MINISTRY OF HEALTH OF UKRAINE
ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Organization and Economy of Pharmacy
with post-diploma specialization

APPROVED

Vice-rector for scientific and pedagogical work

Eduard BURYACHKIVSKY

September 1st, 2024

WORK PROGRAM IN THE DISCIPLINE

PHARMACOECONOMICS

Level of higher education: second (master's degree)

Field of knowledge: 22 "Health care"

Specialty: 226 "Pharmacy, industrial Pharmacy"

Educational and professional program: "Pharmacy, industrial pharmacy"

2024

The working program is compiled on the basis of the educational and professional program "Pharmacy, industrial pharmacy" for the training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, industrial pharmacy" of the field of knowledge 22 "Health care", approved by the Academic Council of ONMedU (minutes No. 10 dated 27/06/2024).

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The working program was approved at the meeting of the Department of Pharmacy Organization and Economy with post-diploma specialization
Minutes No. 1 dated August 29, 2024.

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Approved by the subject cycle methodical commission for pharmaceutical disciplines of ONMedU
Minutes No._1 dated August 30, 2024.

Head of the subject cycle methodical commission

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Revised and approved at the meeting of the department_____
Minutes No. ____of "___" _____20___
Head of Department _____
(signature) (First Name Surname)

Revised and approved at the meeting of the department _____
Minutes No. ____of "___" _____20___
Head of Department _____
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1. Description of the discipline:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the discipline
Total number of: Credits of ECTS: 3 Hours: 90 Content modules: 3	Branch of knowledge 22 "Health care" Specialty 226 "Pharmacy, Industrial pharmacy" Level of higher education second (master's)	*Full-time education* *Mandatory discipline*
		Year of training: 4
		Semester: VII
		Lectures (6 hours)
		Seminars (0 hours)
		Practical classes (34 hours)
		Lab classes (0 hours)
		Independent work (50 hours)
		including individual assignments (0 hours)
		Final control – graded test

2. The Purpose and Objectives of the Discipline, Competencies, and Program Learning Outcomes

Purpose: formation of students' system of knowledge on conducting pharmacoeconomic research and rational use of funds for health care in modern conditions.

Objectives of the Discipline:

1. Formation of skills andin accordance with educational and qualification characteristics.
2. Providing a theoretical basis for further study of other pharmaceutical and economic disciplines of the curriculum.
3. Creating a base that determines the professional competence and general erudition of pharmacists.
4. Generalization of knowledge on the rational use of medicines, information and communication technologies.
5. Development of ways of rational use of funds for health care by both individual consumers and medical and preventive institutions and the state as a whole, optimization of the process of creation, production and use of medicinal products in the conditions of a market economy.

The process of studying the discipline is aimed at forming elements of the following competencies:

- **general (GC):**

GC02. Knowledge and understanding of the subject area and understanding of professional activities.

GC09. Ability to use information and communication technologies.

GC11. Ability to apply knowledge in practical situations.

- **Special (SC):**

SC01. Ability to integrate knowledge and solve complex problems of pharmacy in broad or multidisciplinary contexts.

SC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.

SC09. Ability to provide premedical care to patients and victims in extreme situations and

emergency conditions.

SC15. Ability to analyse socio-economic processes in pharmacy, forms, methods and functions of the pharmaceutical supply system and its components in world practice, indicators of need, effectiveness and availability of pharmaceutical care in the context of health insurance and reimbursement of the cost of medicines.

SC24. Ability to use in professional activities knowledge of regulatory and legal acts of Ukraine and recommendations of good pharmaceutical practices.

Program learning outcomes for the educational component (PLO):

PLO03. To have specialised knowledge and skills to solve professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field of pharmacy.

PLO09. To formulate, argue, clearly and concretely communicate to specialists and non-specialists, including higher education students, information based on their own knowledge and professional experience, the main trends in the development of world pharmacy and related industries.

PLO18. To use data from the analysis of socio-economic processes in society for pharmaceutical provision of the population, to determine the effectiveness and accessibility of pharmaceutical care in terms of health insurance and reimbursement of the cost of medicines.

As a result of studying the academic discipline, the student of higher education must:

- **know:**

- current trends in the development of the industry and analyze them;
- laws and trends of modern economic development;
- their social and public rights and responsibilities;
- the regulatory framework of the state's strategy in the fight against dangerous infectious and parasitic diseases;
- principles of compiling pharmaceutical information and creating information products;
- main properties and characteristics of medicines from different pharmacological groups;
- clinical and biopharmaceutical features of various dosage forms;
- basics of pharmacogenetics, chronopharmacology; concepts of bioequivalence of medicinal products and principles of their clinical study;
- concept of original (innovative) drugs and generics;
- the state and features of the human body (physiological, pathological, etc.) and the connection with the effect of the medicinal product on the body;
- determine the optimal mode of drug administration; clinical manifestations (symptoms and syndromes) of diseases for which drugs are prescribed;
- main indicators of effectiveness of medicines; the main criteria for the effectiveness and safety of drugs and their sources
- the legislative framework of Ukraine regarding entrepreneurial activity;
- principles of organizing the work of pharmacies, pharmaceutical companies and their structural units; planning the development and placement of the pharmacy network;
- orders and instructional materials of the Ministry of Health of Ukraine regarding the information and technical support of pharmacists' workplaces;
- organization of appropriate document flow at each pharmacist's workplace; drug pricing;
- normative legal acts of Ukraine on the operation of a pharmacy;
- approaches to the formation of prices for medicines in Ukraine and abroad;
- decision-making process management functions;
- management and successful management;
- the organization of the pharmaceutical system as an object of management;
- ethical and legal norms of pharmaceutical activity;
- models, methods and approaches to management decision-making;
- the organizational structure of the pharmaceutical supply system in Ukraine, its goals, tasks and functions;

- the main mechanisms for ensuring the availability of pharmaceutical care to the population;
- modern principles of world practice in providing pharmaceutical assistance to socially vulnerable population groups;
- basic principles of social management and marketing;
- psychological aspects of providing pharmaceutical care to patients;
- methods of marketing research of the pharmaceutical market;
- formation of an assortment of medicines;
- characteristics of pharmacological groups of drugs;
- determining the need for medicines;
- study of the drug market.
- learn the importance of pharmacoeconomics in the modern health care system, practical activities of pharmaceutical industry specialists;

- **be able to:**

- analyze professional information, make informed decisions, acquire modern knowledge;
- apply knowledge for the modern development of the enterprise;
- to form one's civic consciousness, to be able to act in accordance with it;
- conduct an analysis and formulate conclusions and recommendations regarding the improvement of the economic parameters of the operation of the pharmacy establishment, calculate the price of medicinal products or medical products for the end user;
- justify the plan of organizational, methodical and production measures aimed at coordinating the activity program, solving financial and social issues;
- to plan, organize and conduct operational and final production meetings of employees of the institution (enterprise) with the adoption of relevant management decisions;
- conduct sociological and psychological research on the state of pharmaceutical provision of the population and the degree of its effectiveness;
- conduct marketing research and use their results for general and marketing management of the activities of pharmaceutical organizations;
- learn the basic principles and provisions of evidence-based medicine;
- use different methods of pharmacoeconomic research;
- analyze the results of pharmacoeconomic studies to choose the optimal medical technology among existing alternatives, improve the quality of medical care, optimal use of both budget funds and patient funds;
- use the main methods of pharmacoepidemiological research;
- analyze the results of pharmacoepidemiological studies;
- use systematized information sources to determine the effectiveness and safety of medicinal products, non-medicinal medical technologies;
- to analyze the economic aspects of the therapeutic and unwanted effects of drugs, non-medicinal medical technologies;
- carry out a rational selection of medicinal products taking into account indicators of cost and therapeutic effectiveness, pharmacoeconomic and pharmacoepidemiological indicators to optimize medical supply;
- evaluate the pharmacoeconomic properties of medicinal products when creating standards for the provision of medical care for various diseases, forming the List of vital and important medicinal products, lists for preferential provision of medicinal products, formularies (lists) of medicinal products of medical institutions;
- to create a holistic idea about the possibilities of using the pharmacoeconomics methodology in solving various problems of the professional activity of pharmacy specialists.

Master the skills:

- use of various sources and forms of transmission of pharmaceutical information;
- to analyze the formation of drug prices, including taking into account the state regulation of drug prices;
- conduct and apply the results of pharmacoeconomic studies;
- rational use of funds for health care in modern conditions;

- use mathematical modeling for calculations in pharmacy;
- apply basic methods of pharmacoepidemiological research;
- calculate the cost of treatment;
- analyze the results of pharmacoepidemiological studies;
- systematize information sources to determine the effectiveness and safety of medicinal products, non-medicinal medical technologies;
- to analyze the economic aspects of the therapeutic and unwanted effects of drugs, non-medicinal medical technologies;
- carry out a rational selection of medicinal products taking into account indicators of cost and therapeutic effectiveness, pharmacoeconomic and pharmacoepidemiological indicators to optimize medical supply;
- evaluate the pharmacoeconomic properties of medicines when creating standards for the provision of medical care for various diseases, forming the List of vital and important medicines, lists for preferential provision of medicines, formularies (lists) of medicines for medical institutions.

3. Content of the Discipline

Content module 1. General pharmacoeconomics: theoretical foundations, information sources and mathematical modeling in pharmacoeconomics.

Topic 1. Pharmacoeconomics as a science. Pharmacoeconomic categories.

Evidence-based medicine: concepts, methodology, fundamental principles, basic terms of evidence-based medicine, objective reasons for the formation of the principle of evidence in the field of health care. International experience of evidence-based medicine. Pharmacoeconomics as one of the possible ways to optimize state funds for health care. Pharmacoeconomics as a science: purpose, tasks, subject and objects of study. Pharmacoeconomics as an essential component of evidence-based medicine. Consumers of the results of pharmacoeconomic studies. The role of pharmacoeconomics in the professional activity of a modern pharmacist. Characteristics of the main pharmacoeconomic categories, their significance for conducting pharmacoeconomic studies.

Topic 2. Fundamentals of pharmacoepidemiology: clinical effectiveness of medical technologies.

Pharmacoepidemiology as a modern applied science: purpose and tasks, practical significance. Types and methods of pharmacoepidemiological studies, their characteristics. Selection of indicators of effectiveness of medical technologies when conducting pharmacoepidemiological studies. Significance of pharmacoepidemiological research results for pharmacoeconomic calculations. Factors affecting the results of pharmacoepidemiological studies. Study of the structure of drug consumption. ATC/DDD method of drug consumption analysis. Application of the results of quantitative pharmacoepidemiological studies of drug consumption to improve the quality of medical care.

Topic 3. The system of pharmacological supervision in Ukraine.

Modern methods of collecting, analyzing and systematizing information about unwanted and side effects of medicines. International experience of exchanging information on side effects of drugs. The system of pharmacological supervision in Ukraine: legislative framework, organizational structure, main tasks and areas of activity. The procedure for reporting side effects of medicines. Monitoring system of spontaneous reports on unwanted effects of medicinal products. Drug safety as a pharmacoeconomic category. Safety criteria of medical technologies. Medical and socio-economic significance of side effects of drugs. Definition, types of side and unwanted effects of drugs. Factors contributing to the development of side effects.

Topic 4. Fundamentals of pharmacoinformatics.

Pharmacoinformatics as a science. Information sources: concepts and classification. Evaluation of the quality of clinical information according to the technologies of evidence-based medicine. Levels of evidence in medicine and pharmacy, their definition (level of evidence). Pharmacoinformatics as a source

of evidence-based medicine arguments when choosing the optimal solution in medical practice, organization of medical supply. Systematic reviews: definition of concepts, structure, principles of creation and use in conducting pharmacoeconomic studies. Meta-analysis: concept, purpose, task, scope of use. Concept of information database. International information databases on the proven effectiveness and safety of drug therapy, the principles of their operation. The use of databases when conducting pharmacoeconomic studies, when organizing the medical supply of the population.

Topic 5. Costs as a pharmacoeconomic category. Costs optimization for public health care.

Classification of pharmacoeconomic costs. Types, purpose and characteristics of direct medical costs (fixed, average, variable, marginal, non-calculable). Characteristics of direct non-medical costs. Indirect costs. The relevance of costs in relation to the patient and the state. Principles of reimbursement of costs for medicines. Stages of cost calculation in pharmacoeconomic studies. Cost discounting. Factors contributing to the growth of state spending on public health. Directions for optimizing budgetary (and extra-budgetary) costs for health care. Pharmacoeconomics as one of the possible ways to optimize state funds for health care.

Topic 6. Mathematical modeling in pharmacoeconomics.

Mathematical modeling: concepts, basic principles. Objects and types of modeling. Stages of modeling. The practical value of mathematical modeling when conducting pharmacoeconomic analysis.Mathematical modeling using the "decision analysis" method: principle of the method, stages of building the "decision tree" model, scope of application. Mechanism of cost calculation using "decision tree". Pharmacoeconomic evaluation of treatment using the construction of a "decision tree" on the example of individual diseases. Mathematical Markov model: principle of the method, scope of application. The concept of Markov cycles, Markov states, Markov assumption, termination of the Markov process. Construction of the "tree of Markov cycles" model. Pharmacoeconomic evaluation of treatment using the Markov method on the example of certain diseases.

Content module 2. Applied pharmacoeconomics: application of pharmacoeconomic research methods in practical medicine and pharmacy.

Topic 7. Types and methodology of pharmacoeconomic evaluations. Cost of Illness Analysis (COI). Cost-Minimization Analysis (CMA).

Pharmacoeconomic analysis methodology proposed by the International Society for Pharmacoeconomic Research and Treatment Outcomes (ISPOR). Stages of pharmacoeconomic analysis. The structure of the report on the pharmacoeconomic analysis.

General characteristics of the pharmacoeconomic method "cost of illness": purpose, features of implementation, method of calculations, advantages and disadvantages of the method, scope of application. Principles of using the results of pharmacoeconomic analysis using the "total cost of disease" method. Calculations of tariffs for medical technologies on the example of individual diseases.

General characteristics of the pharmacoeconomic method "cost minimization": purpose, conditions of implementation, features of the method, main stages of implementation, method of calculations, advantages and disadvantages of the method, scope of practical application. The value of bioequivalence studies in determining the identical effectiveness of generic drugs and original drugs. Regulatory framework for bioequivalence research in Ukraine. Using the "cost minimization" method on the example of individual diseases, when comparing original and generic drugs (on the example of individual drugs).

Topic 8. Effectiveness of medicines as a pharmacoeconomic category. Cost-Effectiveness Analysis (CEA).

Effectiveness of medicines in conducting pharmacoeconomic studies. Selection of indicators and criteria for the effectiveness of medicinal products during pharmacoeconomic analysis. General characteristics of the pharmacoeconomic method "cost-effectiveness": purpose, conditions of implementation. features of the method, main stages of implementation, method of calculations, advantages and disadvantages of the method, scope of practical application. Requirements for the

selection of therapy efficiency units when conducting pharmacoeconomic studies using the "cost-effectiveness" method. Calculation of the cost of a unit of efficiency (cost efficiency ratio - CER) and its use in choosing the optimal medical technology. Pharmacoeconomic evaluation of treatment using the "cost-effectiveness" method on the example of certain diseases. The concepts of "dominant alternative" and "reference drug (or treatment scheme)" when comparing medical technologies based on the results of pharmacoeconomic studies. Calculation of the incremental indicator (cost efficiency growth factor - ICER).

Topic 9. Quality-of-Life Trials and Issues. Cost-Utility Analysis (CUA)

"Quality of life": definition of the concept, its components and significance for clinical and pharmacoeconomic research. The main factors determining the impact of medical technologies on the quality of life of patients.General and special questionnaires for determining the quality of life. WHO requirements for quality of life questionnaires. Interpretation of quality of life survey data using various tools. Peculiarities of the study of quality of life depending on the nosology and contingent of patients. QALY indicator: definition of the concept and method of calculation. DALY indicator: definition of the concept and method of calculation. Alternative means of determining the usefulness of medical technologies: "gambling" and "equal exchange" methods. Use of various indicators of usefulness (utility) of medical technologies in pharmacoeconomic analysis.

General characteristics of the pharmacoeconomic method "cost-utility": purpose, features of the method, main stages of implementation, method of calculations, advantages and disadvantages of the method, scope of practical application. Calculation of the cost-utility ratio - CUR (cost of a unit of utility) and its use when choosing the optimal medical technology among existing alternatives. Pharmacoeconomic evaluation of treatment using the "cost-utility" method on the example of individual diseases and therapy schemes. Peculiarities of choosing utility units for various diseases. Calculation of the cost of an additional unit of utility (incremental indicator – ICUR).

Topic 10. Cost-Benefit Analysis (CBA). Sensitivity Analysis.

General characteristics of the cost-benefit (benefit) pharmacoeconomic method: purpose, features of the method, main stages of implementation, method of calculations, advantages and disadvantages of the method, scope of practical application. Direct, indirect and intangible benefits of medical technology. The concept of "net" benefit and the methodology of its calculations when conducting pharmacoeconomic studies. Methods of evaluating the results of medical technologies in monetary terms: the "human capital" method, the "willingness to pay" assessment; their limitations and shortcomings. The reliability of the results of pharmacoeconomic studies is a condition for their practical use. Objective factors affecting the variability of the results of pharmacoeconomic studies. Sources of information about possible fluctuations of initial parameters during pharmacoeconomic studies.

Topic 11. Pharmacoeconomic research in the development of standards in health care. Fundamentals of the formulary system.

Quality of medical care: concepts, criteria and features of assessment. The Donabedian Triad.Standardization in health care: concepts, objects of standardization, types and categories of standards, stages of their creation and implementation in health care practice. Standards of medical technologies (national, regional, medical and preventive institutions): principles of creation and significance for assessing the quality of medical care. International experience in the development and implementation of standards for the treatment of diseases in health care. Application of the results of pharmacoeconomic studies in the creation of treatment standards for various diseases. The list of basic (vital) medicines, its structure, order of creation, significance at the current stage of development of the health care system. Purpose and main functions of the formulary system. Stages of development and implementation of the formulary system in health care practice. Form systems of different countries of the world. The form as the main element of the form system: definition of the concept, structure, stages of creation. Pharmacoeconomic justification of the choice of drugs for the formulary. Restrictions on the use of medicinal products when creating a formulary. Using the results of frequency, ABC and VEN analysis when creating a formulary as a criterion for the rationality of drug therapy.

Topic 12. The use of pharmacoeconomic studies in the development and promotion of new medicines.

Prerequisites for the development of medicines. Traditional approaches to the development of medicines. Stages of developing a medicines, stages of the research cycle. Components of scientific research before introducing the drug to the pharmaceutical market. Application of pharmacoeconomic studies in the creation of new medicines. Factors determining the promotion of a medicinal product on the pharmaceutical market. The importance of pharmacoeconomic research in the light of modern trends in the development of the pharmaceutical market in Ukraine. Application of pharmacoeconomic studies in regulating the life cycle of drugs on the pharmaceutical market. Calculation of the coefficients of liquidity of the drug price and solvency adequacy.

4. The Structure of the Discipline

Names of topics	**Number of hours**					
	Total	**including**				
		lectures	**seminars**	**Practical classes**	**Lab classes**	**ISW**
Content module 1. General pharmacoeconomics: theoretical foundations, information sources and mathematical modeling in pharmacoeconomics.						
Topic 1. Pharmacoeconomics as a science. Pharmacoeconomic categories.	8	2	-	2	-	4
Topic 2. Fundamentals of pharmacoepidemiology: clinical effectiveness of medical technologies.	8	-	-	4	-	4
Topic 3. The system of pharmacological supervision in Ukraine.	6	-	-	2	-	4
Topic 4. Fundamentals of pharmacoinformatics.	4	-	-	-	-	4
Topic 5. Costs as a pharmacoeconomic category. Costs optimization for public health care.	10	2	-	4	-	4
Topic 6. Mathematical modeling in pharmacoeconomics.	8	-	-	4	-	4
Total according to content module 1	44	4	-	16	-	24
Content module2. Legal regulation of the circulation of drugs and medical devices, activities of specialists in the pharmaceutical sector of Ukraine.						
Topic 7. Types and methodology of pharmacoeconomic evaluations. Cost of Illness Analysis (COI). Cost-Minimization Analysis (CMA).	10	2	-	4	-	4
Topic 8. Effectiveness of medicines as a	8	-	-	4	-	4

pharmacoeconomic category. Cost-Effectiveness Analysis (CEA).						
Topic 9. Quality-of-Life Trials and Issues. Cost-Utility Analysis (CUA)	4	-	-	2	-	2
Topic 10. Cost-Benefit Analysis (CBA). Sensitivity Analysis.	4	-	-	2	-	2
Topic 11. Pharmacoeconomic research in the development of standards in health care. Fundamentals of the formulary system.	8	-	-	4	-	4
Topic 12. The use of pharmacoeconomic studies in the development and promotion of new medicines.	4	-	-	-	-	4
Total according to content module 2	38	2	-	16	-	20
Graded test	8	-	-	2	-	6
Total hours	**90**	**6**	**-**	**34**	**-**	**50**

5. Topics of lectures / seminars / practical / laboratory classes

5.1. Topics of lectures

No	Topic name	Number of hours
1	Topic 1. Lecture session 1. Pharmacoeconomics as a science. Pharmacoeconomic categories.	2
2	Topic 5. Lecture session 2. Costs as a pharmacoeconomic category. Costs optimization for public health care.	2
3	Topic 7. Lecture class 3. Types and methodology of pharmacoeconomic evaluations. Cost of Illness Analysis (COI). Cost-Minimization Analysis (CMA).	2
	Total	**6**

5.2. Topics of seminar classes

Seminar classes are not provided.

5.3. Topics of practical classes

No	Topic name	Hours
1.	Topic 1. Practical class 1. Pharmacoeconomics as a science. Pharmacoeconomic categories.	2
2.	Topic 2. Practical class 2-3. Fundamentals of pharmacoepidemiology: clinical effectiveness of medical technologies.	4
3.	Topic 3. Practical class 4. The system of pharmacological supervision in Ukraine.	2

4.	Topic 5. Practical class 5-6. Costs as a pharmacoeconomic category. Costs optimization for public health care.	4
5.	Topic 6. Practical class 7-8. Mathematical modeling in pharmacoeconomics.	4
6.	Topic 7. Practical class 9-10. Types and methodology of pharmacoeconomic evaluations. Cost of Illness Analysis (COI). Cost-Minimization Analysis (CMA).	4
7.	Topic 8. Practical lesson 11-12. Effectiveness of medicinal products as a pharmacoeconomic category. Cost-Effectiveness Analysis (CEA).	4
8.	Topic 9. Practical lesson 13. Quality-of-Life Trials and Issues. Cost-Utility Analysis (CUA)	2
9.	Topic 10. Practical lesson 14. Cost-Benefit Analysis (CBA). Sensitivity Analysis.	2
10.	Topic 11.Practical lesson 15-16. Pharmacoeconomic research in the development of standards in health care. Fundamentals of the formulary system.	4
11.	Practical lesson 17. Graded test	2
	Total:	34

5.4. Topics of laboratory classes

Laboratory classes are not provided.

6. Independent higher education student work

Preparation of written answers to problematic questions

No	Title of the topic / types of assignments	Hours
1.	Topic 1. Preparation for practical classes 1	4
2.	Topic 2. Preparation for practical classes 2-3	4
3.	Topic 3. Preparation for practical classes 4	4
4.	Topic 4. Preparation of written answers to problematic questions	4
5.	Topic 5. Preparation for practical classes 5-6	4
6.	Topic 6. Preparation for practical classes 7-8	4
7.	Topic 7. Preparation for practical classes 9-10	4
8.	Topic 8. Preparation for practical classes 11-12	4
9.	Topic 9. Preparation for practical classes 13	2
10.	Topic 10. Preparation for practical classes 14	2
11.	Topic 11. Preparation for practical classes 15-16	4
12.	Topic 12. Preparation of written answers to problematic questions	4
13.	Practical lesson 17. Preparation for graded test	6
	Total	50

7. Teaching methods

Lectures: problem-based lectures, lectures-visualizations, narration, explanation, conversation, instruction, discussion, dispute, discussion of problem situations, situational learning, illustration (including multimedia presentations), demonstration, presentation of the results of own research.

Practical classes: Methods by the presentation and perception of information :

- Verbal: narrative, explanation, conversation, instruction, discussion, debate, discussion of problem situations, situational learning.
- Visual: illustration (including multimedia presentations), demonstration, method of direct

observation, presentation of the results of own research.

● Practical: assignments; training tasks

Independent work: independent work with the recommended basic and additional literature, with electronic information resources.

Independent work in the study of the academic discipline is ensured methodological developments for independent work, visual teaching aids (video lectures, presentations), information resources of the department, topics of independent work

8. Forms of control and assessment methods (including criteria for assessing learning outcomes)

Current control: oral survey, control written works, evaluation of reports, evaluation of activity in the class, testing (pen-and-paper or computerized), evaluation of required skills

Final control: graded test.

Assessment of current learning activities in a practical class:

1. Assessment of theoretical knowledge on the topic of the lesson:
- methods: survey, solving a situational task
- maximum grade - 5, minimum grade - 3, unsatisfactory grade - 2.
2. Assessment of practical skills on the topic of the lesson:
- methods: assessment of the correctness of practical skills
- maximum grade - 5, minimum grade - 3, unsatisfactory grade - 2.

The grade for one practical lesson is the arithmetic mean of all components and can only have an integer value (5, 4, 3, 2), which is rounded by the statistical method.

Evaluation of the current educational activity in a practical class:

1. Evaluation of theoretical knowledge on the topic of the class:
- methods: survey, solving a situational clinical problem;
- the highest grade available is 5, the lowest passing grade is 3, the failing (unsatisfying) grade is 2.
2. Evaluation of practical skills on the subject of the lesson:
- methods: standardized and include control of vocabulary, grammar, and communication skills;
- the highest grade available is 5, the lowest passing grade is 3, and the failing (unsatisfying) grade is

Current Evaluation Criteria at Practical Classes

Rating	Evaluation criteria
"5"	The higher education (HE) student is fluent in the material required, demonstrates versatile and deep knowledge of the program material, can perform the tasks provided for in the program successfully; has mastered the content of the required and additional literature, and has realized the interrelationship of individual sections of the discipline and their importance for the future profession; has demonstrated creative abilities in understanding and using educational program material and the ability to update and replenish knowledge independently; level of competence - high (creative);
"4"	The HE student has demonstrated complete knowledge of the educational program material, successfully performs the tasks provided by the program, has mastered the basic literature recommended by the program, and is capable of independent updating and renewal in the course of further education and professional activities, but makes minor mistakes, which are eliminated by the student him/herself when the examiner points them out; the level of competence is sufficient (constructive and variable);
"3"	The HE student does not have sufficient knowledge but knows the fundamental curriculum material to the extent necessary for further education and subsequent work in the profession; copes with the tasks provided by the program, makes some mistakes in the answers at the exam and when completing the exam tasks, but has the necessary knowledge to overcome the mistakes made under the guidance of a scientific and pedagogical worker; level of

	competence - average (reproductive);
"2"	The HE student does not acquire knowledge of program material, makes fundamental mistakes in the assignments provided by the program, cannot use the knowledge in further studies on their own, did not manage to master the skills of independent work; the level of competence is low (receptive-productive)

Only those applicants who have fulfilled the requirements of the curriculum in the discipline, have no academic debt and their average score for the current academic activity in the discipline is at least 3.00 are allowed to take the final control in the form of a graded test.

Assessment of learning outcomes during the final control

Evaluation of learning results during the final control

The content of the evaluated activity	Scores
Answers to theoretical questions.	2
Solving a situational problem with evaluation of the obtained results	3

Template of a question paper for graded test:

QUESTION PAPER FOR GRADED TEST № ____

1. Evidence-based medicine: concept, methodology, fundamental principles, basic terms of evidence-based medicine, objective reasons for the formation of the principle of evidence in healthcare.
2. Classification of pharmacoeconomic costs.
3. Situational task. Using the ATC/DDD methodology, evaluate the use of mucolytic drugs in N-region during N-year, given the following data:

The number of children in N-region is 189002.

Over the past year, N-region has used:

Ambroxol 15 mg tablet No. 20 - 4320 packs (DDD - 0.12 g).

Bromhexin, tablet 0.08, No. 25 - 3218 packs (DDD - 0.024 g).

Justify your answer: what does the level of medication consumption you have determined indicate? What is the level of treatment effectiveness?

4. Situational task. Calculate the direct medical costs for the treatment of one child with pneumonia for 3 years, given the following information:

- the cost of a course of treatment for the first year is 3645 UAH;
- in each subsequent year, the cost of treatment increased by 3%;
- the discount rate is 2%.

Criteria for evaluating the learning outcomes of education seekers during graded test

Rating	Evaluation criteria
Excellent	The student correctly, accurately and completely completed all the tasks of the examination ticket, clearly and logically answered the questions posed by the examiners. Thoroughly and comprehensively knows the content of theoretical issues, fluent in professional and scientific terminology. Thinks logically and constructs an answer, freely uses acquired theoretical knowledge when analyzing practical tasks. When solving a situational problem, he correctly interpreted the initial data, answered all the questions correctly and convincingly substantiated his point of view, could propose and justify an alternative solution to certain issues. When solving a calculation task, he strictly followed the algorithm of its execution.
Good	The student completed all the tasks of the examination ticket in a sufficiently complete manner, clearly and logically answered the questions posed by the examiners. He knows the content of theoretical issues deeply and comprehensively,

	and has professional and scientific terminology. Thinks logically and constructs an answer, uses acquired theoretical knowledge when analyzing practical tasks. But when teaching some questions, there is not enough depth and argumentation, it makes insignificant mistakes, which are eliminated by the applicant himself when the examiner points them out. When solving the situational problem, he assumed insignificant errors or inaccuracies in the interpretation of the initial data, answered all the questions without significant errors, fully substantiated his point of view, but the proposal of an alternative option caused difficulties.
Satisfactorily	The student of education incompletely completed all the tasks of the examination ticket, the answers to additional and leading questions are vague and vague. Possesses a basic amount of theoretical knowledge, uses professional and scientific terminology inaccurately. Experiences significant difficulties in constructing an independent logical answer, in applying theoretical knowledge in the analysis of practical tasks. There are significant errors in the answers. When solving a situational problem, he interpreted the raw data with errors, made inaccuracies in the answers to questions, did not properly justify his answers and interpreted the wording, experienced difficulties in completing tasks and proposing alternative options. When solving the calculation task, significant errors were made in the algorithm and execution technique.
Unsatisfactory	The student of education did not complete the task of the examination ticket, in most cases did not answer the additional and leading questions of the examiners. He did not master the basic amount of theoretical knowledge, he showed a low level of mastery of professional and scientific terminology. Answers to questions are fragmentary, inconsistent, illogical, cannot apply theoretical knowledge when analyzing practical tasks. There are a significant number of gross errors in the answers. When solving a situational problem, he could not interpret the original data, or made significant mistakes in his answers; could not justify his decisions or did it unconvincingly. He did not offer alternative options. When solving the calculation task, gross mistakes and errors were made in the execution algorithm.

9. Distribution of points, obtained by the student

The grade for the discipline consists of 50% of the grade for the current academic performance and 50% of the grade for the exam. The obtained average score for the academic discipline for applicants who have successfully mastered the work program of the academic discipline is converted from a traditional four-point scale to points on a 200-point scale, as shown in the table:

Table of Converting the Traditional Grades into the Multi-Point Grading Scale

National Grade	200-Point Grading Scale
Excellent ("5")	185 - 200
Good ("4")	151 - 184
Satisfactory ("3")	120-150
Unsatisfactory ("2")	Below 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in learning the educational component. The conversion of the traditional grade (average score for the academic discipline) into a 200-point grade is performed by the information and technical department of the University.

According to the obtained points on a 200-point scale, the achievements of the applicants are evaluated according to the ECTS rating scale. Further ranking according to the ECTS rating scale allows you to evaluate the achievements of students from the educational component who are studying in the same course of the same specialty, according to the points they received.

The ECTS scale is a relative-comparative rating, which establishes the applicant's belonging to the group of better or worse among the reference group of fellow students (faculty, specialty). An "A" grade on the ECTS scale cannot be equal to an "excellent" grade, a "B" grade to a "good" grade, etc. When converting from a multi-point scale, the limits of grades "A", "B", "C", "D", "E" according to the ECTS scale do not coincide with the limits of grades "5", "4", "3" according to the traditional scale. Acquirers who have received grades of "FX" and "F" ("2") are not included in the list of ranked acquirers. The grade "FX" is awarded to students who have obtained the minimum number of points for the current learning activity, but who have not passed the final examination. A grade of "F" is given to students who have attended all classes in the discipline, but have not achieved a grade point average (3.00) for the current academic activity and are not admitted to the final examination.

Applicants who study in one course (one specialty), based on the number of points scored in the discipline, are ranked on the ECTS scale as follows:

Converting the Traditional Grade and the Sum of Points on the ECTS Scale

Evaluation on the ECTS scale	Statistical indicator
A	Top 10% students
B	The next 25% students
C	The next 30% students
D	The next 25% students
E	The next 10% students

10. Methodological support

- Working program on the educational component
- Syllabus
- Methodical developments for practical classes
- Methodical recommendations for independent work of higher education applicants
- Multimedia presentations
- Situational/case tasks
- Scenarios of role-playing games (if necessary)
- Electronic bank of test tasks by subdivisions from the educational component
- Educational and methodical literature:

1. Pharmacoeconomics: education. manual for students higher education closing III-IV levels of accreditation/ L. V. Yakovleva and others; under the editorship L. V. Yakovleva. Vinnytsia: New Book, 2017. 207 p.
2. Pharmacoeconomics: study guide for students of specialty 226 "Pharmacy. Industrial pharmacy" / L.M. Unhurian, I.V. Vyshnytska, O.I. Bieliaieva. etc.; under the editorship L.M. Unhurian Odesa: ONMedU, 2020. 92 p.

11. Graded test questions

1. Evidence-based medicine: concepts, methodology, fundamental principles, basic terms of evidence-based medicine, objective reasons for the formation of the principle of evidence in the field of health care.
2. Pharmacoeconomics as a science: purpose, objectives, subject and objects of study. Pharmacoeconomics as an essential component of evidence-based medicine.
3. The current state and prospects of pharmacoeconomics in Ukraine.
4. Characteristics of the main pharmacoeconomic categories: efficacy, clinical efficacy and safety of drugs, compliance, costs, economic efficiency, utility from the standpoint of pharmacoeconomics, their value.
5. Pharmacoepidemiology as a modern applied science: purpose and tasks, practical significance.
6. Types of pharmacoepidemiological studies (prospective and retrospective, qualitative and quantitative).
7. Methods of pharmacoepidemiological research, their characteristics.
8. The concept of the prescribed daily dose of the drug (DDD). ATC/ DDD method of drug consumption analysis.

9. Safety of medicines as a pharmacoeconomic category. Criteria for safety of medical technologies.
10. The system of pharmacological supervision in Ukraine: legal framework, organizational structure, main tasks and activities. Procedure for reporting adverse drug reactions.
11. Pharmacoinformatics as a science: concept, purpose, objectives, scope. Information sources: concepts and classification.
12. Systematic reviews: definition, structure, principles of creation and use in pharmacoeconomic research.
13. Meta-analysis: concept, purpose, objectives, scope. Criteria for selection of clinical trials for meta-analysis. The value of meta-analysis results for pharmacoeconomics.
14. The concept of information database. International information databases on the proven effectiveness and safety of drug therapy, the principles of their operation. Cochrane database. Evidence-based medicine database. Bibliographic databases.
15. The use of databases in pharmacoeconomic research, in the organization of drug supply.
16. Classification of pharmacoeconomic costs.
17. Mathematical modeling: concepts, basic principles. Objects and types of modeling.
18. Stages of modeling. The practical significance of mathematical modeling in pharmacoeconomic analysis.
19. Mathematical modeling by the method of "decision analysis": the principle of the method, the stages of construction of the model "decision tree", the scope.
20. The mechanism for calculating costs using the "decision tree". Pharmacoeconomic evaluation of treatment by constructing a "decision tree" on the example of individual diseases.
21. Mathematical model of Markov: the principle of the method, scope.
22. Construction of the model "tree of Markov cycles". Pharmacoeconomic evaluation of treatment using the Markov method on the example of individual diseases.
23. General characteristics of the pharmacoeconomic method "total cost of the disease": purpose, features, methods of calculation, advantages and disadvantages of the method, scope.
24. Pharmacoeconomic evaluation of treatment by the method of "total cost of the disease".
25. General characteristics of the pharmacoeconomic method "cost minimization": purpose, conditions, features of the method, the main stages of implementation, the method of calculation, the advantages and disadvantages of the method, the scope of practical application.
26. Pharmacoeconomic analysis of drug therapy schemes and other medical technologies using the method of "cost minimization" on the example of individual diseases.
27. General characteristics of the pharmacoeconomic method "cost-effectiveness": purpose, conditions. features of the method, the main stages of the method, the method of calculations, the advantages and disadvantages of the method, the scope of practical application.
28. The concept of reference drug (or treatment regimen) when comparing medical technologies based on the results of pharmacoeconomic research. Calculation of incremental indicator (cost-effectiveness growth factor - ICER).
29. "Quality of life": definition of the concept, its components. The value of quality of life for clinical and pharmacoeconomic studies. "Quality of life" as a criterion of usefulness (utilitarianism) of medical technologies.
30. General characteristics of the pharmacoeconomic method "cost-benefit (benefit)": purpose, features of the method, the main stages of implementation, the method of calculation, the advantages and disadvantages of the method, the scope of practical application.
31. Direct, indirect and intangible benefits of medical technology. The concept of "pure" benefit and the methodology of its calculations in pharmacoeconomic research.
32. Standardization in health care: concepts, objects of standardization, types and categories of standards, stages of their creation and implementation in health care practice.
33. Formular system as a necessary component of the standardization process in medicine, the basis for optimizing the supply of medicines. The purpose and main functions of the formulary system. Form as the main element of the form system: definition, structure, stages of creation. Form manual: structure and purpose. Form committee, its composition and functions.
34. The concept of frequency, ABC and VEN analysis. Principles and stages of frequency, ABC and VEN

analysis.
35. The concept of vital and essential drugs. The list of vital and most important medicines as a document of state guarantees of quality of medical care, its structure, the order of creation, value at the present stage of development of health care system.

12. Recommended literature

Basic

1. Pharmacoeconomics: from theory to practice / edited by Renée J.G. Arnold. Description: Second edition. | Milton Park, Abingdon, Oxon; Boca Raton, FL: CRC Press, [2020]. 320 p.
2. Clinical Pharmacy Education, Practice and Research: Clinical Pharmacy, Drug Information, Pharmacovigilance, Pharmacoeconomics and Clinical Research/ edited by Dixon Thomas, Elsevier Inc. 2019. 516 p.
3. Isao Kamae. Health Technology Assessment in Japan: Policy, Pharmacoeconomic Methods and Guidelines, Value, and Beyond/ The University of Tokyo, Japan. Springer Nature Singapore Pte Ltd. 2019. 269 p.

Additional

1. Rascati KL. Essentials of Pharmacoeconomics. Philadelphia: Lippincott Williams & Wilkins; 2014. 295 p. URL: https://docplayer.net/89684649-Essentials-of-pharmacoeconomics.html
2. Methodical approaches to teaching pharmacoeconomics at the faculty of pharmacy/ Vyshnytska Iryna, Unhurian Liana, Bieliaieva Oksana, Smyrnova Olha. Scientific foundations of modern pedagogy: collective monograph / Bets I., Bets Yu., Filippov M., etc. International Science Group. Boston: Primedia eLaunch, 2020. P. 76-82 Available at: DOI: 10.46299/isg.2020.MONO.PED.II
3. Hashemi-Meshkini A, ShekoufehNikfar S, Glaser E, Jamshidi A, Hosseini SA. Cost-Effectiveness Analysis of Tocilizumabin Comparison with Infliximab in Iranian Rheumatoid Arthritis Patients with Inadequate Response to DMARDs: A Multistage Markov Model. Value in Health Regional Issues. 9C (2016), p. 42–48.
4. Mueller D, Tivey D, Croce D. Health-technology assessment: Its role in strengthening health systems in developing countries Strengthen Health Syst 2017; 2(1). P. 6–11.
5. SIAPS. 2017. Applying Principles of Pharmacoeconomics to Improve Medical Product Selection and Use in Low- and Middle-income Countries: Trainer's Guide. Submitted by the Systems for Improved Access to Pharmaceuticals and Services Program to the US Agency for International Development. 89 p.

13. Electronic resources:

1. Base of standards of medical care in Ukraine. Internet resource - http://www.moz.gov.ua/ua/portal/standards.html
2. Chootipongchaivat S. Tritasavit N, Luz A, Teerawattananon Y, Tantivess S. Policy Brief and Working Paper. Conducive Factors to the Development of Health Technology Assessment in Asia. January 2016. URL: http://www.idsihealth.org/wp- content/uploads/2016/02/CONDUCIVE-FACTORS-TO-THE-DEVELOPMENT_resize.pdf.
3. Compendium online: website. URL: https://compendium.com.ua/
4. Drug Search Base: Website. URL: https://tabletki.ua/.
5. Drug Search Base: Website. URL: http://likicontrol.com.ua/.
6. FDA. URL: Access: https://www.fda.gov
7. International Society for Pharmacoeconomic and Outcomes Research (ISPOR). URL: https://www.ispor.org/
8. Investopedia. Opportunity cost. URL: https://www.investopedia.com/terms/o/opportunitycost.asp.
9. Legislation of Ukraine: website. URL: http://zakon.rada.gov.ua/laws
10. Marseille E, Larson B, Kazi DS, Kahnj JG, Rosen S. Thresholds for the cost-effectiveness of interventions: alternative approaches. URL: http://www.who.int/bulletin/volumes/93/2/14-138206/en/.
11. Medscape Search Base: Website. URL: https://www.medscape.com/pharmacists.
12. National library of medicine. URL: https://pubmed.ncbi.nlm.nih.gov/

13. Normative-directive documents of the Ministry of Health of Ukraine: website. URL: http: // mozdocs.kiev.ua
14. Pharmacy weekly: website. URL: https://www.apteka.ua/.
15. Regulatory framework of NTA Ukraine: website. URL: https://www.hta.ua
16. State Register of Medicines of Ukraine: website. URL: http://drlz.com.ua/
17. TreeAge. URL: https://www.treeage.com/.
18. WHO. URL: https://www.who.int