

## **ICD-11: Organizational and Legal, Medical and Pharmaceutical, Social and Economic Issues of Implementation of the Program of State Guarantees of Medical Care in 2022 in Ukraine, Based on The Fundamental Principles of the European Union**

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**Abstract.** The development of health care and the pharmaceutical industry is based on the principles of the Constitution of Ukraine, the fundamental principles of the European Union, the basics of medical and pharmaceutical law. The Ministry of Health of Ukraine and the National Health Service of Ukraine are responsible for the protection of human rights and freedoms, human life and health, patients, and the nation's gene pool, as well as privileged categories of citizens. State institutions on the basis of the Constitution of Ukraine, Laws of Ukraine, regulations of

Ukraine and Resolutions of the Cabinet of Ministers of Ukraine during the implementation of the "Program of Medical Guarantees" for 2022 decide organizational and legal, medical and pharmaceutical, social and economic issues of the program of state guarantees of medical care population in 2022 according to ICD-11.

**Keywords:** ICD-11, organization and economics of pharmacy, drug technology, forensic pharmacy, medical and pharmaceutical law, medicines, circulation, state guarantee programs, medical care.

**Introduction.** Ukraine, as a country that shares the fundamental principles of the European Union, deserves to be granted the status of a candidate for membership in the European Union (EU) – said the President of the European Parliament Robert Mezzola. The President of Latvia also supported the position of granting Ukraine EU candidate status, which is a political decision, and the EU should do so [1-3].

Earlier, on February 23, 2022, Polish President Andrzej Duda and Lithuanian President Gitanas Nausėda after a meeting with Ukrainian President Volodymyr Zelensky in Kyiv noted that Ukraine deserves the status of a candidate for EU membership, and Lithuania and Poland will support it in this [4].

At the same time, the President of the European Commission Ursula von der Leyen noted that she supports Ukraine's accession to the EU [5]. Ukraine's recovery must combine large-scale investment with ambitious reforms, such as [6]:

- ✓ modernize the administrative potential of Ukraine;
- ✓ firmly establish the rule of law and the independence of the judiciary;
- ✓ fight corruption;
- ✓ get rid of the oligarchs;
- ✓ build a fair, stable and strong competitive economy; and thus, firmly support Ukraine on its European path.

At present, when everyone understands that there is no other alternative than Ukraine's accession to the EU, the management of the Lviv Medical Institute (LMI), General Director, Doctor of Medical Sciences, Associate Professor Ihor Hayduchok (<https://medinstytut.lviv.ua/>) and Vice-Rector for Academic Affairs, Ph.D. in Pedagogical Sciences, Associate Professor, Honored Doctor of Ukraine O.M. Humeniuk. together with the Estonian scientific publishing house SSP OÜ (<https://ssp.ee/>) promote the policy of quality assurance of higher education of doctors and pharmacists by improving the internal quality assurance system of LMI, aimed at meeting the needs and rights of participants in the educational process, in accordance with modern European practices based on the principles of publicity (transparency), academic integrity, competitiveness, flexibility, adaptability and integrativity, taking into account the International Classification of Diseases (ICD-11) [7], covid, postcovid and longcovid complications [8-10] for ensuring the right of patients to access essential medicines (drugs) [11-15] of all classification and legal, clinical and pharmacological, and nomenclature and legal groups [16-23].

**The purpose of the study** was to consider organizational and legal, medical and pharmaceutical, social and economic issues of the system of legal relations "doctor-patient-pharmacist-lawyer" on the implementation of the program of state guarantees of medical care and provision of drugs in 2022, based on fundamental EU principles, constitutional, criminal legal, medical and pharmaceutical law and ICD-11.

**Materials and methods.** The information base of the study consisted of medical law, pharmaceutical law, forensic pharmacy, health care organization, criminology, pharmacy, industrial pharmacy, organization and management of pharmacy, criminal law, administrative law, economics, legislative, normative and legal, instructive and methodical documents of the UN, USA, EU, Ukraine (more than 200 documents) and scientific publications (more than 200 articles) on the topic of work were worked out in the work. To achieve this goal, the methods of normative and legal, documentary, retrospective, forensic and pharmaceutical, comparative, system and graphic analysis were used. Microsoft Excel 2010 (descriptive characteristics: minimum and maximum value, average value) was used to process the results and determine the consistency between the studied parameters.

These studies are a fragment of research work of LLC "Lviv Medical Institute" on "Improving the circulation of drugs during pharmacotherapy on the basis of evidence and forensic pharmacy, organization, technology, biopharmacy and pharmaceutical law" (state registration number 0120U105348, deadline 2021- 2026), Kharkiv Medical Academy of Postgraduate Education on "Improving the organizational and legal procedure for providing patients with drugs from the standpoint of forensic pharmacy, organization and management of pharmacy" (state registration number 0116U003137, deadline 2016-2020) and "Pharmaceutical and medical law: integrated approaches to the circulation system from the standpoint of forensic pharmacy and organization of pharmaceutical business "(state registration number 0121U000031, deadline 2021-2026).

**Results and discussion.** The training of modern doctors and pharmacists using distance learning due to quarantine of Covid-19 demonstrated the methodological,

informational, psychological, pedagogical, and professional readiness of scientific and pedagogical workers, students, and listeners to use modern Internet information technology systems. Information technology tools such as Google, Zoom messengers, Moodle platform, Kahoot provide a fast, accessible and high-quality environment for the exchange of information, communication and competencies between tutors and students, but need to increase the level of control over the effectiveness of knowledge acquisition by listeners (students) [24-38]. Personal communication with the listener (student) during the quarantine of Covid-19 played a leading role in creating distance-comfortable conditions during training (communication with the use of services and messengers was actively used at all levels and stages).

It is the activity of the teaching staff of LMI, deans (MD, Acting Professor, Academician of the Ukrainian Academy of Sciences Pyndus T.O.; Ph.D., Associate Professor Kovalishyn O.A.; Ph.D., Associate Professor Pindus V.B., Ph.D., Associate Professor Soronovych I.I.), Lviv Medical College "Monada" (Deputy Director – Hayduchok O.I.) and Lviv Medical College "Medic" (director – Solotva Y.I.) contribute to the policy of quality assurance of higher and secondary special education.

According to Mrs. Humeniuk O.M., the policy of quality assurance in higher education in LMI is implemented through the implementation of such procedures and measures as: – development and approval of educational programs in accordance with Higher Education Standards, a certain level of the National Higher Education Qualifications Framework and European Higher Education Area; – constant monitoring and periodic review of educational programs, their modernization and analysis for compliance with the requirements of students and the labor market; – introduction of student-centered learning, teaching and assessment; – improving the quality of the contingent of applicants for higher education; – strengthening the human resources of the Institute; – providing the necessary resources for the organization of the educational process, including the independent work of higher education applicants for each educational program; – organization of information management, including the collection, analysis and use of relevant information for effective management of the educational process; – introduction of a survey system as a tool for feedback from internal and external stakeholders; – ensuring publicity of information about the activities of the Institute; – implementation of self-assessment of the quality of education and educational activities as a basis for external quality assurance; - creation of an effective system and mechanisms for ensuring academic integrity, prevention and detection of academic plagiarism in the scientific works of the academic community of the Institute. Therefore, at the departments of LMI (Ph.D., Associate Professor Ryabukha O.I.; MD, Prof. Manenko A.K.; Ph.D., Associate Professor Tsisnetska A.V.; Ph.D., Associate Professor, Soronovich I.I., Ph.D., Associate Professor Baik O.L. and others) with the participation of the teaching staff of the Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy (Head of the Department – Doctor of Pharmaceutical Sciences, Professor Viktoriia Shapovalova, <https://med.edu.ua/golovna/faculties-departments/department-of-medical-and-pharmaceutical-law/>) of the Kharkiv Medical Academy of Postgraduate Education (Acting Rector – Doctor of Medical Sciences, Professor Korop O.A.,

<https://med.edu.ua/>) and the Estonian scientific publishing house SSP OÜ (<https://ssp.ee/index.php/mpm/article/view/40>) work on the preparation of lectures, publications and collaboration with general practitioners and pharmacists on drug pharmacotherapy for the use of drugs in accordance with ICD-11. That is, ICD-11 (new version released on June 18, 2019), as noted by the Director-General of the World Health Organization (WHO) Dr. Tedros Adhan Gebreyesus, gives us the opportunity to understand the variety of reasons why people get sick and die, and use measures to prevent suffering and save their lives [39, 40].

WHO experts note that the release of a new version of ICD-11 is the basis for tracking trends and statistics in health care worldwide and contains approximately 55,000 unique codes of injuries, diseases and causes of death (death). Provides health professionals around the world in a common language that allows them to share health information. However, ICD-11 is compiled in conjunction with WHO-adopted international non-proprietary names (INNs) for pharmaceuticals (medicines and medical devices) and can be used for cancer registration. ICD-11 has been developed for use in a large number of languages: the central multilingual platform provides the use of functionality and presentation of data in all languages into which it is translated. WHO assists countries in preparing for the use of the new ICD-11 [41].

As stated in the recommendations of the Ministry of Health of Ukraine [42], burnout is a phenomenon, not a disease. For the first time, gambling addiction is classified as a mental disorder. This disorder is characterized as a behavioral addiction to gambling – online and offline. They will be able to diagnose it if a violation of personal, family, social behavior is observed, which is observed for at least 12 months. Approaches to the classification of stroke have changed: now it is a disease of the brain, not the circulatory system. A separate innovation, the whole section is devoted to sexual health. Specific symptoms for diagnosing post-traumatic stress disorder have been clarified and complex post-traumatic stress disorder has been added. Allergies are diseases of the immune system: such grouping will improve the understanding of human reactions. Alternative medicine in one section - it is easier to calculate statistics on diseases and conditions, the concepts of which originated in ancient Chinese medicine and are now widely used in China, Japan, Korea, and other countries. Special codes for antibiotic resistance, this will help to more accurately measure the effectiveness of drugs around the world (<https://icd.who.int/en/>).

It is the Constitution of Ukraine that guarantees the basic rights to life, health and safety of a person, citizen, and patient, namely (extract of some articles) [43]:

*Article 3.* Man, his life and health, honor and dignity, inviolability and security are recognized in Ukraine as the highest social value.

Human rights and freedoms and their guarantees determine the content and direction of the state. The state is accountable to man for his activities. The establishment and protection of human rights and freedoms is the main duty of the state.

*Article 16.* Ensuring ecological safety and maintaining ecological balance on the territory of Ukraine, overcoming the consequences of the Chornobyl catastrophe - a

catastrophe of planetary scale, preservation of the gene pool of the Ukrainian people is the duty of the state.

*Article 27.* Everyone has the inalienable right to life.

No one can be arbitrarily deprived of life. The duty of the state is to protect human life.

Everyone has the right to protect his life and health, the lives and health of others from unlawful encroachment.

*Article 46.* Citizens have the right to social protection, which includes the right to provide them in case of full, partial, or temporary disability, loss of breadwinner, unemployment due to circumstances beyond their control, as well as in old age and in other cases provided by law.

This right is guaranteed by the obligatory state social insurance at the expense of insurance premiums of citizens, enterprises, institutions, and organizations, as well as budgetary and other sources of social security; creation of a network of state, municipal, private institutions for the care of the disabled.

Pensions, other types of social benefits and benefits, which are the main source of subsistence, must ensure a standard of living not lower than the subsistence level established by law.

*Article 47.* Everyone has the right to housing. The state creates conditions under which every citizen will be able to build housing, buy it or rent it.

Citizens in need of social protection are provided with housing by the state and local governments free of charge or for a fee available to them in accordance with the law.

No one shall be forcibly deprived of his home except by law.

*Article 48.* Everyone has the right to an adequate standard of living for himself and his family, which includes adequate food, clothing, and housing.

*Article 49.* Everyone has the right to health care, medical assistance, and medical insurance.

Health care is provided by the state financing of the corresponding social and economic, medical, and sanitary and improving and preventive programs.

The state creates conditions for effective and accessible medical care for all citizens. In state and municipal health care facilities, medical care is provided free of charge; the existing network of such establishments cannot be reduced. The state promotes the development of medical institutions of all forms of ownership (for the official interpretation of the provisions of part three of Article 49, see in the Decision of the Constitutional Court of Ukraine No. 10-rp/2002 of 29.05.2002).

The state cares about the development of physical culture and sports, ensures sanitary and epidemiological well-being.

*Article 50.* Everyone has the right to a safe environment for life and health and to compensation for damage caused by violation of this right.

Everyone is guaranteed the right of free access to information about the state of the environment, the quality of food and household items, as well as the right to its dissemination. Such information cannot be classified by anyone.

It should be noted that the protection of human rights and freedoms, life and health of man and patient, including privileged categories of citizens, in the field of health care and pharmaceuticals entrusted to the Ministry of Health of Ukraine and the National Health Service of Ukraine (NHSU), according to the Resolution of the Cabinet of Ministers of Ukraine of December 27, 2017 No. 1101 "On the establishment of the National Health Service of Ukraine" [44].

That is, the NHSU is a central executive body, whose activities are directed and coordinated by the Cabinet of Ministers of Ukraine through the Minister of Health, which implements state policy in the field of state financial guarantees of medical care.

According to the Resolution of the Cabinet of Ministers of Ukraine dated 29.12.2021 No. 1440 "Some issues of implementation of the program of state guarantees of medical care in 2022" [45] and in accordance with Article 19 of the Law of Ukraine "On State Budget of Ukraine for 2022" [46] The Ministers of Ukraine decided:

1. To approve the Procedure for implementation of the program of state guarantees of medical care of the population in 2022, which is attached.

2. To establish that the Procedure approved by this resolution is applied since January 1, 2022.

3. Within five days from the date of entry into force of this Resolution, the Ministry of Health shall submit to the National Health Service a list of state and / or communal ownership institutions that perform the functions of expert and regional neonatal screening centers, as well as a list of administrative territorial units designated for each of these health care facilities to provide relevant medical services.

4. The Council of Ministers of the Autonomous Republic of Crimea, oblast, Kyiv, and Sevastopol city state administrations:

- 1) ensure the distribution of centrally purchased medicines and medical devices in accordance with the volume of relevant medical services payable under the medical guarantee program in 2022, among all health care providers who have entered into an agreement with the National Health Service, regardless of organizational and legal forms and forms of ownership in accordance with the requirements of the Procedure for the use of funds provided in the state budget for the implementation of programs and implementation of centralized health measures, approved by the Cabinet of Ministers of Ukraine of March 17, 2011 No. 298;

- 2) within five working days from the date of entry into force of this resolution to submit to the National Health Service a list of health care facilities identified as ready to provide medical care in the context of the spread of infectious diseases, epidemics, and other emergencies.

It should be noted that citizens and patients of Ukraine should not incur financial, moral, ethical, and legal costs in case of illness or refuse to receive the necessary medical care due to inability to pay for it. The protection and restoration of the rights of the citizen and the patient is entrusted to a lawyer. Therefore, organizational and legal, medical and pharmaceutical, social and economic issues of the system of legal relations "doctor-patient-pharmacist-lawyer" for the implementation of the program of state guarantees of health care in 2022, should be based on fundamental principles of

the European Union, ICD-11, constitutional, criminal and legal, medical and pharmaceutical law.

According to the National Health Insurance Fund, state-guaranteed medical and pharmaceutical services are available to all who need them, regardless of their state of health and financial capacity. In turn, the NHSU guarantees that it will purchase specific medical services/groups of services in accordance with the terms of their purchase under the 2022 Medical Guarantee Program. The terms of purchase are designed for health care facilities that have already provided medical services under the Medical Guarantee Program, as well as for health care facilities that wish to enter into a contract with the National Health Insurance Fund for the first time. Specifications and conditions of procurement of medical services to be provided under the Medical Guarantees Program in 2022 [47]:

1. *Surgical operations for adults and children in a hospital one day:*

- Specification of medical services;
- Terms of purchase of medical services.

2. *Readiness to provide medical care in the context of the spread of infectious diseases, epidemics, and other emergencies:*

- Specification of medical services;
- Terms of purchase of medical services.

3. *Vaccination against acute respiratory disease covid-19 caused by coronavirus SARS-CoV-2:*

- Specification of medical services;
- Terms of purchase of medical services.

4. *Emergency medical care:*

- Specification of medical services;
- Terms of purchase of medical services.

5. *Primary care:*

- Specification of medical services;
- Terms of purchase of medical services.

6. *Medical care for acute stroke:*

- Specification of medical services;
- Terms of purchase of medical services.

7. *Medical care for acute myocardial infarction:*

- Specification of medical services;
- Terms of purchase of medical services.

8. *Medical care during childbirth:*

- Specification of medical services;
- Terms of purchase of medical services.

9. *Medical care for newborns in complex neonatal cases:*

- Specification of medical services;
- Terms of purchase of medical services.

10. *Surgical operations for adults and children in hospital:*

- Specification of medical services;
- Terms of purchase of medical services.

11. *Inpatient care for adults and children without surgery:*

- Specification of medical services;
- Terms of purchase of medical services.

12. *Prevention, diagnosis, observation, treatment and rehabilitation of patients in an outpatient setting:*

- Specification of medical services;
- Terms of purchase of medical services.

13. *Dental care for adults and children:*

- Specification of medical services;
- Terms of purchase of medical services.

14. *Pregnancy management in an outpatient setting:*

- Specification of medical services;
- Terms of purchase of medical services.

15. *Treatment of patients by hemodialysis in an outpatient setting:*

- Specification of medical services;
- Terms of purchase of medical services.

16. *Treatment of patients by peritoneal dialysis in an outpatient setting:*

- Specification of medical services;
- Terms of purchase of medical services.

17. *Mammography:*

- Specification of medical services;
- Terms of purchase of medical services.

18. *Hysteroscopy:*

- Specification of medical services;
- Terms of purchase of medical services.

19. *Esophagogastroduodenoscopy:*

- Specification of medical services;
- Terms of purchase of medical services.

20. *Colonoscopy:*

- Specification of medical services;
- Terms of purchase of medical services.

21. *Cystoscopy:*

- Specification of medical services;
- Terms of purchase of medical services.

22. *Bronchoscopy:*

- Specification of medical services;
- Terms of purchase of medical services.

23. *Support and treatment of adults and children with tuberculosis at the primary level of medical care:*

- Specification of medical services;
- Terms of purchase of medical services.

24. *Diagnosis and treatment of adults and children with tuberculosis in outpatient and inpatient settings:*

- Specification of medical services;



- Terms of purchase of medical services.
- 25. *Diagnosis, treatment and support of people living with HIV (and suspected HIV):*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 26. *Treatment of persons with mental and behavioral disorders due to the use of opioids with the use of maintenance replacement therapy:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 27. *Chemotherapeutic treatment and support of adults and children with cancer in outpatient and inpatient settings:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 28. *Radiological treatment and support of adults and children with cancer in outpatient and inpatient settings:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 29. *Treatment and support of adults and children with hematological and oncohematological diseases in outpatient and inpatient settings:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 30. *Inpatient psychiatric care:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 31. *Psychiatric care provided by mobile multidisciplinary teams:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 32. *Medical rehabilitation of infants born prematurely and / or ill during the first three years of life:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 33. *Medical rehabilitation of adults and children from three years with musculoskeletal disorders:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 34. *Medical rehabilitation of adults and children from three years with a lesion of the nervous system:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 35. *Inpatient palliative care for adults and children:*
  - Specification of medical services;
  - Terms of purchase of medical services.
- 36. *Mobile palliative care for adults and children:*
  - Specification of medical services;
  - Terms of purchase of medical services.

37. *Inpatient care for patients with acute respiratory disease COVID–19 caused by coronavirus SARS–COV–2:*

- Specification of medical services;
- Terms of purchase of medical services.

It should be noted that the pharmaceutical industry is returning to pre-war levels [48]. Thus, if in the first days of the full-scale Russian invasion only half of pharmacies operated in Ukraine, now there are 80%, i.e., more than 16 thousand pharmacies, and this is the ability to optimize legal relations in the chain "doctor-patient-pharmacist" and provide health care facilities with vital drugs of all classification and legal, clinical and pharmacological, normative and legal groups for the treatment of wounded military, civilian, planned operations, chronic diseases of privileged categories of citizens, etc.

Thus, the current training of doctors and pharmacists, as well as their professional development on the basis of ICD-11, constitutional, criminal law, medical and pharmaceutical law is in the system of legal relations "doctor-patient-pharmacist-lawyer" within the specialty "Medicine", "Pharmacy, industrial pharmacy" in the areas of "Health care organization", "Organization of pharmaceutical business, drug technology, clinical and forensic pharmacy"; in terms of organizational and legal, medical and pharmaceutical, social and economic implementation of the program of state guarantees of medical care in 2022.

**Conclusions.** The development of health care and the pharmaceutical industry is based on the principles of the Constitution of Ukraine, the fundamental principles of the European Union, the basics of medical and pharmaceutical law. The Ministry of Health of Ukraine and the National Health Service of Ukraine are responsible for the protection of human rights and freedoms, human life and health, patients, and the nation's gene pool, as well as privileged categories of citizens. State institutions on the basis of the Constitution of Ukraine, Laws of Ukraine, regulations of Ukraine and Resolutions of the Cabinet of Ministers of Ukraine during the implementation of the "Program of Medical Guarantees" for 2022 decide organizational and legal, medical-pharmaceutical, social and economic issues of the program of state guarantees of medical care population in 2022 in accordance with ICD-11 and are based on the fundamental principles of the European Union.

**Conflict of interests.** The authors declare that they have no conflict of interests or/and competing interests.

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