THE PECULIARITIES OF IMPLEMENTATION OF MEDICAL ACTIVITIES IN THE REPUBLIC OF BELARUS

Minsk, August 2020

REVERA

Public health service has traditionally been a complicated sector in terms of legal regulation. Moreover, the Belarusian medical services market has some specific features with respect to regulation of particular branches of practical medicine and licensing.

REVERA's team has compiled a comprehensive guide reflecting the specifity of the Belarusian market and describing the opportunities for doing business in Belarus. When preparing our guide, we were relying on legal norms as well as on law enforcement practice.

This guide will be helpful for existing medical centres as well as companies that consider doing business in the medical services sector in Belarus.

Anna Aniskevich – manager of REVERA's Life Science business line, attorney

Our expertise

The REVERA team is involved in the implementation of global pharmaceutical and healthcare projects, including those related to the protection of international pharmaceutical companies within their restructuring.

1. Advising on appropriate forms of presence in the Belarusian market
2. Assessment for criteria of operating via permanent establishment in the territory of the Republic of Belarus
3. Consulting on issues of determination of price for pharmaceuticals, medical devices and medical equipment
4. Protection of intellectual property rights, including rights to trademarks and patents
5. Support of the activity of office in the Republic of Belarus regarding ongoing legal matters
6. Assessment of advertisement and promotion of medical goods for compliance with the legislation of the Republic of Belarus
7. Protection of interests in procedures of public procurement of medical goods
8. Consulting on matters of medical goods registration in the Republic of Belarus
9. Structuring of relations with distributors

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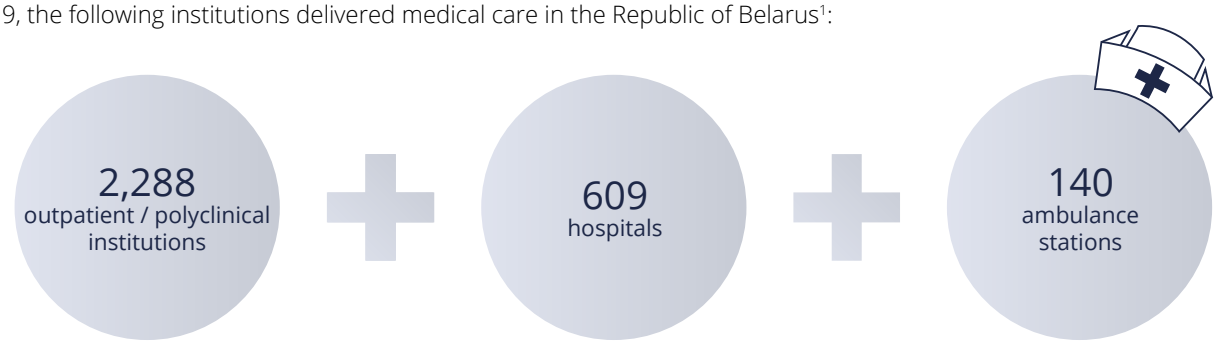
1. CHARACTERISTICS OF THE PUBLIC HEALTH SYSTEM AND THE MEDICAL SERVICES MARKET OF THE REPUBLIC OF BELARUS

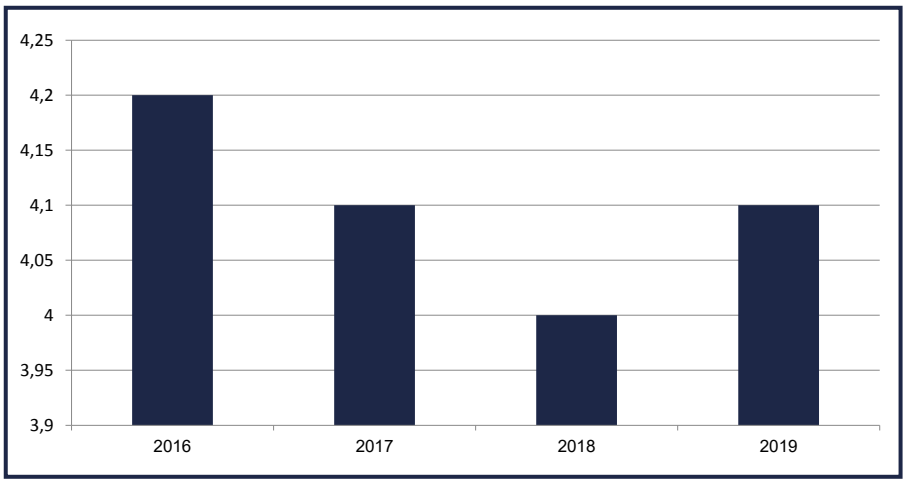
In 2019, the following institutions delivered medical care in the Republic of Belarus[1]:



Main figures of the public health system of the Republic of Belarus are as follows:

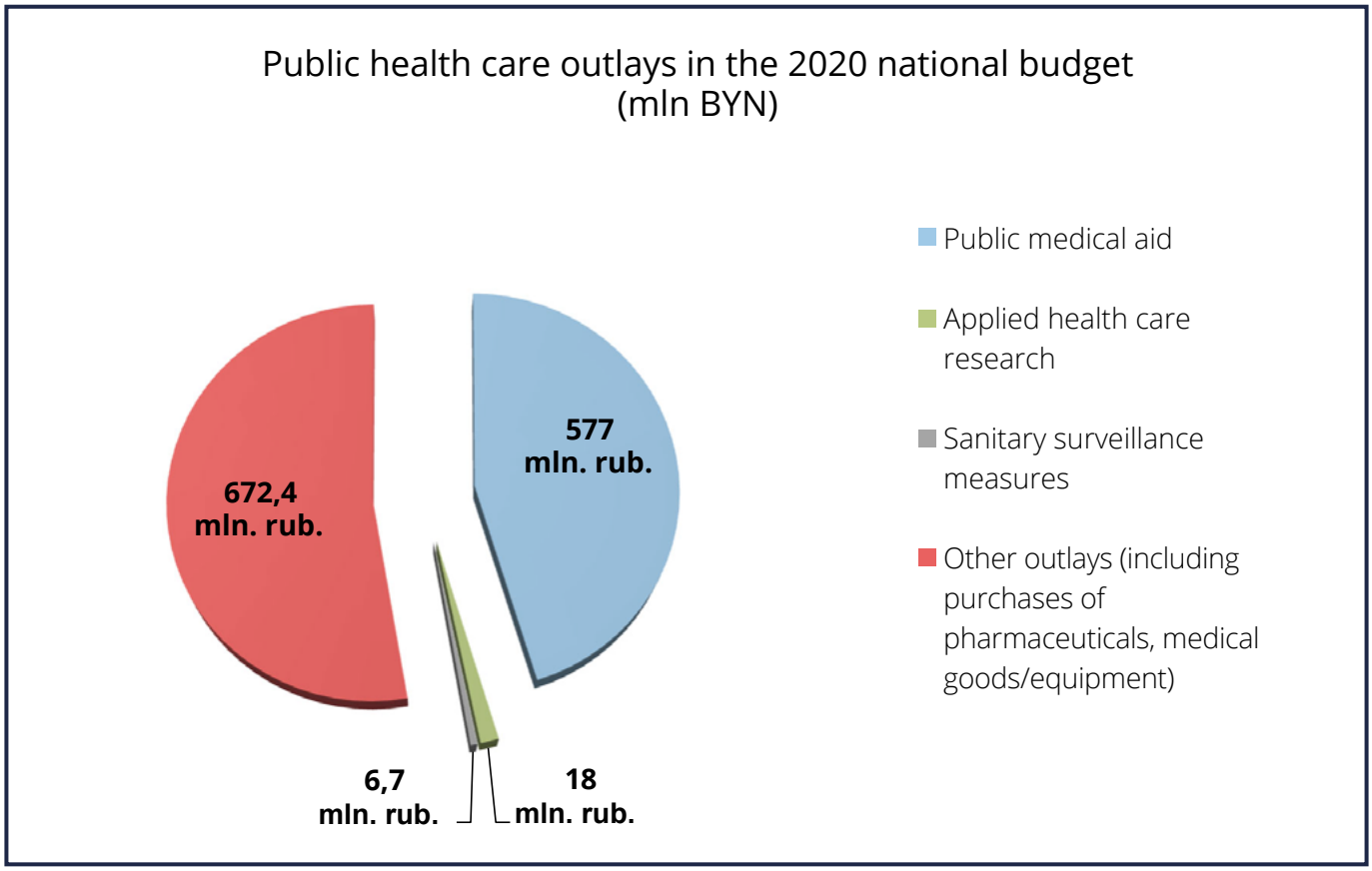
Index	2013	2014	2015	2016	2017	2018	2019
Number of medical specialists							
total, '000 people	49,3	51,1	53,2	54,5	54,8	55,4	55,6
From among the total number of medical specialists – the number of practitioners							
total, '000 people	37,3	38,7	40,4	41,5	42,0	42,5	42,9
per 10,000 people	39,4	40,8	42,5	43,7	44,3	44,9	45,6
Number of mid-level healthcare providers							
total, '000 people	122,7	123,9	126,1	125,8	126,3	126,9	126,4
per 10,000 people	129,5	130,7	132,8	132,4	133,1	133,9	134,4
Number of hospitals	646	641	640	636	622	612	609
Number of hospital beds							
total, '000 people	84,0	82,3	82,0	80,3	80,0	79,5	79,2
per 10,000 people	88,7	86,8	86,3	84,5	84,2	83,9	84,2
Number of outpatient / polyclinical institutions	2 267	2 309	2 325	2 311	2 196	2 230	2 288

Specific weight of outlays of the consolidated national budget of the Republic of Belarus for public health care is normally 4.0 to 4.2% GDP.



[1] Section 1 hereof uses information published on the official websites of the National Statistical Committee, Ministry of Public Health, Ministry of Finance and Ministry of Labour and Social Protection.

The 2020 national budget allocates **1,274.1 mln BYN** to finance the "Public Healthcare" sector. Outlays covered by funds extended by the International Bank for Reconstruction and Development under the project "Modernisation of the public health care system of the Republic of Belarus" account for **122.65 mln BYN** (almost 10% of all national budget's health care outlays).



Despite the availability of free medical services and considerable budgetary financing, public health care still accounts for a large proportion of public expenditures.

Thus health care expenditures in 2019 accounted for 4.5% of all consumer spendings of Belarusian citizens, which is more than 2 times higher than in 2000.

Certain statistical indicators of activities of entities of the Republic of Belarus created in partnership with foreign legal or physical persons **in the sphere of public health care and social services in 2019** are as follows.

- **37** corporate entities with foreign investment
- **152,323** service revenue (ths. BYN)
- **5,378** net profit (ths. BYN)
- **3.7** margin on sales (in percentage terms)
- **37,212.6** foreign investments accumulated in the real sector of economy (ths. USD)

As of January 1, 2020, Belarusian medical institutions employ 42.9 ths. practitioners and 126.4 ths. mid-level healthcare providers.

Number of practitioners (by profile) in 2019:

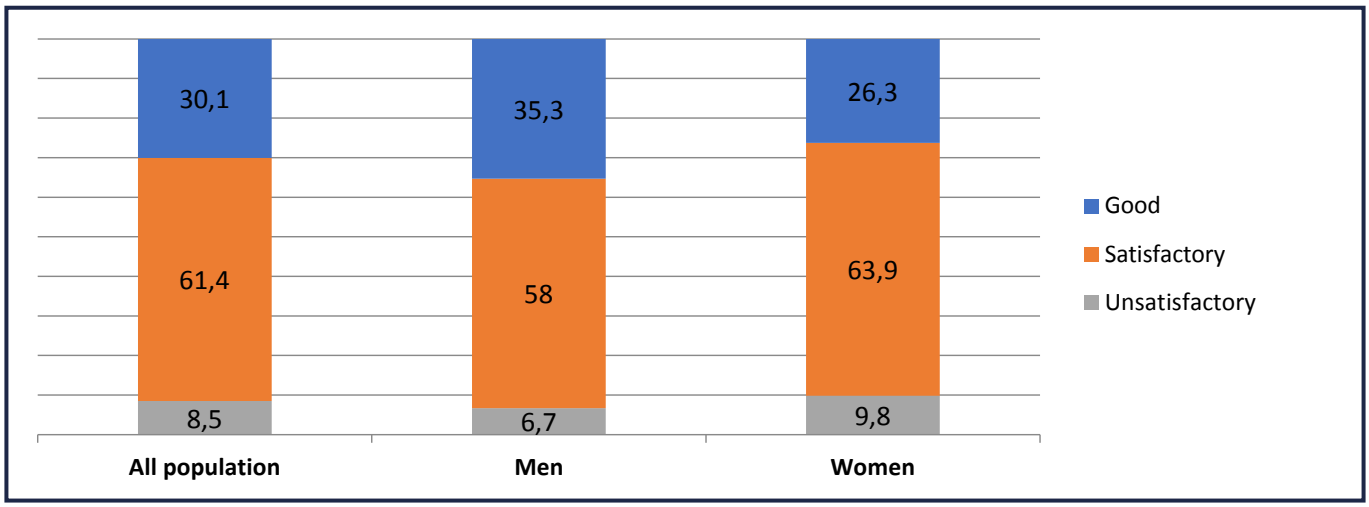
- **pediatric profile** — 4.1 ths. doctors
- **diagnostic profile** — 4.1 ths. doctors
- **surgical profile** — 13.4 ths. doctors
- **therapeutic profile** — 18.5 ths. doctors

The Belarusian employment market faces shortage of medical staff. Medical specialists and nurses are almost always on the top list of eagerly sought workers in the National Vacancies Bank. This is true for both urban and rural areas. As of January 1, 2020, the top 5 professions (specialists/office workers) in the National Vacancies Bank are as follows.

Profession/specialist field	Number of vacancies sought by employers
Urban areas:	
Medical specialist	2,672
Medical nurse (specialist nurse)	2,548
Engineer	1,465
Director	804
Specialist	778
Rural areas:	
Veterinarian	497
Medical nurse (specialist nurse)	408
Veterinary assistant	237
Chief veterinary physician	220
Medical specialist	217

In 2019, the Republic of Belarus had a total population of 9.4 mln. and **127.8 mln. doctor's appointments** (both in outpatient visits and at home).

Therewith, personal assessment of health status (as of early 2020; in percentage of population aged over 16) is as follows:



2. GENERAL APPROACHES TO REGULATING MEDICAL SERVICES

The Republic of Belarus is a socially oriented state and focuses on protecting people's rights and legitimate interests. The right to health care is one of the underlying people's rights. It is exercised through the national medical system.

Law of the Republic of Belarus No. 2435-XII "On public health service" dated 18.06.1993 (hereinafter – the Law) is the legal basis of all medical activities.

Medical activities involve arrangement and administration of medical care, provision of public health and hygiene welfare and arrangement of medical examinations.

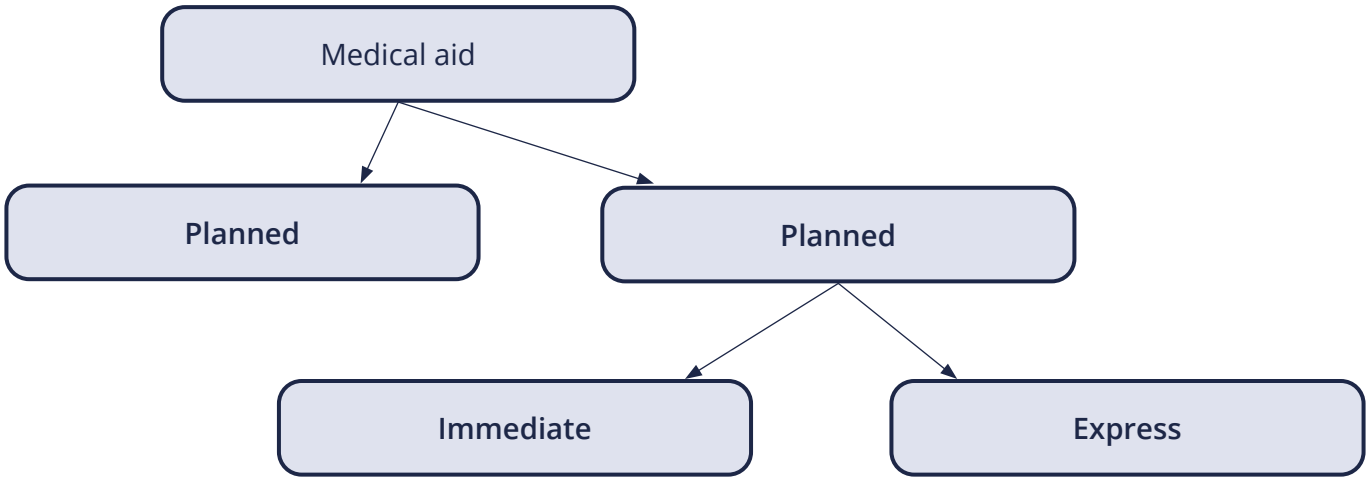
Medical care is a package of medical services aimed at further preservation, strengthening and repair of patients' health, involving medical prophylaxis, diagnostics, treatment, medical rehabilitation and prosthetics carried out by healthcare providers.

The following types of medical care are offered to patients:

I.

No.	Type of medical care	Content	Examples
1	Primary	To be provided where a patient has a common disease, in case of pregnancy/child-bearing, diagnostics or medical prophylaxis	Hygienic and antiepidemic events, vaccination and vaccine prophylaxis
2	Specialty care	To be provided where a patient has a disease requiring special medical treatment techniques.	Prosthetic/orthopedic, rehabilitation aid in stationary and outpatient facilities
3	Hi-tech care	To be provided where a patient has a disease requiring application of new/unique medical treatment techniques involving latest scientific and technical achievements	Cardiac surgery, replacement arthroplasty, transplantation of organs/tissues
4	Social medical care	To be provided where a patient has a chronic illness requiring continuous day-and-night care without a need of intensive medical aid	Treatment of chronic illnesses at the subcompensation stage, with a proximate favourable life forecast
5	Mitigating medical care	To be provided where a patient has a cureless/life-shortening disease requiring medical care techniques aimed at release from pain and/or mitigation of other manifestations of a disease, where other medical care techniques have been exhausted, with the aim of improving patient's life quality	Treatment of chronic sclerosis, obstinate heart failure

II.



Emergency medical aid is administered where a patient suddenly faces an illness, condition and/or acerbation of a chronic illness requiring express or acute , требующих immediate ого *или* express ого medical intervention.

Immediate medical aid is administered where a patient suddenly faces an illness, condition and/or acerbation of a chronic illness that poses threat to patient's and/or other people's life and requires immediate medical intervention.

Express medical aid is administered where a patient suddenly faces an illness, condition and/or acerbation of a chronic illness, or has another illness/condition, that poses no explicit threat to patient's life and requires express medical intervention.

Planned medical aid is administered where a patient has or is assumed to have an illness that does not require immediate or express medical intervention.

As we've noted before, medical aid shall be regarded as a package of medical services.

Therewith, a medical service is a medical intervention or a package of medical interventions, including other operations carried out in administering medical aid.

The Ministry of Public Health of the Republic of Belarus (hereinafter – the MPH) defined a list of medical services and medical interventions in Resolution No. 123 dated 05.12.2016.

It should be noted that certain medical services shall be, in cases stipulated by legislative acts, provided only by state health care facilities. For instance, such medical services include: retrieval and transplantation of organs; change/correction of sex attribute; sterilisation; artificial termination of pregnancy (in some cases); administration of medical aid to patients having a disease posing threat to public health or human immunodeficiency virus; post mortem examinations, etc.

2.1. Medical service procedure

Medical services in the Republic of Belarus may be rendered either for a fee or free of charge. There are different procedures for the provision of medical services to Belarusian nationals and foreign citizens.

2.1.1. Provision of medical services to Belarusian nationals.

Nationals of the Republic of Belarus have a right to affordable health services, which are, particularly, provided by means of:

- administration of free medical care;
- availability of pharmaceuticals;
- accomplishment of measures aimed at public health and hygiene welfare;
- arrangement of medical examinations.

For the purpose of due delivery of medical care, all citizens of the Republic of Belarus are assigned to local state health care facilities, according to the place of residence/stay, and in case of departmental health care facilities – according to the place of work/study/service.

Citizens of the Republic of Belarus are also entitled to medical care in state health care facilities outside their place of residence/stay. Medical care to Belarusian citizens outside their place of residence/stay is delivered in the outpatient or stationary setting by state health care facilities.

While citizens of the Republic of Belarus are entitled to free medical care, the state secures only a limited volume of such care. Normally, minimal public standards are defined, alongside with lists of fee-based medical services.

Principal free medical care services for citizens of the Republic of Belarus offered by state health care institutions include:

- services involving types of medical care provided for in the legislation (primary medical aid in the outpatient setting, in the day-care setting, as well as outside health care facilities; medical social aid on a stationary basis, etc.);
- services, with respect to all types of medical care, in case of sudden occurrence of illness/condition and/or acerbation of a chronic disease, provided in the form of emergency medical aid: immediate or express medical aid;
- services, with respect to all types of medical care, subject to patient's health status, medical indications or contraindications, provided in the form of planned medical care (medical prophylaxis; periodic medical surveillance; medical aid during pregnancy, childbirth, down-lying period, etc.).

A full list of principal free medical care services offered to citizens of the Republic of Belarus by state health care institutions is specified by Resolution of the Council of Ministers of the Republic of Belarus (hereinafter – the Council of Ministers) dated 29.03.2016 No. 259 "On some matters of minimal public social standards in the sphere of health care".

Fee-based medical services are offered in addition to the state-guaranteed basic volume of free medical care and are provided to Belarusian citizens by state health care institutions under written agreements for paid medical services, except where fee-based medical services are rendered on a no-name basis.

For instance, fee-based medical services include: cosmetological services; plastic aesthetic surgery, except surgical services provided on medical indications; reflexotherapeutical services; services involving homeopathy, phytotherapy, weight correction, elaboration of personal diets (with no medical indications), etc.

A full list of fee-based medical services offered to citizens of the Republic of Belarus by state health care institutions is specified by Resolution of the Council of Ministers dated 10.02.2009 No. 182 "On the provision of fee-based medical services by state health care institutions".

2.1.2. Provision of medical services to foreign citizens

Foreigners are entitled to emergency (immediate or express) and/or planned medical aid.

Foreign citizens and stateless persons permanently residing in the Republic of Belarus are entitled to affordable health services (particularly, fee-based and free, immediate and planned), on an equal basis with citizens of the Republic of Belarus, unless otherwise stipulated by legislative acts and/or international treaties of the Republic of Belarus.

Basically, foreign citizens who are temporarily residing or staying in the Republic of Belarus are entitled to medical aid on a fee-paid basis, unless otherwise stipulated by international treaties of the Republic of Belarus.

Therewith, Republic of Belarus has concluded a number of international treaties regulating the delivery of medical care:

No.	Name of international treaty	Main provisions
1	Eurasian Economic Union Treaty (concluded in Astana on 29.05.2014) Member countries: Republic of Belarus Russian Federation Republic of Kazakhstan Kyrgyz Republic Republic of Armenia	1. Member states provide, in their respective territories, the right to free emergency medical aid (immediate and/or express aid) to workers of member states and their family members under the same procedure and upon the same terms as to citizens of employing country. 2. Reimbursement of expenses of a health care facility connected with any emergency medical aid (immediate or express) to workers of member states and their family members is carried out at the cost of respective budgets of the public budget system of employing country, in accordance with applicable health care financing system. 3. Where a patient, after an immediate threat to his/her life or public health has been eliminated, has to receive treatment in a health care facility of employing country, the actual costs of medical services will be paid directly by such patient or from other sources in compliance with laws of employing country, according to applicable tariffs or negotiable prices.
2	Agreement on delivery of medical care to citizens of member states of the Commonwealth of Independent States (concluded in Moscow on 27.03.1997) Member states: Republic of Belarus Republic of Armenia Republic of Kazakhstan Kyrgyz Republic Republic of Moldova Republic of Tadjikistan Republic of Uzbekistan Ukraine	1. Emergency/express medical aid in case of sudden acute conditions/illnesses posing threat to patient's life or public health, accidents, toxications, traumas, childbirth or emergency situations connected with pregnancy, is administered to citizens without delay, free of charge and in full. 2. Right after an immediate threat to patient's life or public health has been eliminated and a patient can be transported, any further medical care will be delivered on a fee-paid basis. 3. Any planned medical care will be delivered on a fee-paid basis, settlement payments being effected according to negotiable prices or applicable price-lists. 4. Planned medical care is delivered to citizens employed under labour agreements/contracts at the cost of employer's funds, in a manner and to the extent as stipulated by respective agreement/contract, or at the cost of citizens' private means.
3	Agreement on mutual granting of equal rights to emergency/express medical aid (concluded in Moscow on 24.11.1998) Member states: Republic of Belarus Republic of Kazakhstan Kyrgyz Republic Russian Federation Republic of Tadjikistan	Citizens of member states are provided with equal rights to free emergency/express medical aid, on an equal basis with citizens of a host country.

No.	Name of international treaty	Main provisions
4	Agreement between the Government of the Republic of Belarus and the Government of the Russian Federation on delivering medical care to citizens of the Republic of Belarus in health care facilities of the Russian Federation, and to citizens of the Russian Federation in health care facilities of the Republic of Belarus (concluded in Saint-Petersburg on 24.01.2006)	Equal rights to medical care, including free treatment in respective health care facilities, are granted to the following citizens of the Russian Federation: 1) permanently residing in the Republic of Belarus; 2) Heroes of the Soviet Union and holders of the Order of Glory of three degrees; 3) temporarily residing in the territory of the Republic of Belarus and employed by entities of the Republic of Belarus under employment contracts. Citizens of the Russian Federation temporarily residing in the Republic of Belarus have equal rights with the citizens of the Republic of Belarus to emergency medical aid and medical care in case of socially dangerous diseases during their stay in the Republic of Belarus . The same rights are granted to citizens of the Republic of Belarus residing in the Russian Federation.

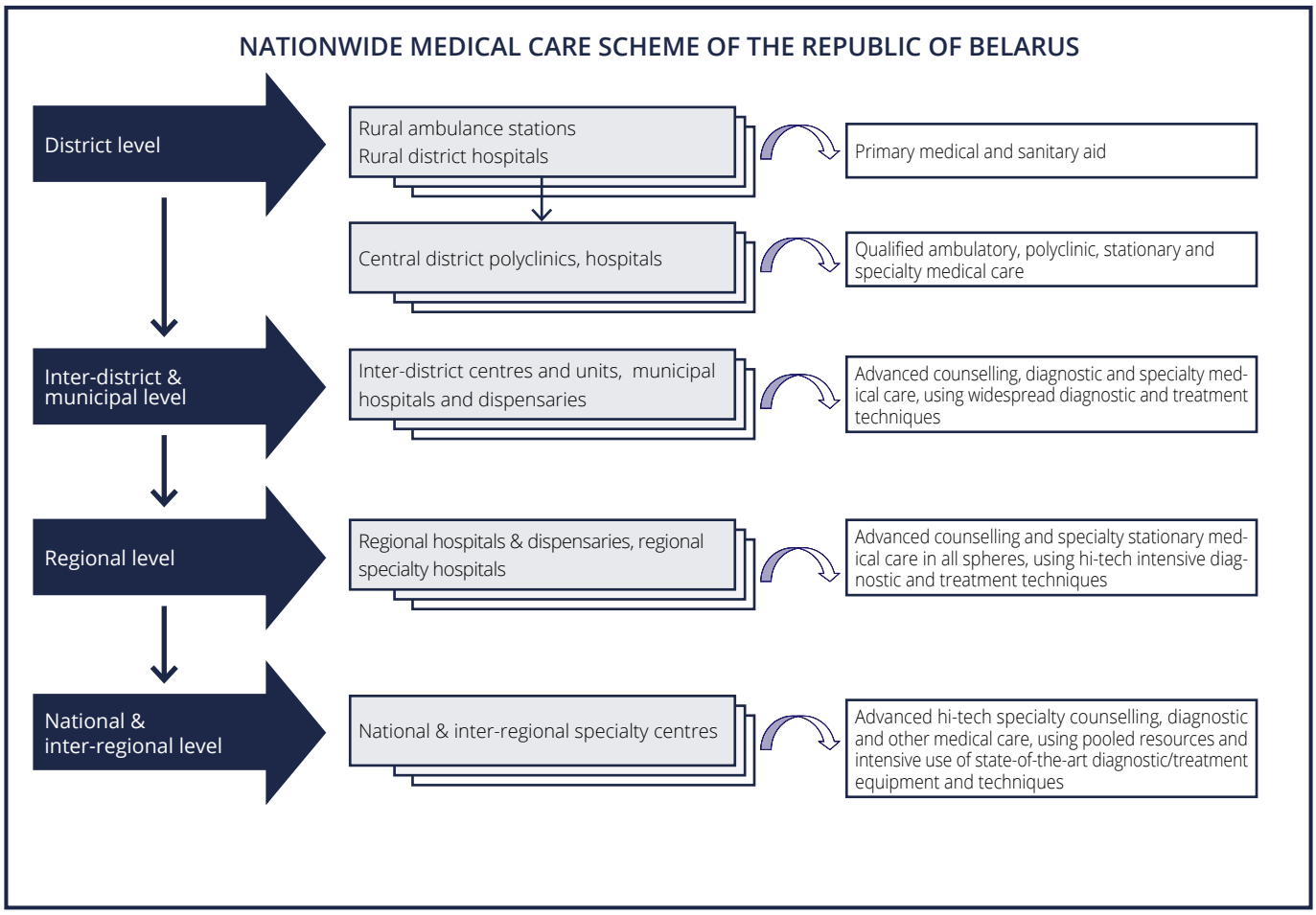
A full list of legal acts regulating international relations with respect to medical aid can be found on MPH's website: https://goo.su/1o6n

At present, the Belarusian government is taking measures to enhance contractual and legal regulation of relations involving health care. Draft international treaties with Uzbekistan, Qatar, Iraq, Serbia, Indonesia and other countries are being prepared.

2.2. Types of health care facilities

At present, public health care of the Republic of Belarus is a 4-level system with a distinct structure of health care facilities: from rural district hospitals to national scientific practical centres.

The national system of health care facilities, and the nationwide scheme of delivering medical care, is as follows:



According to current legislation, **a health care facility** is a legal entity **focusing on medical and/or pharmaceutical activities**.

Health care facilities are divided into 2 categories:

- state health care facilities, including state health centres and state unitary enterprises;
- non-state health care facilities.

The above facilities have been created in accordance with the official nomenclature of health care facilities prescribing that:

- **a hospital facility** is a health care facility providing medical aid on a stationary basis (a hospital, clinic, dispensary, health centre, maternity clinic, child care centre, hospice, university clinic);
- **an outpatient/polyclinic entity** is a health care facility providing medical aid in the outpatient setting and/or carrying out medical examinations (an ambulance station, polyclinic, dispensary, health centre, medical/rehabilitation expert board, military health board, medical/sanitary unit);
- **a clinical entity** is a health care facility providing medical aid to general public and used as a clinical base by educational institutions offering medical/pharmaceutical degree programmes and/or career enhancement courses for medical/pharmaceutical workers, or by research institutions for scientific purposes;
- **a health centre** is a health care facility providing pooling of high-end medical technologies, administering speciality medical care, providing medical rehabilitation, organisational/tutorial functions, sanitary/hygienic measures or epidemiological response;
- **a scientific and practical centre** is a centre involved in scientific work in the field of health care;
- **a central district/municipal hospital (polyclinic, pharmacy)** is a hospital (polyclinic, pharmacy), additionally providing organisational/tutorial management of municipal health care facilities located in respective district/municipal territories.

Health care facilities are entitled to create, in accordance with the procedure established by legislation, as their **structural subdivisions and/or standalone subdivisions**, hospitals, polyclinics, ambulance stations, pharmacies, health posts, feldsher-midwife stations, maternity welfare centres, infant feeding centres, pharmacy warehouses, analytical laboratories, pharmaceutical referral centres, etc.

A full nomenclature of health care facilities is given in the appendix to MPH Resolution No. 35 dated 28.09.2005 "On defining a nomenclature of health care facilities".

Other entities, alongside with their core activities, as well as individual entrepreneurs, may also carry out medical and/or pharmaceutical activities in the manner prescribed by the laws.

By the end of 2019, Belarus had 2,288 outpatient / polyclinical institutions, 609 hospital facilities and 140 emergency/express aid stations.

2.3. Brief description of some types of medical activities

Provision of medical services is at present one of the most dynamic and prospective economic spheres in the Republic of Belarus.

The turnover of commercial market of medical services in the Republic of Belarus shows a tendency towards annual growth. This is due to a number of factors, most important being price rise and growth in demand for fee-based medical services, which, particularly, is due to a heavy load on state medical institutions, shortfall of highly qualified medical staff and up-to-date medical equipment. We believe that the COVID-19 pandemic might play the pivotal role in the future growth of the private market of medical services. In such circumstances, development of non-state (private) market of medical services will be a prospective and promising trend. The following types of hi-tech medical care are among the most sought-after medical services: endovascular surgery, transfusiology, donorship, dentistry, endoprosthetics, assisted reproductive technology, neurology & neurosurgery, plastic surgery, etc.

2.3.1. Dentistry

Dentistry services in the Republic of Belarus are provided by state and private dentistry institutions. The network of providers is very broad.

Dentistry services are provided under licenses for medical activities (ref. section 3).

A large portion of dentistry services is not on the list of free medical services guaranteed by the state. Thus, the following services are rendered on a fee-paid basis:

- dentistry services, preferred by patient, particularly prosthetic dentistry, except such services rendered to Belarusian nationals for free in accordance with legislation;
- dental implantation with further prosthesis, except such services rendered to Belarusian nationals under 18;
- orthodontic bite correction, except bite correction provided to Belarusian nationals under 18 for free by means of functional dental plates.

Dentistry services are classified as fee-based medical services subject to tariffs regulated by MPH (in coordination with the Ministry of Trade). This means that legal entities shall independently establish fixed tariffs for fee-based medical services rendered by then, however such tariffs cannot exceed the established maximum tariffs and must be harmonised with the limit standards of profitability (ref. section 5 "Price formation" for details).

2.3.2. Donorship and transfusiology

Donorship in the Republic of Belarus is regulated by law "On the donorship of blood and blood components".

The law regulates relations in the field of donorship and relations involving processing, storage, realisation, transfusion of

blood or blood components for the purposes of medical care and other purposes established by the law.

Therewith, the law does not apply to any relations pertaining to the sampling, processing and storage of plasma used for the commercial production of pharmaceuticals.

'Donorship' implies a system of arrangements including procurement, processing, storage, transfusion and realisation of blood and/or blood components.

Donorship and transfusiology activities are subject to licensing for medical activities.

Procurement, processing, storage and realisation of blood and/or blood components in the territory of the Republic of Belarus is carried out by blood transfusion facilities, i.e. state health care facilities and medical research institutions involved in activities in the field of transfusiology and medical biotechnology.

Sampling of blood and/or blood components is carried out by blood transfusion facilities, either directly or by means of mobile blood sampling teams.

Transfusion of blood and/or blood components may be carried out by health care facilities, medical research institutions and other medical institutions.

Blood may be donated by Belarusian nationals, as well as foreign citizens and stateless persons permanently residing in the Republic of Belarus, aged between 18 and 60, having full legal capacity, having required medical examination certificates, and having no illnesses/conditions hindering donation of blood and/or blood components .

At donor's option, donor's function may be performed either on a remuneration basis, or on a non-repayable basis. Concrete fees are specified by Resolution No. 693 of the Council of Ministers dated 02.06.2011 "On some issues pertaining to donorship of blood and blood components".

Procedures of procurement, processing, storage and realisation of blood and blood components by blood transfusion facilities in the territory of the Republic of Belarus are regulated by MPH Resolution No. 38 dated 19.05.2011 "On approval of Regulations on procurement, processing, storage and realisation of blood and blood components by blood transfusion facilities in the territory of the Republic of Belarus".

2.3.3. Reproductive technology

Activities involving assisted reproductive technology are regulated by the Assisted Reproductive Technology Law.

'Assisted reproductive technology' implies techniques of medical care involving arrangement of all or some of stages of conception and/or prematurity of embryo(s), until transfer in uterus, are carried out in laboratory conditions.

The Assisted Reproductive Technology Law applies to 3 types of assisted reproductive technology:

1. Extracorporal fertilisation.

2. Surrogacy.

3. Artificial insemination.

Basically, in order to use assisted reproductive technology, a patient must be at least 18 years of age, have full legal capacity, have proper medical examination certificates, and have no contraindications against assisted reproductive technology. Extracorporal fertilisation and artificial insemination are not applied to females of 50 years of age and older.

Donors may provide germinal cells either on a remuneration basis, or on a non-repayable basis. Procedures of payment are specified by Resolution No. 643 of the Council of Ministers dated 13.07.2012 "On the procedure of payment of remuneration to donors of germinal cells and the Unified Register of donors of germinal cells".

2.3.4. Transplantation

Activities involving transplantation are regulated by the Human Organs and Tissues Transplantation Law.

'Transplantation' implies substitution in a patient, by means of a medical intervention, of any missing or mutilated human organs/tissues failing to perform crucial functions, by human organs/tissues received obtained means of organ retrieval. Human organs/tissues are anatomical structures (complete organs, segments of organs, combinations of cells) not defining distinctive personal traits.

In Belarus, retrieval and transplantation of organs are carried out only by state health care facilities.

Transplantation may be carried out only where other methods of medical care fail to save patient's life or repair patient's health. Transplantation is carried out pursuant to an official statement confirming that transplantation is required, and pursuant to respective clinical protocols.

A list of human organs/tissues subject to transplantation has been defined by MPH Resolution No. 134 dated 29.08.2012 "On some issues of transplantation of human organs/tissues".

Human organs/tissues may not be subject of civil transactions, unless such transactions are consummated on a non-repayable basis. Any compensatory transactions and advertising of supply or demand of human organs/tissues are prohibited.

Donors of organs/tissues may be live persons or dead persons. The following live persons cannot act as donors:

- a person that is not patient's spouse or relative (unless bone marrow or hemopoietic stem cells are retrieved, or crossed transplantation is carried out);

- minors (unless bone marrow or hemopoietic stem cells are retrieved);
- persons duly declared as legally incapable and persons of unsound mind;
- persons having illnesses posing threat to patient's life or health;
- pregnant women;
- orphaned children and children deprived of parental care.

Organs may be retrieved from a dead donor from the moment death has been pronounced. Organs may not be retrieved from a dead donor where:

- such person, while alive, or another person duly authorised by him/her, has declared, prior to his/her death, that his/her organs shall not be retrieved for transplantation purposes after death;
- where a state health care facility or another duly authorised body had been notified of such person's refusal to allow retrieving his/her organs for transplantation purposes prior to his/her death, by means of oral or written declaration in the presence of a medical specialist, other state health care officers, or other persons that should be capable to witness such refusal.

Outpatient/stationary medical care involving operations and/or services rendered to both children and adult population requires licensing.

Procedures for acquiring and terminating licenses, requirements to applicants and holders of licenses have been established by the Regulation on Licensing of Certain Types of Activities approved by Edict No. Edict No. 450 dated 01.09.2010 (hereinafter – Edict No. 450). A list of operations and services subject to licensing of medical activities is given in cl. 26 of Appendix 1 to Edict No. 450. It is one of the broadest lists of types of activities subject to licensing (the list is attached as annex to this section).

Apart from cl. 26 of Appendix 1 to Edict No. 450, licensing procedures are regulated by Resolution of the Council of Ministers No. 307 that specifies a list of procedures (surveys/operations) pertaining to works and services subject to subject to licensing of medical activities. This regulatory act will take effect on August 28, 2020. The list from the act is attached as annex to this section.

Licensing of medical activities is carried out by MPH. Licenses are issued to Belarusian companies and individual entrepreneurs (IEs), as well as to foreign companies provided they have a duly established representative office in the territory of Belarus. You should also note that some types of licensable works and services, such as transplantation of organs/tissues, may be carried out only by state health care institutions (ref. section 2 of the guide)

Therewith, no license is required for the following activities:

- medical activities carried out by state health care facilities, educational institutions, social service institutions and the Belarusian Red Cross society; however, such activities may be only carried out where such institutions comply with other special requirements established by legislation;
- spa services: these are complex recreative and curative, cosmetic and/or relaxing services aiming at harmonising physical and/or psycho-emotional state of patients, improving aesthetic appearance and keeping fit, **except for services classified as medical activities**.

3.1. Requirements to license applicants

Licensing requirements and requirements to applicants for licenses for medical activities are as follows:

3.1.1. General licensing requirements and conditions:

- an applicant shall possess, on the basis of a right of ownership, economic control, operative management, or another lawful ground, premises, equipment and transport facilities required for respective licensable activities;
- an applicant shall have a duly appointed person in charge of licensable activities;
- an applicant shall have, on its staff, an employee in charge of technical maintenance and repair of medical equipment and medical products, or shall have agreements on technical maintenance and repair of medical equipment and medical products with a provider of maintenance, assembly, setup and repair services for medical equipment and medical products;

3.2. For legal entities, foreign entities

3.2.1. CEO or another manager must have:

- university degree in medicine;
- qualification category 1 or AAA (highest);
- certificate of advanced training or re-education with respect to a health care facility or specialisation in accordance with licensable works/services/activities applied for by applicant (hereinafter – licensable works/services);

3.2.2. At least one employee per each claimed work/service, in any area of operations, must have:

- university degree in medicine and/or vocational secondary medical education;
- healthcare providers having university degree in medicine must have qualification category 1 or AAA (highest);
- healthcare providers having vocational secondary medical education must have a qualification category (except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category);
- healthcare providers having university degree in medicine must have a record of service in a specialist field complying with licensable works/services of at least 3 years;
- certificate of advanced training or re-education in a specialist field complying with licensable works/services;

3.2.3. Other healthcare providers must have:

- university degree in medicine and/or vocational secondary medical education;
- certificate of advanced training or re-education in a specialist field complying with licensable works/services;
- qualification category, except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category (for privately-owned entities);
- healthcare providers having university degree in medicine must have a record of service in a specialist field complying with licensable works/services of at least 3 years (for privately-owned entities);

3.3. Individual entrepreneurs

3.3.1. Must have:

- university degree in medicine and/or vocational secondary medical education;
- qualification category 1 or AAA (highest) – for those having university degree in medicine;

- a record of service in a specialist field complying with licensable works/services of at least 3 years – for those having university degree in medicine;
- qualification category, except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category, – for those having vocational secondary medical education;
- certificate of advanced training or re-education in a specialist field complying with licensable works/services.

3.3.2. Healthcare providers from among individual entrepreneurs must have:

- university degree in medicine and/or vocational secondary medical education;
- qualification category, except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category;
- a record of service in a specialist field complying with licensable works/services of at least 3 years – for those having university degree in medicine;
- certificate of advanced training or re-education in a specialist field complying with licensable works/services.

3.4. Termination of a license

A license will be terminated:

- where licensee (a legal entity or an individual entrepreneur) is dissolved (terminates activities);
- where a licensing authority or a court decides to terminate license.

A license will be terminated by the decision of MPH in the following cases:

- where licensee (legal entity) is being reorganised (except where licensee (legal entity) is being reorganised by way of transformation, spin-off or accession of another legal entity);
- by virtue of licensee's written notice to MPH of the decision to terminate a licensable activity;
- where licensee has not applied for a license within 6 of deciding to introduce amendment to license;
- in case of violation (particularly, gross violation) of Edict No. 450, licensing requirements and conditions, committed within 12 consecutive months after licensee reported elimination of a similar violation that had not been cured during inspection;
- where licensee has failed, within the period prescribed by respective requirements (order), to cure a breach that resulted in suspension of license, or has failed to give a written notice to MPH of such curing;
- where licensee continues carrying out a licensable activity (or any component works/services) during the period of suspension of license.

Upon court order, a license may be terminated:

- where MPH has adopted an unlawful decision to amend a license;
- where licensee impedes activities of MPH or another supervisory authority aiming to verify compliance with Edict No. 450, licensing requirements and conditions, and particularly impedes any lawful instructions or requirements of officers of such authorities given in their official capacity, furnishes any unreliable documents or other data pertaining to licensable activities;
- where amendments have been made into a license on the ground of any unreliable data furnished by licensee, provided such data are required or are of importance in deciding on such amendments.

Gross violations of Edict No. 450 and licensing requirements/conditions with respect to medical activities are as follows:

- execution of works and/or provision of services involving any licensable activities that have resulted in a long-term decay of health which is confirmed by a decision of an MPH's supervisory medical board;
- use of medical equipment, pharmaceuticals, medical products, treatment/diagnostic techniques not registered and/or not approved for medical use/application in the Republic of Belarus;
- non-compliance with licensing requirements/conditions;
- carrying out of licensable activities in places not prescribed by license;
- lack of medical documentation required for licensable activities/services;
- lack of medical equipment/products required for licensable activities/services;
- lack of full-time employee in charge of maintenance/repair of medical equipment/products, or lack of agreement for maintenance/repair of medical equipment/products; lack of operational medical equipment, proper calibration of respective medical equipment;
- failure to furnish MPH, within one month of duty assignment, with documents confirming appointment of CEO of a health care facility, director of a standalone unit of an entity not being a health care facility, appointment of other healthcare providers instead of those indicated in license documents, appointment of additional healthcare providers in addition to those indicated in license documents.

List of operations and services requiring medical license

1. midwifery
2. allergology & immunology
3. anesthesiology & critical care medicine
4. vaccination
5. venereology
6. gastroenterology
7. haematology
8. genetics
9. gynecology
10. dermatology
11. diagnostics:
    - laboratory: general clinical (non-invasive), biochemical techniques, microbiological, haematological, genetical, immunological, cytological, clinico-morphological (histological), parasitologic, HIV diagnostics;
    - radio diagnostics: roentgenologic, nuclear, computer tomography, magnetic resonance imaging, ultrasonic, heat imaging;
    - anatomico-pathological;
    - functional;
    - endoscopic
12. retrieval/transplantation of tissues:
    - retrieval of tissues;
    - transplantation of tissues;
    - arrangement of blood donorship, procurement, processing, storage of blood and/or blood components, preparations from donated blood
13. infestious diseases
14. cardiology
15. combustiology
16. cosmetology
17. remedial gumnastics
18. massage
19. narcology
20. neurology
21. alternative medical activities:
    - homeopathy;
    - manual therapy;
    - reflexotherapy
22. nephrology
23. general medical practice
24. oncology, particularly radiation therapy, mammalogy & oncohematology
25. orthopedics
26. otorhinolaryngology, particularly audiology
27. ophthalmology
28. pediatrics, particularly neonatology
29. primary medical aid
30. proctology, particularly coloproctology
31. occupational pathology
32. prosthetics: mammary glands; joints; eyes; ears
33. psychiatry
34. psychotherapy
35. pulmonology
36. radiology
37. rehabilitation/recreation therapy
38. rheumatology
39. emergency medical aid
40. dentistry:
    - therapeutic;
    - surgical;
    - orthodontic;
    - orthopedic;
    - dental mechanics
41. therapy
42. toxicology
43. traumatology
44. urology, particularly andrology
45. physiotherapy
46. phthisiology
47. surgery, particularly angiosurgery, periatric surgery, cardiosurgery, neurosurgery, ophthalmology surgery, particularly microsurgery, plastic aesthetic surgery, roentgen-endovascular, thoracal, maxillo-facial, endoscopic surgery
48. extracorporal treatment techniques, particularly hemosorption, dialysis (acute & chronic hemodialysis), plasmapheresis
49. endocrinology

List of procedures (surveys/operations) involving works/services subject to licensing of medical activities

Physiotherapy

1. Application of curative physical factors of electromagnetic nature:

1.1. galvanisation;
1.2. electrophoresis by direct/impulse current;
1.3. hydrogalvanic baths;
1.4. electrodiagnostics;
1.5. electrostimulation;
1.6. transcerebral electrotherapy;
1.7. diadynamic therapy;
1.8. amplipulse therapy;
1.9. interference therapy;
1.10. short pulse electroanalgesia;
1.11. electrotherapy with low frequency pulse currents;
1.12. electromesonic therapy, hydrophoresis;
1.13. electrolipolysis;
1.14. ultratone therapy;
1.15. darsonvalism;
1.16. franklinism;
1.17. pulse low frequency physio therapy;
1.18. inductothermy;
1.19. ultrahigh frequency therapy;
1.20. microwave, radio frequency therapy, radio frequency skin lifting, radio frequency non-invasive lipolysis;
1.21. high-tone therapy;
1.22. megnetic therapy, magnetic stimulation;
1.23. ultraviolet irradiation;
1.24. optical, infrared irradiation (using medical equipment);
1.25. laser therapy, laser non-invasive lipolysis;
1.26. photo-epilation, laser epilation, electro epilation, elos-epilation.

2. Application of curative physical factors of mechanical nature:

2.1. ultrasound therapy, ultrasound cavitation (non-invasive lipolysis);

2.2. vibro therapy, particularly via electrostatical field;

2.3. shock-wave therapy;

2.4. hardware-based traction therapy, traction in water;

2.5. non-contact hydromassage (using medical equipment);

2.6. mechanical hardware-based massage (using medical equipment);

2.7. gravity therapy;

2.8. local barotherapy, normal oxygen barotherapy;

2.9. pneumo-compression therapy;

2.10. vacuum therapy;

2.11. roller-vacuum massage.

3. Application of curative physical factors of artificially modified air medium:

3.1. inhalant therapy;

3.2. hypoxi-therapy;

3.3. air ion therapy (using medical equipment);

3.4. halo therapy, spele-climato-therapy (except procedures using equipment providing concentration of fine-grained dry aerosol of natural mineral salt no more than 0.3 mg/cub. m);

3.5. ozone therapy;

3.6. carboxi-therapy (via injections).

4. Application of curative physical factors of thermic nature, naturally occurring curative physical factors:

4.1. hardware-based thermic therapy (using medical equipment), combined thermic therapy in a SPA capsule;

4.2. cryo therapy, non-invasive cryo lipolysis;

4.3. applications of paraffin, ozokerite, mud, peat, clay, naphthalan (except applications using perfumes/cosmetics);

4.4. hydrobalneo-therapy (except bathing using perfumes/ cosmetics, showers/baths involving pressure of air bubbles or water jets in water environment below 1.5 atm);

4.5. gymnocolon, colonohydro therapy.

Cosmetology

5. Gas/liquid, chemical, mechanical, hardware-based skin peeling (except surface peeling using perfumes/cosmetics, or without any medical products).

6. Injection mesonic therapy, particularly using medicinal agents or medicinal gases, injection lipolytic therapy.

7. Injection outline correction using bio-degradable implants.

8. Injection correction of functional wrinkles, local hyperhydrosis using medicinal agents on the basis of botulinum toxin A.

9. Injection therapy of age-related skin changes/illnesses by autologous plasma enriched with thrombocytes.

10. Cryo therapy of skin illnesses, cryo destruction of scars, venous lakes, hyperpigmentation spots, hyperkeratosis, cryomassage.

11. Non-invasive lipolysis: laser, radio frequency, ultrasonic, cryolipolysis.

12. Mechanical destruction of viral skin neoplasms.

13. Cryodestruction, electro coagulation, radio-coagulation, plasma, chemical, laser destruction of benign skin neoplasms, vermillion border, particularly of viral ethiology, and electro coagulation of inflammatory skin infiltrates.

14. Electro coagulation, radio-coagulation, plasma destruction, photo-coagulation, laser coagulation of venous lakes, hyperpigmentation spots, skin hyperkeratosis.

15. Electro coagulation, radio-coagulation, photo-destruction, laser destruction of scars resulting from inflammatory skin illnesses.

16. Elimination of pigmental skin impregnation (tattoos, etc) by way of electro-coagulation, radio-coagulation, plasma destruction, laser destruction, laser discoloration.

17. Photo-therapy by intensive pulsed light, of age-related changes and illnesses of skin, and cosmetic skin defects.

18. Laser ablative/non- ablative skin lifting (laser rejuvenation).

19. Photo-epilation, laser epilation, electro-, elos-epilation.

20. Ultrasonic SMAS- lifting, radio frequency lifting.

21. Suture facelift.

Plastic aesthetic surgery

22. Surgical correction of innate, age-related and/or acquired modifications/defects of head, neck, corpus, limbs, edea.

23. Surgical correction, particularly using medical equipment with various power sources, of shape/ size of segments of head, neck, corpus, limbs, using liposuction, lipofilling, lipo-modelling, lipolysis.

24. Surgical correction of innate, age-related and/or acquired modifications/defects using implants (except non-absorbable skinless liquid or gel-like implants), autotransplantation of tissues.

25. Surgical correction, particularly using medical equipment with various power sources, of age-related skin changes, scars, benign and vascular skin neoplasms.

26. Laser aesthetic surgery, particularly of age-related skin changes, scars, benign and vascular skin neoplasms.

27. Surgical removal of benign skin neoplasms, hypoderm, conjunctive tissue, involving plastic removal of defects.

28. Endoscopic and other hardware-based aesthetic surgical correction of head, neck, corpus, limbs.

29. Minimally invasive techniques to correct age-related and acquired changes of head, neck, corpus, limbs, edea:

29.1. correction of expression wrinkles, innate and acquired functional changes using medicinal agents on the basis of botulinum toxin A;

29.2. correction of innate, age-related and acquired changes/deformities by biodegradable implants;

29.3. autotransplantation of hair follicles and implantation of artificial hair;

29.4. dermabrasion (mechanical, hardware-based using medical equipment with various power sources, chemical);

29.5. implantation of suture.

Massage therapy

30. Manual massage therapy using special massage techniques.

31. Manual massage therapy using special tools (instrumental).

Again, medical aid is a complex of medical services aimed at preservation, promotion and repair of patient's health including medical prophylaxis, diagnostics, treatment, medical rehabilitation and prosthetics rendered by healthcare providers. A medical service is a medical intervention or a package of medical interventions, or other actions/operations within the framework of medical care.

Principal statutory requirements to activities involving medical services are specified below.

4.1. Quality of medical care

MPH Order No. 732 dated 07.07.2014 "On establishing indicators of quality of public medical care in the outpatient setting" has specified sociological indices with respect to medical aid or public health care functioning, namely:

- quality indicators with respect to public medical care in the outpatient setting (Appendix 1);
- guidelines to compute quality indicators with respect to public medical care in the outpatient setting (Appendix 2).

Recommended quality indicators with respect to public medical care in the outpatient setting have been established for the following positions:

- CEO/director (doctors must have a qualification category, efficient medical surveillance for patients with malignant neoplasms, level of operating activity (for medical specialists of surgical profile), compliance with health and hygiene regime, application of IT technology and other quality indicators);
- primary care physician, general practitioner (coverage of patients of working age through dispensary monitoring, vaccination coverage of children (0–18) (for general practitioners), roentgen/photofluorographic surveys, level of early diagnostics of oncological diseases (stages I + II), and other quality indicators);
- primary care pediatrist (implementation of immunoprophylaxis programmes, timely and proper formalisation of medical documentation when transferring teenagers to adult polyclinics, etc.).

Nonetheless, there is no such legal notion as "quality of medical care". One may state that it is a suite of characteristics reflecting correspondence of rendered aid to patient's needs/expectations, current level of medical science and technology. Quality of medical care normally implies that each patient is provided with a suite if diagnostic and medical assistance that results in optimal results for each patient.

Estimating quality of medical care implies defining the correspondence of actual results of diagnostic, curative, rehabilitation and preventive measures to any expected results. It is estimated by means of standards of medical technologies, and in the absence thereof – in comparison with any generally accepted technologies.

There is no list of cases allowing to acknowledge medical aid as unsatisfactory. Medical/pharmaceutical professionals must ably perform their job duties, and medical aid must be provided on the basis of clinical protocols or medical care techniques elaborated for a concrete illness (p. 1 art. 14 and par. 2 p. 1 art. 51 of the Law). Non-compliance with these protocols/techniques may signify that medical aid is of poor quality.

Each patient is entitled to:

- receive medical care;
- choose an attending doctor and a health care facility;
- contribute to choosing techniques of medical care;
- be provided, while in a health care facility, with conditions complying with applicable sanitary requirements and securing safety and protection of personal dignity;
- regardful and humane attitude from health care professionals;
- receive, in an available form, information on own health status, used medical care techniques, qualification of attending doctor, other healthcare providers directly involved in medical care;
- choose persons that may be furnished with information on his/her health status;
- refuse medical care, particularly medical intervention, except in particular cases (for instance, where his/her illness poses public threat). Compulsory health survey and treatment is applied to such categories as carriers of dangerous infectious diseases (art. 28 of the Law), psychiatric patients or chronic alcoholics, drug addicts, solvent abusers (art. 30 of the Law);
- relief of pain resulting from illness and/or medical intervention, by any and all means of medical care, with regard to respective medical/diagnostic capacities of health care facilities (art. 41 of the Law).

Where a patient believes that, during any medical aid procedures, any of the above rights have not been respected in full or have been infringed, medical aid may also be acknowledged as unsatisfactory.

Patient's rights will be infringed where: no comprehensive survey has been carried out, unjustified enhancement of indication to use any medications, aggravation of health, increase in duration and/or frequency of illnesses or applications for medical aid, a lengthy treatment period due to complications, etc.

In case of unsatisfactory medical aid, a patient may petition respective health care facility orally, in writing (particularly, on a no-name basis) or electronically. Where such petition has not taken effect, such patient may file a complaint/motion to the health care board of the local executive committee. Moreover, patients may use hot lines and help lines of health care boards in all regional and Minsk municipal executive committees. Patients may also make notes in books of recommendations and concerns, on websites of medical facilities and on the official national portal for quality rating of services (качество-услуг.бел/RatingPortal).

Patients may also petition a law enforcement agency (a local police office, according to the location of respective health care facility) stating that (as appropriate):

- medical worker failed to administer medical aid to a patient without good excuse (art. 161 of the Criminal Code of the Republic of Belarus dated 09.07.1999 No. 275-3 (hereinafter – CC));
- medical worker has unduly discharged his/her professional duties inflicting (carelessly) a grievous or a minor bodily injury (art. 162 CC)[2];
- a medical/pharmaceutical or another worker has deliberately, without any professional need or need of service, divulged any data involving medical secrecy (data on the existence of an illness, diagnosis or results of medical survey, particularly about HIV/AIDS) (art. 178 CC);
- a person without proper medical degree/permit carries out medical/pharmaceutical activities (art. 335 CC);
- a health care facility uses, for diagnostic or curative purposes, any radiation equipment that is out-of-operation or has not been checked for proper technical characteristics (art. 16.5 of the Administrative Code of the Republic of Belarus).

In case any such facts are revealed, defaulters may be brought to administrative or criminal responsibility.

A patient may file an action with the court seeking that a health care facility shall reimburse fees for medical services rendered (where medical aid was administered on a fee-paid basis – in such a case the applicant should check terms and conditions of his/her agreement with the health care facility), an action seeking compensation for damage to health, or compensation for moral injury (p. 1 art. 933 of the Civil Code).

An expert appraisal may be called for by a law enforcement agency or by a judicial body, in order to check the quality of medical services rendered. Such expert appraisals are carried out by the Department for complex medico-legal examinations of the Central Office of the State Committee for Forensic Examinations of the Republic of Belarus.

4.2. Special requirements to particular types of services as exemplified by dentistry

Dental health service in the Republic of Belarus is a component of the nationwide health care system. Dental care is delivered in medical/preventive institutions under the MPH, departmental medical institutions, and private dental clinics/offices.

Dentistry polyclinics/departments/offices are arranged and operated in strict compliance with sanitary riles for the arrangement, fitting and operation of outpatient/polyclinical dental institutions, labour safety and personal hygiene rules.

Minimal composition and floor areas of particular premises of medical offices are specified by the Health and hygiene requirements for medical institutions, particularly in terms of health and hygiene measures to prevent infectious illnesses in such institutions, as approved by MPH Resolution No. 73 dated 05.07.2017 (hereinafter – MPH Resolution No. 73).

Description of premise	Mandatory minimal suite of premises
Room/office: 1. stomatologist, 2. childrens stomatologist, 3. stomatologist-therapist, 4. stomatologist-surgeon, 5. stomatologist-orthopedist, 6. stomatologist-orthodontist	12 sq.m., increased by 10 sq.m. per each additional dental device (7 sq.m. per additional dental chair without a dental device).
Minimal suite of premises for dental mechanical operations	A suite of premises must be defined with account of technology used to produce dentures. In case of a dental laboratory with 1 or 2 full-time dental mechanics, it can be accommodated in 2 room or 1 room with different work areas, where plastering, polishing, polymerising and brazing processes will be combined, and an individual work station for each dental mechanic. Therewith, floor area of such rooms (or total floor area of both rooms) shall be at least 14 sq.m. Where there are 3 or more full-time dentists, only plastering, polishing, polymerising and brazing processes may be combined in one room, with different work areas. 1. Dental mechanics' room – at least 7 sq.m., 4 sq.m. per each dental mechanic, but at most 10 dental mechanics in one premise. 2. Polymerising, plastering, polishing, brazing work processes – at least 7 sq.m. 3. Casting work processes – at least 4 sq.m.
Small dentist's operating room	Floor area must be at least 18 sq.m.

[2] Grievous bodily injury – an injury posing threat to patient's life or resulting in a loss of eyesight, hearing or any organ, or defunctionalisation of any organ, interruption of pregnancy, mental aberration/illness, or another decay of health resulting in steady loss of faculty in at least one-third, or resulting in another decay of health involving a trauma of a skeleton bone, for a period of over four months, or resulting in a disfigurement of face or neck (art. 147 CC).

A minor bodily injury – is an injury posing no threat to patient's life, however causing a long-term decay of health for a period of up to four months, or a steady loss of faculty in less than one-third (art. 149 CC).

There are also other requirements for dental rooms prescribed by MPH Resolution No. 73:

- Rooms providing dental surgical services must be equipped with washstands with taps allowing elbow (contactless/pedal/other non-hand) control and wall-mounted elbow (contactless) dosage units for liquid soap and antiseptics (cl. 48).
- Dental rooms must be equipped with duly approved air treatment/disinfection devices (cl. 51).
- Deep cleanings in dental operating rooms must be carried out at least once each seven days (cl. 59).
- Medical workers, when delivering dental medical care, must cover their hair with a head-dress (cl. 90).
- For the purposes of dental (operating, therapeutic) aid, only sterilised medical tools shall be used, packed in individual kits/packages (except small endodontic tools) (cl. 110).

4.3. Licensing requirements to medical activities

In accordance with cl. 323 of Edict No. 450, licensing requirements and conditions imposed on holders of a medical activities license (licensees) are as follows:

- compliance with all licensing requirements and conditions imposed on applicants;
- compliance with requirements/conditions established by regulatory legal acts, particularly mandatory requirements of technical regulatory legal acts, with respect to quality and conditions of works/services in the field of medical activities, such as requirements of Good Manufacturing Practice and Good Pharmacy Practice, special sanitary rules, requirements of EAEU acts;
- new CEO/director of a health care facility, CEO/director of a standalone unit of an entity not being a health care facility, other healthcare providers must be appointed instead of initially declared officers, where license is acquired within one month of such officer(s) being dismissed, unless staff schedule is amended;
- documents must be furnished to MPH, within one month from the date of appointment, confirming appointment of CEO/director of a health care facility, CEO/director of a standalone unit of an entity not being a health care facility, other healthcare providers instead of initially declared officers, or officers in addition to initially declared officers;
- documents must be furnished to MPH, within one month, on any amendments of staff schedule with regard to healthcare providers.

A particular licensing requirements (condition) is that any licensable activities must be carried out only in places specified by license, unless services are rendered at the place of patient's residence/stay (where such services are provided for in the legislation) (cl. 325 of Edict No. 450).

Licensees carrying out licensable activities in communities located in areas of radioactive contamination are exempt from the following licensing requirements/conditions (subcl. 324.1 cl. 324 of Edict No. 450):

1. CEO/director of a health care facility and/or his/her deputy shall have qualification category 1 or AAA (highest);

2. at least one employee per each declared operation/service involving licensable activities, in all areas of such activities, must have:

- healthcare providers having university degree in medicine, – qualification category 1 or AAA (highest);
- healthcare providers having vocational secondary medical education, – a qualification category, except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category;

3. other healthcare providers must have a qualification category, except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category (for privately-owned entities);

4. individual entrepreneurs must have:

- qualification category 1 or AAA (highest) – for those having university degree in medicine;
- qualification category, except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category, – for those having vocational secondary medical education;
- qualification category, except masseuse nurses (massage specialists) and dental mechanists not requiring a qualification category.

Entities aiming at providing works/services involving licensable activities that are allowed only for medical professionals with vocational secondary medical education, provided CEO/director of such legal entity (foreign entity) and/or his/her deputy complies with licensing requirements/conditions with regard to vocational secondary medical education, need not have (subcl. 324.2 cl. 324 of Edict No. 450):

- university degree in medicine;
- qualification category 1 or AAA (highest);
- document confirming career enhancement or re-training under a health care facility programme or a degree programme corresponding to declared licensable works/services.

4.4. Health/hygiene requirements

Sanitary (health and hygiene) rules are state by-laws specifying requirements to safe working environment. They are aimed at preserving health and vital activity of people in various spheres, including medical activities.

Sanitary/hygiene requirements are binding upon citizens, state bodies, legal entities and officers, regardless of their subordination and ownership pattern.

A list of sanitary/hygiene requirements with regard to medical services is given in the table below.

Type of health/hygiene requirements	Peculiarities
Health/hygiene requirements to providers of medical care, particularly with regard to arrangement of health and hygiene measures to prevent infectious illnesses, as approved by MPH Resolution No. 73	There are requirements to allocation, territory, water supply, lighting, microclimate and maintenance of buildings/premises providing medical care and health/hygiene measures to prevent infectious illnesses in such entities: • health care facilities: under construction/reconstruction, operational; • other entities that, alongside with core activities, also carry out medical activities in the manner prescribed by the laws; • individual entrepreneurs carrying out medical activities in accordance with the procedure established by legislation. Sanitary norms/regulations are binding upon all entities providing medical care. Approved by Appendix 1 "Minimal suites and floor areas of premises of medical care providers", etc.
Specific health/hygiene requirements, as approved by Resolution of the Council of Ministers No. 847 dated 11.12.2019	There are specific health/hygiene requirements to sanitary/protective zones of operational, projected, erected buildings impacting human health and nearby environment, except requirements stipulated by legislative acts.
Specific health/hygiene requirements, as approved by Resolution of the Council of Ministers No. 130 dated 03.03.2020	There are specific health/hygiene requirements to maintenance and operation of health care facilities, other entities and individual entrepreneurs carrying out medical or pharmaceutical activities.
On disinfection and sterilisation activities in health care institutions (MPH Order No. 165 dated 25.11.2002)	The following guidelines have been approved: • guideline "Basic requirements to arrange and supervise compliance with disinfection and sterilisation policies in medical and prophylactic institutions"; • guideline "Disinfection, pre-sterilisation cleaning and sterilisation of medical products"; • guideline "Safety measures in handling disinfectants during disinfection actions"; • guideline "Computation of requirement of disinfectants in medical and prophylactic institutions".
Sanitary norms/regulations "Requirements for health and hygiene measures to prevent viral hepatitis", as approved by MPH Resolution No. 11 dated 06.02.2013	Specify requirements to arrangement of health and hygiene measures to prevent emergence and dissemination of viral hepatitis, particularly of types involving: • fecal-oral transfer mechanism – viral hepatitis A, viral hepatitis E; • parenteral transfer mechanism – viral hepatitis B, viral hepatitis D, viral hepatitis C. The sanitary norms/regulations are binding upon all state bodies, other entities, natural persons, particularly individual entrepreneurs.
Regarding revision of departmental regulations and standards regulating HIV/AIDS issues (MPH Order No. 351 dated 16.12.1998)	The following guidelines were approved: • guideline to prevent intrahospital HIV infection and prevent professional infection of healthcare providers; • guideline to arrange prophylaxis of HIV infection via donated blood; • guideline for autopsy surveys in case of assumption of HIV/AIDS (for departments of morbid anatomy and forensic bureaus); • recommendations to arrange local briefings for healthcare providers on the HIV/AIDS problem.
Sanitary regulations/norms 2.6.1.8-38-2003 "Hygienic requirements to arrangement and operation of X-ray rooms, X-ray machines and X-ray imagings", as approved by Resolution of Chief State Medical Officer of the Republic of Belarus No. 223 dated 31.12.2003	The regulations are regulatory documents that specify basic requirements and norms to secure radiation safety of staff and patients during medical X-ray procedures with diagnostic, prophylactic, therapeutic or research aims. The requirements are binding upon all legal and natural persons involved in X-ray surveys, regardless of their subordination and ownership pattern. These rules apply to all entities involved in designing, construction, reconstruction/modernisation, installation and operation of X-ray rooms and X-ray machines, including mobile photofluorographic rooms and machines.
Sanitary norms/regulations "Health/hygiene requirements for handling medical wastes", as approved by MPH Resolution No. 14 dated 07.02.2018	Specify health/hygiene requirements to disinfection, collection and disposal of spent medical products, blood, other biological liquids, and to collection and temporary storage of medical wastes, for entities of all ownership patterns and for individual entrepreneurs administering medical aid. Do not apply to: • wastes classified as utility wastes, in accordance with legislation ; • radioactive wastes; • mercuric wastes; • pharmaceuticals, except residues of cytostatic pharmaceuticals and medical products remaining after the preparation/use of cytostatic pharmaceuticals.

Violation of sanitary regulations/norms will entail administrative (art. 16.8 AVC) or criminal (art. 336 CC) responsibility.

Free tariffs are applied to medical services not subject to state price adjustment. Such tariffs are established by legal entities and individual entrepreneurs independently, based on market conditions.

However, a list of fee-based medical services is used in the Republic of Belarus. tariffs on such services are regulated by MPH in coordination with the Ministry of Antitrust Regulation and Trade. The following types of fee-based medical services are included:

- stomatological services (orthopedic and dental mechanical)
- gnostic services (laboratory, radio-, ultrasonic, functional, endoscopic diagnostics)
- medical clearance providing issuance of a health certificate allowing to drive manually operated vehicles

Guideline on establishing and applying tariffs on fee-based medical services approved by MPH Resolution No. 14 dated 03.02.2015 is the principal regulatory act establishing a uniform regulation procedure with regard to tariffs on fee-based medical services that are statutorily regulated by state.

Price formation for the above medical services is subject to a category of persons provided with fee-based medical services.

Provision of medical services to Belarusian nationals and foreign citizens permanently residing in the territory of the Republic of Belarus.

Tariffs on fee-based medical services rendered by legal entities and individual entrepreneurs to Belarusian nationals, as well as to foreign citizens permanently residing in the territory of the Republic of Belarus, are regulated by the MPH in coordination with the Ministry of Antitrust Regulation and Trade, by way of establishing:

- maximum limit tariffs
- limit profitability norm
- maximum limit markups

In such a case, legal entities and individual entrepreneurs shall *independently establish fixed tariffs* on fee-based medical services provided by them *within the constraints of established maximum limit tariffs and with account of the limit profitability norm.*

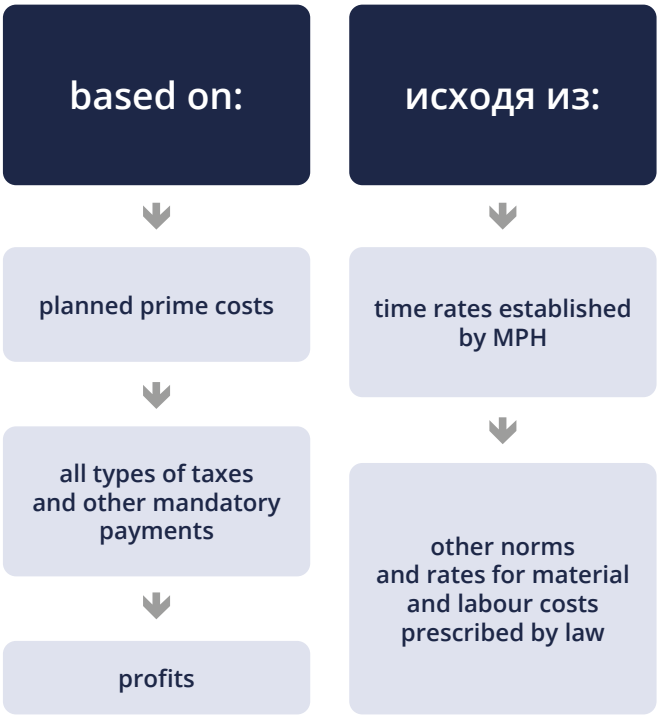
Provision of medical services to foreign citizens and stateless persons temporarily residing/staying in the Republic of Belarus.

Tariffs on fee-based medical services rendered by legal entities and individual entrepreneurs to foreign citizens and stateless persons temporarily residing/staying in the Republic of Belarus *are established by them independently without regard to maximum limit tariffs or limit profitability norm.*

In both (I and II) above cases, other provisions may be stipulated by legislative acts and international treaties of the Republic of Belarus.

5.1. Procedure for establishing tariffs on fee-based medical services subject to state price adjustment

Tariffs on fee-based medical services are set by legal entities and individual entrepreneurs:



Expenditures are included in planned prime costs that are established by legal entities and individual entrepreneurs independently, unless otherwise prescribed by law.

Tariffs on fee-based medical services are established based on associated time rates established by MPH and other norms and rates for material and labour costs prescribed by law .

Respective norms and rates are, in particular, approved by the following regulatory legal acts:

- MPH Resolution No. 103 dated 30.09.2011 "On establishing time rates and material usage rates with respect to fee-based dentistry medical services rendered by legal entities regardless of their subordination and ownership pattern and individual entrepreneurs, and declaring void MPH Resolution No. 125 dated November 28, 2007";
- MPH Resolution No. 65 dated 15.06.2009 "On approving time rates for endoscopic, ultrasonic and functional medical interventions in state health care facilities";
- MPH Resolution No. 34 dated 10.05.2017 "On establishing time rates and material usage rates with respect to fee-based laboratory diagnostics medical services rendered by legal entities regardless of their subordination and ownership pattern and individual entrepreneurs";
- Other acts.

With respect to fee-based medical services not subject to statutory cost norms/rates, tariffs are established on the basis of economically feasible norms/rates of material/labour costs as approved by CEO/director of a legal entity or individual entrepreneur.

Tariffs established by legal entities and individual entrepreneurs with respect to fee-based medical services shall be published in their respective price lists.

Where there is no regular tariff for a particular one-time fee-based medical service, a fee shall be based on a one-time calculation agreed upon with customer.

5.1.1. Limit maximum tariffs

Limit maximum tariffs are maximum tariffs limiting tariffs for respective medical services to be established by legal entities or individual entrepreneurs.

Limit maximum tariffs with respect to each fee-based medical service subject to state price adjustment have been defined by particular regulatory legal acts:

Stomatological services (orthopedic and dental mechanical)	• MPH Resolution No. 15 dated 03.02.2015 № 15 «On establishing limit maximum tariffs on stomatological services (orthopedic and dental mechanical) and stomatological services involving radio-diagnostics»
Diagnostic services (laboratory, radio-, ultrasonic, functional, endoscopic diagnostics)	• MPH Resolution No. 13 dated 03.02.2015 «On establishing limit maximum tariffs on services involving radio-, ultrasonic, functional, endoscopic diagnostics» • MPH Resolution No. 16 dated 03.02.2015 «On establishing limit maximum tariffs on services involving laboratory diagnostics»
Medical clearance providing issuance of a health certificate allowing to drive manually operated vehicles	• MPH Resolution No. 3 dated 21.01.2016 «On establishing limit maximum tariffs on services involving medical clearance providing issuance of a health certificate allowing to drive manually operated vehicles»

5.1.2. Limit profitability norm

Limit profitability norm is a duly limit profit-to-costs ratio expressed in percentage terms.

The standard limit profitability norm to be used in evaluating profit sums to be included in any tariffs on fee-based medical services has been established as **30 percent to planned prime costs.**

5.1.3. Limit maximum markups

Legal entities and individual entrepreneurs **are entitled to apply markups (extra charges) in excess of established tariffs** for any fee-based medical services rendered, upon customer's request, during night hours, on public holidays or feast days.

Where there are grounds to apply more than one markup in excess of an established tariff on a fee-based medical service, the total markup value shall be defined by summing up respective markups.

Limit maximum markups in excess of an established tariff on a fee-based medical service shall amount to at most:

30%

- for providing fee-based medical services during night time

50%

- for providing fee-based medical services on state holidays and public holidays

5.1.4. Tariffs are net of cost of any used pharmaceuticals, medical products and other materials

Tariffs on fee-based medical services shall be established by legal entities and individual entrepreneurs *net of cost of any used pharmaceuticals, medical products and other materials, that shall be paid by customers additionally.*

MPH's norms for consumption of pharmaceuticals, medical products and other materials with respect to fee-based medical services may be reduced by CEOs/directors of legal entities and individual entrepreneurs, subject to applied technology, material/technical status and other factors.

With respect to those types of fee-based medical services that are not subject to MPH's norms for consumption of pharmaceuticals, medical products and other materials, costs shall be defined on the basis of consumption norms approved by CEO/director of respective legal entity or individual entrepreneur.

Costs of pharmaceuticals and medical products shall be defined based on retail prices established pursuant to Edict of the President of the Republic of Belarus No. 366 dated August 11, 2005 "On establishing prices on pharmaceuticals, medical products and medical equipment" and respective consumption norms.

Costs of other materials (non-medical products) used for the purposes of fee-based medical services shall be defined by legal entities and individual entrepreneurs based on prices established in accordance with legislation and respective consumption norms.

5.1.5. Discounts

Legal entities and individual entrepreneurs are entitled to apply discounts from any tariffs on fee-based medical services established by them.

Legal entities and individual entrepreneurs independently elaborate and approve procedures for the application of such discounts, respective rates and conditions.

However, it should be noted that a health services agreement, according to art. 396 of the Civil Code of the Republic of Belarus is a public agreement. This implies that prices for goods/works/services, as well as other conditions of a public agreement shall be established as equal for all consumers, except where discounts may be granted to certain categories of consumers in accordance with legislation.

6. MEDICAL INSURANCE

From early 2020, the Belarusian market of medical insurance has shown a steady growth in all statistical key figures, such as sums of insurance contributions, insurance payments, etc. this trend is driven mostly by the voluntary insurance sector boosted (naturally) by medical insurance programmes. Already in 2019, rates of growth of insurance contributions in this segment of voluntary insurance, as compared to 2018, amounted to a considerable value of 133.8%. Therewith, specific weight of administration costs of insurance enterprises in the aggregate total of insurance contributions in 2019 had reduced, as compared with 2018, by 1.2 percentage points down to 22.9%.

Edict of the President of the Republic of Belarus No. 530 dated 25.08.2006 "On insurance activities" (hereinafter – Edict No. 530) is the principal legal framework for medical insurance activities in the Republic of Belarus. According to Edict No. 530, medical insurance includes the forms of compulsory and voluntary insurance.

6.1. Compulsory medical insurance

The following types of compulsory medical insurance are provided in the Republic of Belarus:

- compulsory medical insurance for foreign citizens and stateless persons temporarily residing/staying in the Republic of Belarus
- compulsory insurance against industrial accidents and occupational diseases

The procedures and conditions of these types of compulsory medical insurance are regulated by (accordingly) chapters 15 and 16 of Edict No. 530.

6.1.1. Insurance for foreign citizens and stateless persons temporarily residing/staying in the Republic of Belarus

Both legal and natural persons may act as policy holders, after they have concluded an agreement for compulsory medical insurance for foreign citizens and stateless persons temporarily residing/staying in the Republic of Belarus.

A foreign citizen or a stateless person in behalf of which a compulsory medical insurance agreement has been concluded acts as the insuree.

A medical institution that has incurred expenses in administering emergency medical aid to an insuree acts as the beneficiary under the agreement.

Foreign citizens temporarily residing/staying in the Republic of Belarus must have an agreement for compulsory medical insurance or agreement for medical insurance concluded with a foreign insurance enterprise, in case they require emergency medical aid from a medical institution.

Some foreign citizens are exempt from the compulsory medical insurance requirement, such as: foreign citizens petitioning for the status of refugee or additional protection in Belarus; citizens of states having international agreements/treaties regulating the issues of free emergency medical aid; citizens passing through the territory of Belarus; heads and officers of diplomatic missions and consular institutions, etc.

Compulsory medical insurance applies to property interests associated with any eventual harm to insuree's life or health and with costs incurred by a medical institution in administering emergency medical aid.

An insured event is an event of decay of insuree's health due to sudden illness or accident, during the currency of compulsory medical insurance agreement, requiring emergency medical aid and incurring respective medical institution's costs.

A medical insurance agreement must:

- specify the name of respective foreign insurance enterprise and its location, telephone number(s) of the foreign insurance enterprise or an international assistance service, as well as citizen's full name (including patronymic(s), if any);
- cover the entire territory of the Republic of Belarus;
- be effective during the entire period of foreign citizen's stay or temporary residence in the Republic of Belarus;
- specify an insured amount of at least 10,000 euros.

An agreement on compulsory medical insurance shall be concluded in writing: an insurance policy must be issued and filled up on the basis of data communicated by insuree, in accordance with insuree's identity card, or electronically by way of exchanging documents via insurer's official website.

6.1.2. Insurance against industrial accidents and occupational diseases

Legal entities of the Republic of Belarus, standalone subdivisions of legal entities carrying out activities in the territory of the Republic of Belarus, representative offices of foreign entities in the Republic of Belarus and individual entrepreneurs registered in the Republic of Belarus may act as policy holders, as well as natural persons not being individual entrepreneurs provided they are permanently residing in the territory of the Republic of Belarus and employing insurees.

Insurees are citizens of the Republic of Belarus, foreign citizens or stateless persons temporarily residing/staying in the Republic of Belarus, whose life/health is subject to compulsory insurance against industrial accidents and occupational diseases.

This type of insurance applies to property interests of insurees and other natural persons associated with any eventual decay of health, occupational disability or death due to an industrial accident or occupational disease.

An industrial accident is an event resulting in a decay of health of an insuree involving any of the following circumstances:

- in discharge of his/her employment duties, execution of work, provision of services, creation of an intellectual property object by order of policy holder (its duly authorised officer);
- beyond office hours, when walking through policy holder's territory to/from workplace, or when ordering equipment, tools, appliances, personal protective gear, or when performing other activities pursuant to internal work regulations, prior to starting, or after finishing employment duties;
- when using a vehicle furnished by policy holder, to/from workplace, or when using a vehicle as shiftman during a rest period between shifts;
- when working under the rotational team/expedition method during a rest period between shifts, or when travelling on a ship during off-duty time (beyond shift hours or ship works);
- when using a personal vehicle used for policy holder's purposes, under a duly executed agreement/contract between such insuree and policy holder, or under the terms of labour agreement, or when using another vehicle, or when walking on foot for the purposes of a task allotted by policy holder (its duly authorised officer);
- when travelling to/from point of destination during official trip.

An occupational disease (chronic or acute), in its turn, is insuree's illness resulting (exclusively or predominantly) from any impact of harmful production/workflow factor entailing temporary (during at least one day) or persistent loss of occupational capacity, or death.

Life and health of the following groups of citizens are subject to compulsory insurance against industrial accidents and occupational diseases:

- those working under labour agreements/contracts;
- persons appointed to supreme public offices, deputies and members of the Parliament working as professionals, chairmen of local councils of deputies, and judges;
- persons working under civil law agreements for works, services or creation of intellectual property objects, at workplaces provided by policy holder;
- persons performing reimbursable works/services as members/participants of production co-operatives;
- acting as heads of peasant/farm holdings, CEOs/directors of legal entities being sole owners of such entity's property and earning reward for their labour;
- students (except attendees/trainees), persons engaged for gainful occupation during internships, work placements, probation periods, medical specialists, persons that obtained a university degree in medicine beyond the Republic of Belarus and engaged for gainful occupation during clinical residency training;
- persons retained in correctional facilities, occupational therapy centres and those engaged for paid work.

The above persons are acknowledged as insurees regardless of whether policy holder actually discharges its obligations with respect to insurance contributions under the compulsory insurance policy against industrial accidents and occupational diseases.

The rate of insurance contributions under a compulsory insurance policy against industrial accidents and occupational diseases normally amounts to 0.6% of insurance base. Such insurance base is formed by all payments accrued to employee in a reporting month, except payments not subject to contributions[3] (public welfare payments, educational allowances/grants, etc.).

National unitary enterprise BelGosStrakh is the sole insurer with respect to compulsory insurance policies against industrial accidents and occupational diseases.

6.2. Voluntary medical insurance

The following types of voluntary medical insurance are offered in the Republic of Belarus:

- against accidents
- against accidents and diseases during trips abroad
- insurance of medical expenses

Voluntary medical insurance involves an agreement concluded between a policy holder and an insurer, in accordance with legislation.

Terms and conditions of agreements of voluntary insurance are specified by the rules of respective types of insurance, as approved by insurer or an association of insurers. Such rules of respective type of insurance (duly approved by insurer or an association of insurers) must be attached to each voluntary insurance agreement. Such attachment of rules to each voluntary insurance agreement must be attested by respective record in each agreement. Voluntary insurance tariffs are established by insurers.

As from 01.09.2019, rules of voluntary insurance are no longer required to be harmonised with the Ministry of Finance: they are furnished on a notification basis concurrently with respective notice, basic insurance tariffs and an economico-mathematical feasibility study[4].

Moreover, the Ministry of Finance is entitled to define minimal (standard) requirements to the conditions and procedures of certain types of voluntary insurance. Thus, minimal (standard) requirements to the conditions and procedures of voluntary insurance of medical expenses are defined by a Guideline approved by Resolution No. 11 of the Ministry of Finance dated 22.03.2019.

Voluntary insurance agreements must be executed in writing. Voluntary insurance agreements may be concluded by insurance enterprises in writing in any form provided for by civil procedure laws and Edict No. 530, and electronically via an official website of:

[3] Resolution of the Council of Ministers No. 115 dated 25.01.1999

[4] p. 2 subcl. 1.1 cl. 1 of Edict No. 175 "On insurance services"

- insurer
- an enterprise that concludes insurance agreement on insurer's behalf and is authorised, in accordance with legislation, to identify policy holders (insurees, beneficiaries) or their representatives without bodily presence of such persons.

Procedures for concluding voluntary insurance agreements has been established by Resolution No. 37 of the Ministry of Finance dated 20.06.2014 "On some matters pertaining to insurance activities".

When concluding a voluntary insurance agreement, insurers are entitled to use independently elaborated forms of insurance policies/certificates.

6.2.1. Voluntary insurance against accidents

This type of insurance applies to lawful property interests of insurees (beneficiaries) pertaining to any eventual harm to insuree's life/health due to an accident, or a disease arising (being diagnosed) for the first time during the currency of such insurance agreement, or during clinical trials of medical products/equipment.

An accident is a sudden, unforeseen, undeliberate (on insuree's part) event occurring during the currency of insurance agreement and involving a trauma, wound, mutilation or another injury inflicting harm to insuree's life/health.

6.2.2. Voluntary insurance against accidents and diseases during trips abroad

This type of insurance applies to property interests of insurees pertaining to any eventual harm to insuree's life/health due to a sudden illness or accident during a trip abroad, and entailing expenses on express medical care for insuree, as well as other care/aid, in accordance with insurance terms and conditions.

Insurance events are the following events occurring during the currency of an insurance agreement and entailing expenses on express medical care for insuree, as well as other care/aid, in accordance with insurance terms and conditions:

- infliction of harm to insuree's health due to sudden illness or accident during a trip abroad
- infliction of harm to insuree's life due to sudden illness or accident during a trip abroad

6.2.3. Voluntary insurance of medical expenses

Voluntary insurance of medical expenses applies to lawful property interests of policy holders or insurees pertaining to the reimbursement of expenses to a medical facility, individual entrepreneur, policy holder or insuree due medical care delivered to an insuree under a voluntary insurance agreement (voluntary insurance programme), in case of insurable event.

Insurance event is an event involving beneficiary's expenses due to medical care delivered to an insuree under a voluntary insurance agreement (voluntary insurance programme), due to insuree's sudden decay of health, accident, chronic illness or acerbation of an illness.

As of January 1, 2020, 16 insurance enterprises are offering services in the insurance market of the Republic of Belarus (half of them are state-run or parastatal (over 50%) companies, and 6 enterprises are foreign invested).

7. ADVERTISING OF MEDICAL SERVICES

Belarusian legislation contains general requirements to advertising, as well as special requirements to advertising techniques with respect to medical care methods and works/services involving medical activities.

General requirements to advertising in the territory of Belarus have been established in art. 10 of Law of the Republic of Belarus No. 225-3 dated 10.05.2007 "On advertising" (hereinafter – the Advertising Law).

Special requirements to advertising techniques with respect to medical care methods and works/services involving medical activities have been established by art. 15 of the Advertising Law and by MPH Resolution No. 63 dated 23.07.2013 "On the implementation of the "Advertising Law" of the Republic of Belarus No. 225-3 dated May 10, 2007" (hereinafter – Resolution No. 63).

7.1. General advertising requirements

General advertising requirements	Description
Requirements to contents of ads	1. Advertisements in the territory of Belarus shall be placed in the Belarusian and/or Russian languages. This provision does not apply to advertisements placed by radio-/TV-programmes, in print media and in information resources of the national Internet segment, provided they: • place information exclusively in a foreign language(s); • contain advertisements of trademarks and/or service marks; • contain advertisements involving any commonly used foreign terms that have come into general use in the original writing and/or having no equivalent in the Belarusian and/or Russian languages; • contain any material in a foreign language: names/descriptions of goods, stage names/pseudonyms, original names of creative teams or art works, website/domain names, offers of job placements/enrolments to persons speaking fluently a foreign language. 2. Advertising involving advertiser's entrepreneurial activities must contain advertiser's name, tax identification number, and where advertiser is an individual entrepreneur, – its full name and initials. Where advertiser is a foreign/international legal entity (or a non-corporate organisation), a foreign citizen or a stateless person not having a tax identification number, such advertiser's advertisements shall specify (instead of TIN) the name of country or locality where such advertiser resides or permanently stays. The above requirements do not apply to: • advertisements placed/disseminated on TV, radio programmes, outdoor advertising media, vehicles, cellular mobile communication facilities by communication operators, • advertisements placed/disseminated in the Internet network and containing any links to a website(s) specifying the above data. 3. Advertisements containing information on the type of any licensable activities are allowed only where provider of such activities has a special permit (license) for respective activity. 4. Any warning notices and other compulsory advertising information shall be applied in bold letters and using a colour vividly contrasting with the background colour. 5. Any foot-notes specified in an advertisement specifying any additional information, telephone numbers, website links, number and date of print issue, shall be applied in distinct letters and using a font with a size of at least two times less than the largest font used in such advertisement. Such information in a TV/multimedia ad must occupy at least a five seconds of ad duration секунд, and where such ad lasts for less than five seconds – must persist during the entire ad duration, and in case of a radio ad – must be vocalised.
Advertisements shall not	• encourage/advocate/instigate violence, cruelty or unsafe acts posing threat to health of people, state property or private property, or compromising safety of corporate entities or citizens, as well as other unlawful acts; • contain any promise/guarantee of future efficiency/yield of advertised activity. Use of data about efficiency/yield of advertised activity in the preceding period is allowed where advertiser has accounting/financial data attested by an audit firm (or an auditor – individual entrepreneur).

General advertising requirements	Description
Advertisements shall not use	• names, pseudonyms, images or utterances of Belarusian nationals without consent granted by them or their duly authorised representatives, unless otherwise stipulated by this Law or the President of the Republic of Belarus; • images or utterances of medical or pharmaceutical employees, non-profit organisations carrying out activities in health care, except they are used in social advertising, advertising of advertiser's medical activities, or in advertisements aimed exclusively at medical/pharmaceutical professionals and placed/disseminated at venues of medical/pharmaceutical exhibitions, workshops, conferences and similar events, or in specialised printed matter meant for medical/pharmaceutical professionals; • names of corporate entities, trademarks and/or service marks, emblems and other symbols, pictures/images of corporate property by unauthorised persons.
Advertisements shall not contain	Any use, alongside with Belarusian and/or Russian language, of a foreign language, where such foreign text is identical, in terms of content and technical layout, to the Belarusian and/or Russian text.

7.2. Special requirements

Special requirements to advertising techniques with respect to medical care methods and works/services involving medical activities, as established by the Advertising Law, are as follows:

Special requirements to advertising	Description
Advertisements must be approved by MPH	Advertisements must be approved by MPH (p. 1 art. 15 of the Law). Approval period is 15 to 30 calendar days. Effective period of such approval is 1 year. Exemptions (where such approval is not required): • advertising at venues of medical/pharmaceutical exhibitions, workshops, conferences and similar events meant only for medical/pharmaceutical professionals; • in specialised printed matter according to the list specified in MPH Resolution No. 63 dated 23.07.2013 ("Healthcare" journal, "Medical Bulletin" newspaper, etc.); • advertising of works/services involving medical activities, provided it contains only data specified in respective license and contact information.
Advertising is prohibited	• advertising of medical care techniques not approved by MPH in accordance with laws; • advertising of works/services in the field of health care that are not officially classified as works/services involving medical activities.
Advertisements shall not use	• information addressing minors directly; • information on indications, application methods, curative/therapeutic effect of advertised object, not corresponding to data provided by core data sheet; • any assertions claiming that curative/therapeutic effect of advertised object is absolutely guaranteed; • references to real cases of healing after using advertised object, or any expression of gratitude for healing; • information that might convey the impression that consumers need not refer to a doctor if using advertised object and/or may obtain diagnostic/treatment services without a direct contact with a doctor; • assertions or assumptions claiming that consumers may have a certain condition requiring application of advertised object, or assertions that might convey the impression that healthy consumers might need to use advertised object; • recommendations of state bodies and other entities, in order to enhance the advertising effect.
Advertising must contain	Clear indication that information is of advertising nature and that advertised object is a medical care technique, a work and/or a service involving a medical activity.

Special requirements to advertising techniques with respect to medical care methods and works/services involving medical activities, as established by Resolution No. 63, are as follows:

Special requirements	Description
General requirements to ad content	• advertising texts must be set forth in plain language, without any misleading scientese words/phrases; • a special reference must be set forth warning that advertised object has medical contraindications and adverse reactions.
Ads must not contain	• anatomic/naturalistic images of human body, organ or organ segments mutilated by disease process; • references to such illnesses as tuberculosis, sexually transmitted diseases, other socially dangerous infectious illnesses, human immunodeficiency virus, oncological illnesses, chronic insomnia, diabetes and other metabolic diseases; • information encouraging violation of common norms of healthy life-style, healthy eating, road safety, sexual safety; • imperatives compelling consumers to use/apply advertised object; • any claims that use of advertised object is safe, particularly due to the fact that it is of natural origin and has no adverse reactions; • information that might convey the impression in consumers that advertised object has a high speed of curative/therapeutic effect; • images of children associated with an advertised object that is meant only for adults or that cannot be legally sold to children; • information that might contribute to developing a sense of fear, possibility of illness or decay of health in consumers, if they would not use/apply advertised object.
Other requirements	• there must be no claims that advertised medical care methods are equivalent or superior to other similar medical care methods; • information on advertised works/services involving medical activities shall correspond to information of works/services specified in respective special permit (license), except in cases stipulated by Edict No. 450 not requiring a special permit (license) for medical activities; • all advertisements of medical services involving artificial termination of pregnancy must contain a warning of possible harmful effects for female health.

The above requirements to advertising techniques with respect to medical care methods and works/services involving medical activities equally apply to advertising in such media as TV, Internet, radio ads and pharmacy ads.

The list of specialised print media that are allowed to place/disseminate advertisements of medical care methods and works/services involving medical activities without MPH's approval has been endorsed by Appendix 1 to MPH Resolution No. 63 dated 23.07.2013.

This list includes 45 specialised print media, such as: "Healthcare" journal, "Medical Bulletin" newspaper, "Medical Knowledge" journal, "Vitebsk State Medical University Bulletin" journal, "Pharmacy Bulletin" journal, etc.

8. TELEMEDICINE AND OTHER MEDICAL INFORMATION TECHNOLOGY TECHNIQUES

8.1. Telemedicine

Telemedicine is a package of institutional and technical arrangements allowing conducting of remote councils of physicians and/or medical counselling enabling a patient or a consulting physician to receive remote counselling from another medical professional using information and communication technology.

The national system for telemedical counselling (hereinafter – the NSTC) is the key element and basis for developing telemedicine technology in Belarus. The NSTC enables medical specialists in various health care facilities (at district, regional, national levels) to take remote opinions on complicated cases from experts.

As of July 20, 2020, this type of counselling is used by 264 health care facilities, and the number of consultations is growing annually. Thus, in the first six months of 2020, there have been over 13,000 consultations, while during the entire year of 2019 there were 16,534 consultations, and in 2018 – 7,909 consultations. The technique allows increasing inclusiveness and quality of public medical care, regardless of locality of patients, as well as decrease expenses of health care facilities and patients – both financial and time expenditures. For instance, patients no longer have to be redirected from the district level to the regional level.

NSTC's prime functions include:

- forming standard medical information electronically – a "telemedical patient record", including text information (anamnestic data, complaints, external survey data, survey results), digital graphical data, video data (tomograms, X-ray photograms, ultrasound scannings, micrography images, etc.) to be furnished to consultants;
- reception by consultant and interpretation of acquired information, processing of graphical pictures, preparing consultant's opinion;
- procuring reliable and prompt information sharing, storing all data at a specialised server;
- archiving information, easy and prompt access to archived data;
- procuring distinction of individual access to medical information;
- procuring data protection during transmission through data channels.

At the present day, current legislation only regulates the telemedical consultation in the doctor-to-doctor format, where one doctor (particularly, in patient's presence) requests a consultation from another doctor via a remote communication link. Therewith, Belarus does not have any legislative regulation of telemedicine activities in the doctor-to-patient format.

On the one hand, lack of MPH's regulation allows implementing pilot telemedical projects on the basis of existing health care facilities, with no need to consider any strict constraints.

On the other hand, there are projects similar to telemedical projects that are not normally agreed upon with the regulator. As there are no distinct criteria to delimitate medical activities from other activities, it may result in the acknowledgment of some services as medical activities that are subject to licensing.

At the present day, several pilot projects involving telemedical consultations in the doctor-to-patient format are implemented in Belarus. 2021 will probably see new regulations for this sphere, as a new edition of the Law will be adopted.

8.2. Electronic health care

Electronic health care is application of electronic communication technology for the purposes of health care services: treatment of patients, training of medical workers, detection of illnesses and monitoring of public health care trends.

Recently, a Concept for developing electronic health care system till 2022 has been adopted. It comprises basic principles of building a national electronic health care system and integrating it into the existing nationwide automated information system.

It is expected that the concept will result in a centralised health care information system (CHCIS). It will amalgamate various medical information technologies into a single information space and will allow creating an integrated electronic medical chart with an analytical decision-making system, personal accounts for patients and a system to compile various statistical forms/reports. The comprehensive project will combine computing, information and telecommunication infrastructure.

The automated information system (hereinafter – the AIS) "Electronic prescription" will be a crucial component of the project. The system is meant to provide turnover of electronic prescriptions in the Belarusian health care system. It is a centralised system for electronic writing out and dispensing pharmaceuticals in outpatient and stationary conditions, including privileged pharmacological support. As of July 1, 2020, the system comprises 599 health care institutions, and over 5.5 mln. electronic prescriptions have been issued.

The system provides for the following functions:

- creation and maintenance of register of electronic prescriptions;
- automating the process of writing prescriptions electronically by medical professionals, respective data being transmitted to the centralised electronic prescriptions repository;
- automating the process of drug dispensing under electronic prescriptions by pharmacies, respective data being transmitted to the centralised electronic prescriptions repository;
- doctors' access to information on all medications written for a patient, particularly by other doctors/facilities;
- prompt access to information on prescribed/dispensed medications, allowing compiling required analytical materials.

9. MEDICAL ETHICS AND ANTI-BRIBERY RESTRICTIONS

9.1. Medical ethics

Medical and pharmaceutical workers, in performing their office duties, must be guided by certain ethical rules and morality norms.

Respective medical ethics rules have been established by MPH Resolution No. 64 dated 07.08.2018 "On medical ethics and deontology rules" aiming at increasing responsibility and efficiency of medical/pharmaceutical workers and public credit to the health care system.

Medical ethics rules comprise moral/ethical norms to be observed by medical/pharmaceutical workers, particularly in their intercourse with patients and other persons, colleagues, representatives of state agencies/entities.

9.1.1. Morality principles for medical/pharmaceutical workers

Professional activities of medical/pharmaceutical workers shall be based on the principles of humanism, benevolence, moderation, professionalism, confidentiality and tolerance:

- The principle of humanism involves implies that medical/pharmaceutical workers must show trust, empathy, respect and compassion in all their relations with patients, colleagues and other persons.
- The principle of benevolence implies advertent and empathic attitude to patient's needs. Each medical/pharmaceutical worker's action must be oriented to a good cause.
- The principle of moderation implies that medical/pharmaceutical workers must at all times be able to manage their actions, emotions, be considerate in their intercourse with patients, colleagues and other persons.
- The principle of confidentiality implies privacy of medical secrecy, non-disclosure of information on patient's health status and other data, in delivering medical care.
- The principle of tolerance implies appreciation and tolerance to patients and other persons, respect for their views and opinions, particularly inadmissibility of any discrimination between religions and/or ethnicities, prohibition of privileges and/or restrictions with respect to races, political and other views, gender, age, ethnic or social origin, language or other attributes.
- The principle of professionalism comprises competence, promptness in obeying, discipline, eagerness to acquire and develop professional skills, as well as workmanlike and prompt performance of job duties.

Medical/pharmaceutical workers, in performing their job duties, shall not tolerate formalism or red-tapery, any disparagement towards patients, colleagues and other persons.

Medical/pharmaceutical workers shall also administer medical aid, within the compass of their powers, to all those who need it outside health care facilities.

9.1.2. Relations of medical/pharmaceutical workers with patients and other persons

Medical/pharmaceutical workers must abide by the following norms of mutual relations with patients and other persons:

- efficiently tackle performance targets involving their office duties;
- inform patients and other persons of methods and aims of proposed treatment procedures, medical interventions, eventual risks, peculiarities of use of pharmaceuticals, medical products, their possible adverse effects, of any possible alternative treatment methods;
- inform patients of any poor prognosis when delivering medical care, provided all mutual relations of patients with attending physicians comply with requirements of medical ethics and deontology and are easily understandable for persons without special medical knowledge.

Medical/pharmaceutical workers must refrain from:

- rough, formal or indelicate treatment of patients and/or other persons;
- disclosure of medical secrecy;
- misrepresenting or providing unreliable information when consulting patients/visitors of health care facilities or pharmacies with respect to application/storage of pharmaceuticals;
- negative impact of any personal, family, social or other circumstances on medical/pharmaceutical workers' behaviour in discharge of their office duties.

The Belarusian state acknowledges the importance of medical secrecy and provides adequate protection of social relations involving medical secrecy. Divulgence of medical secrecy is acknowledged as a crime by Belarusian laws and entails criminal responsibility under article 178 of the Criminal Code.

9.1.3. Medical/pharmaceutical workers' relations with colleagues, representatives of state agencies and other entities

Medical/pharmaceutical workers' mutual relations with colleagues shall be based on the principles of professional ethics, mutual respect and confidence, involving:

- showing competence and insisting on (self-)discipline for everyone;
- respect of human rights, dignity, personal and business reputation of each corporate member, mutual trust;
- creating and maintaining propitious staff morale;
- proper (theoretical and practical) skills to handle and resolve conflict situations;
- seeking help in case of any professional cumbers;
- developing tutorship: transferring positive experience/skills, rendering professional aid to younger colleagues.

Medical/pharmaceutical workers, in performing their job duties,

shall not use any words or expressions derogating dignity or business reputation of their colleagues, comment or discuss their colleagues' professional qualities.

Medical/pharmaceutical workers shall show respect for representatives of state agencies and other entities, at all times be regardful, undemonstrative, responsible and punctual.

In performing their job duties, medical/pharmaceutical workers are not entitled to impede authorised officers of state agencies in performing their lawful actions.

9.2. Anti-bribery restrictions

Anti-bribery laws impose restrictions on medical officers. such officers include, in particular:

- CEO/directors of health care (pharmaceutical) facilities and their deputies (for instance, chief physician);
- CEO/directors of structural subdivisions of health care (pharmaceutical) facilities and their deputies (for instance, division managers, chief accountant);
- CEO/directors and specialists of health care committees/departments of local executive committees and administrative bodies;
- doctors/physicians (as persons authorised to perform legally significant actions, for instance, issue prescriptions or sign sick lists).

Principal prohibitions and restrictions have been established by the Anti-Bribery Law.

Officers are prohibited to:

- accept gifts;
- carry out trips at the expense of another person, having an official relationship with such officer.

Exceptions to prohibitions:

- souvenirs may be accepted during protocol/official events;
- trips are allowed where:

– it is an official business trip;
– at the invitation of spouse, close relative (including relatives in-law or by marriage);
– in accordance with an international treaty/agreement between official bodies of different states;
– upon CEO/director's consent and at the expense of a public association/fund.