

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Annex to Para. 1.4  
Licensing Conditions of Performing Business Activity Related  
to Health Care Practice

**List  
of Permitted Types of Health Care as per Specialties:**

<b>Medical Specialties</b>	<b>At State and Communally- Owned Establish- ments</b>	<b>At Privately Owned Health Care Establish- ments</b>	<b>Natural persons (business entities)</b>
Obstetrics and gynecology	+	+	+ (except pregnancy monitoring and delivery)
Allergology	+	+	+
Anesthesiology	+	+	
Bacteriology	+	+	+
Virology	+	+	+
Gastroenterology	+	+	+
Hematology	+	+	+
Genetics (laboratory)	+	+	+
Genetics (medical)	+	+	+
Geriatrics	+	+	+
Hygiene, child and youth	+	+ (except state sanitary and epidemiological oversight functions)	+ (except state sanitary and epidemiological oversight functions)
Occupational Hygiene	+	+ (except state	+ (except state

		sanitary and epidemiological oversight functions)	sanitary and epidemiological oversight functions)
Nutrition Hygiene	+	+ (except state sanitary and epidemiological oversight functions)	+ (except state sanitary and epidemiological oversight functions)
Disinfecting	+	+	+
Derma-venerology	+	+	+
Child's allergy	+	+	+
Child's anesthesiology	+		
Child's gastroenterology	+	+	+
Child's hematology	+	+	+
Child's gynecology	+	+	+
Child's derma-venerology	+	+	+
Child's endocrinology	+	+	+
Child's immunology	+	+	+
Child's cardio-rheumatology	+	+	+
Child's neurology	+	+	+
Child's nephrology	+	+	+
Child's oncology	+		
Child's orthopedics and traumatic surgery	+	+	+
Child's otolaryngology	+	+	+
Child's ophthalmology	+	+	+
Child's pathology anatomy	+		
Child's psychiatry	+		
Child's pulmanology	+	+	+
Child's dentistry	+	+	+
Child's urology	+	+	+
Child's phthisiology	+		

Child's surgery	+	+	+
Pediatric infectious diseases	+	+ (except treatment of especially hazardous diseases)	+ (except treatment of especially hazardous diseases)
Child's neurosurgery	+		
Dietology	+	+	+
Endocrinology	+	+	+
Endoscopy	+	+	+
Epidemiology	+	+ (except state sanitary and epidemiological oversight functions)	+ (except state sanitary and epidemiological oversight functions)
General hygiene	+	+ (except state sanitary and epidemiological oversight functions)	+ (except state sanitary and epidemiological oversight functions)
General practice – family medicine	+	+	+
Immunology	+	+	+
Infectious diseases	+	+ (except treatment of especially hazardous diseases)	+ (except treatment of especially hazardous diseases)
Cardiobiology	+	+	+
Clinical biochemistry	+	+	+
Clinical immunology	+	+	+
Clinical laboratory diagnostics	+	+	+
Combustiology	+	+	+
Environmental sanitation	+	+ (except state sanitary and epidemiological oversight functions)	+ (except state sanitary and epidemiological oversight functions)
Laboratory immunology	+	+	+

Laboratory studies of environmental factors	+	+	+
Laboratory studies of environmental physical factors	+	+	+
Laboratory studies of environmental chemical factors	+	+	+
Physiotherapy exercises	+	+	+
Physiotherapy exercises and sport medicine	+	+	+
Emergencies medicine станів	+	+	+
Medical psychology	+	+	+
Microbiology and virology	+	+	+
Narcology	+	+ (except treatment of drug addiction)	+ (except treatment of drug addiction)
Traditional and alternative medicine	+	+	+
Neurology	+	+	+
Neurosurgery	+		
Neonatology	+	+	
Nephrology	+	+	+
Oncological gynecology	+		
Oncology	+		
Oncological otolaryngology	+		
Oncological surgery	+		
Health care organization and administration	+	+	+
Orthodontics	+	+	+
Orthopedic dentistry	+	+	+
Orthopedy and traumatology	+	+	+
Otolaryngology	+	+	+
Ophtalmology	+	+	+
Parasitology	+	+	+
Morbid anatomy	+		

Pediatrics	+	+	+
Youth therapy	+	+	+
Proctology	+	+	+
Radiotherapy	+	+	+
Occupational pathology	+	+	+
Psychiatry	+	+ (except treatment of emergencies and issue of opinions on mental conditions)	+ (except treatment of emergencies and issue of opinions on mental conditions)
Psychotherapy	+	+	+
Psycho-physiology	+	+	+
Pulmonology	+	+	+
Radiation sanitation and hygiene	+	+	+
Radiology	+	+	+
Radionuclides diagnostics	+	+	+
Rheumatology	+	+	+
Rontgenology	+	+	+
Reflex therapy	+	+	+
Sanology	+	+	+
Sexopathology	+	+	+
Sport medicine	+	+	+
Dentistry	+	+	+
Vascular surgery	+	+	
Ship medicine	+	+	+
Forensic histology	+		
Forensic immunology	+		
Forensic examination	+		
Forensic criminology	+		

Forensic toxicology	+		
Forensic cytology	+		
Forensic psychiatric examination	+		
Surdology	+	+	+
Therapeutic dentistry	+	+	+
Therapy	+	+	+
Toxicology	+	+	+
Thoracic surgery	+		
Transplantology	+		
Transfusionology	+	+	
Ultrasonic diagnostics	+	+	+
Urology	+	+	+
Physio-therapy	+	+	+
Phthiology	+		
Functional diagnostics діагностика	+	+	+
Surgery	+	+	+
Surgical dentistry	+	+	+
Cardio-surgery and vascular surgery	+		
<b>Paramedical Specialties</b>			
Dentist	+	+	+
Dental mechanic	+	+	+
Ambulance medical assistant	+	+	+
Medical assistant	+	+	+
Sanitary doctor's assistant	+	+ (except state sanitary and epidemiology oversight functions)	+ (except state sanitary and epidemiology oversight functions)
Epidemiologist assistant	+	+ (except state sanitary and	+ (except state sanitary and

		epidemiology oversight functions)	epidemiology oversight functions)
Sanitary education doctor's assistant	+	+	+
Sanitation and hygiene laboratory assistant	+	+	+
Clinical and diagnostics laboratory assistant	+	+	+
Immunology laboratory assistant	+	+	+
Bacteriology laboratory assistant	+	+	+
Radiology laboratory assistant	+	+	+
Surgery nurse	+	+	+
Nurse	+	+	+
Physiotherapeutic nurse	+	+	+
Massage nurse	+	+	+
Therapeutic physical training nurse	+	+	+
Functional diagnostics nurse	+	+	+
Dietology nurse	+	+	+
Dentistry nurse	+	+	+
Medical statistician	+	+	+

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