

Summary to the work program of the discipline

"LEGAL BASES OF THE ACTIVITY OF THE PHARMACIST" the main educational program of training in the specialty 33.05.01 PHARMACY

1. Goals and objective mastering the discipline "Legal Basis for the Activities of a Pharmacist" (hereinafter referred to as the discipline).

1.1. The purpose of mastering the discipline: - participation in the formation

- general professional competencies GPC 3 (3.1., 3.2), GPC 6 (6.1, 6.2, 6.4)
- professional competencies PC 2 (2.3-2.4), PC 5 (5.3), PC 10 (10.1, 10.2)

1.2. Discipline tasks:

1. Obtaining by students of knowledge about the basic rights and obligations of a pharmacist.
2. The study of the basic concepts and definitions in the field of labor legislation, including labor protection
3. Formation of knowledge about the contract as the main legal form of economic activity in the field of pharmaceutical activity; in particular, the supply contract
4. The study of basic concepts and definitions in the field of forms of ownership.
5. Acquisition of skills in licensing pharmacy organizations and verification of pharmaceutical activities.
6. Obtaining skills to respect the rights of consumers of medicines and other pharmacy products in pharmacy organizations.
7. The study of the types of responsibility of a pharmaceutical worker.

1.3. Requirements for the results of mastering the discipline

As a result of mastering the discipline, the student must:

Know:

- provisions of regulatory legal acts regulating the circulation of medicines and pharmacy products
- fundamentals of the labor legislation of the Russian Federation
- measures of administrative, civil, labor and material liability for violation of legislation in the field of pharmaceutical activity
- liability measures in case of violation of the legislation of the Russian Federation in the field of pharmaceutical activity
- regulatory and social characteristics of the personnel of pharmaceutical organizations
- institutional norms in the field of pharmaceutical personnel management
- labor legislation of the Russian Federation in the field of solving operational tasks of personnel policy
- payroll procedure
- sanitary and epidemiological requirements for the operation of premises and working conditions
- requirements for reporting documentation, structure and composition of reporting documentation for personnel
- labor protection requirements,
- the procedure for concluding contracts for the supply of medicines
- procedure for concluding lease agreements
- consumer protection law
- reliable sources for searching for regulatory legal acts regulating the circulation of medicines and pharmacy products,

- modern medical and pharmaceutical information systems and databases used at the stages of circulation of medicines, including "Honest Sign", the State Information System for Labeling the Movement of Medicines (GIS MDLP), the State Register of Medicines, information systems of Roszdravnadzor and the Ministry of Health of the Russian Federation
- databases of regulatory documents
- modern medical and pharmaceutical information systems and databases used at various stages of work with pharmaceutical personnel (EGIZS portal, personal account of the FRMR portal, NMO portal, Methodological Accreditation Center portal)
- legal acts regulating the work of sites of pharmacy organizations
- rules for filling out the cash book, certificate of the cashier-operator, expenditure and receipt cash orders
- rules for drawing up and filling out shipping documents
- the procedure for the delivery of proceeds for collection
- liability procedure
- the main provisions of the civil legislation of the Russian Federation related to labor activity in a pharmacy organization and the conclusion of contracts for the supply of medicines
- provisions of regulatory legal acts regulating the procedure for licensing pharmacy organizations
- provisions of regulatory legal acts regulating the conduct of control and supervisory activities in the field of pharmaceutical activities
- provisions of regulatory legal acts regulating the creation of various forms of ownership, including individual entrepreneurs and legal entities
- liability for violation of licensing requirements for pharmacy organizations in the field of pharmaceutical activities

Be able to:

- apply the provisions of regulatory legal acts regulating the circulation of medicines and pharmacy products
- apply the basics of the labor legislation of the Russian Federation
- apply institutional norms in the field of pharmaceutical personnel management
- apply the labor legislation of the Russian Federation in the field of solving operational tasks of personnel policy
- apply payroll procedures
- apply sanitary and epidemiological requirements for the operation of premises and working conditions
- comply with the requirements for reporting documentation, the structure and composition of reporting documentation for personnel
- labor protection requirements,
- the procedure for concluding contracts for the supply of medicines
- procedure for concluding lease agreements
- apply consumer protection laws
- monitor and detect falsified and counterfeit medicines (including using the pharmacovigilance information system of the Russian Federation) and pharmacy products and isolate them from other goods during acceptance and storage
- search for information in modern medical and pharmaceutical information systems and databases used at the stages of circulation of medicines, including the State Register of Medicines, information systems of Roszdravnadzor and the Ministry of Health of the Russian Federation
- carry out work in the information system "Honest Sign", follow the necessary procedure when working with the State Information System for Labeling the Movement of Medicinal Products (GIS MDLP).

- to use, within the available limits, pharmaceutical information systems and databases used at various stages of work with pharmaceutical personnel (USIZS portal, personal account of the FRMR portal, CME portal, Methodological Accreditation Center portal)
- fill in the cash book, certificates of the cashier-operator, expenditure and receipt cash orders
- fill out shipping documents
- deposit the proceeds
- control the execution of contracts for the supply of medicines for medical use and other pharmacy products
- carry out supervisory activities over the activities of pharmacy organizations that have licenses for pharmaceutical activities
- monitor the procedure established by law in relation to the compliance of the medicinal products for medical use available in the pharmacy organization with instructions and data on its safety and effectiveness

Own:

- planning the need for a pharmaceutical organization in workers
- admission, evaluation and certification of personnel of a pharmaceutical organization
- organization of training and certification of personnel of a pharmaceutical organization
- formation of a system of incentives for employees
- organization of a special assessment of working conditions
- measures for the organization of labor protection of pharmaceutical personnel
- measures to organize medical examinations of pharmaceutical personnel
- labor actions to find falsified and counterfeit medicines (including using the pharmacovigilance information system of the Russian Federation) and isolate them
- using modern medical and pharmaceutical information systems and databases, including the State Register of Medicines, information systems of Roszdravnadzor and the Ministry of Health of the Russian Federation
- use in the work the information system "Honest Sign", the State Information System for Labeling the Movement of Medicines (GIS MDLP)
- skills to use within the available limits pharmaceutical information systems and databases used at various stages of work with pharmaceutical personnel (USISS portal, personal account of the FRMR portal, CME portal, Methodological Accreditation Center portal)
- office work for maintaining cash, organizational and administrative, reporting documents for retail sales
- office work for maintaining organizational, administrative, payment reporting documents for retail sales
- rules for drawing up and concluding contracts for the supply of medicines for medical use and other pharmacy products
- procedure for licensing pharmacy organizations
- the procedure for controlling the pharmaceutical activities of pharmacy organizations
- the skills of monitoring, analyzing and evaluating the results of their own activities, the activities of colleagues and other health workers to prevent professional errors
- supplier auditing skills
- negotiation skills with suppliers

2. Volume of discipline and types of educational work

Type of study work	Labor intensity		Labor input by semesters (ACh)
	volume in credit units (CU)	volume in academic hours (AH)	
			9
classroom work, including	1.22	44	44
Lectures (L)	0.28	10	10
Laboratory workshops (LW)	not provided		
Practical exercises (PE)	0.94	34	34
Seminars (S)	not provided		
Independent work of the student (IWS)	0.78	28	28
Intermediate certification: exam	1	36	36
TOTAL LABOR CAPACITY	3	108	108

3. The content of the discipline

<i>N o.</i>	<i>Section name</i>	<i>Section content</i>
1.	Pharmaceutical worker in regulations	<p>Pharmaceutical worker in regulations</p> <ul style="list-style-type: none"> ▪ Hierarchy of regulatory legal acts (hereinafter referred to as NLA). Constitution, laws, codes, decrees, resolutions and orders, orders. Entry into force and expiration of NLAs (give examples from NLAs regulating pharmaceutical activities) ▪ Rights and obligations of a pharmaceutical worker in accordance with the Federal Law "On the fundamentals of protecting the health of citizens" ▪ Positions of pharmaceutical workers. Pharmaceutical workers with secondary education in the specialty "Pharmacy". Specialized specialties of pharmacists. ▪ Licensing requirements for pharmaceutical workers (owners of pharmacy organizations - legal entities, owners of pharmacy organizations - individual entrepreneurs, heads of pharmacies, ordinary pharmaceutical specialists). ▪ Raising the qualifications of pharmaceutical workers. Requirements of normative documents. Accreditation procedure. <p>Normative status of a professional standard. Professional standards "Pharmacist" and "Pharmacist". Other pharmaceutical professional standards</p>
2.	The procedure for registration of labor relations with a pharmaceutical worker. Procedures for evaluating pharmaceutical workers.	<p>The procedure for registration of labor relations with a pharmaceutical worker:</p> <ul style="list-style-type: none"> ▪ Features and problems of the labor market in the field of pharmaceutical activity. ▪ The procedure for hiring. Making a personal file. Terms of storage of personnel documents. Entering into the accounting system of pharmaceutical workers.

		<ul style="list-style-type: none"> ▪ Regulations on the personal data protection of an employee. ▪ Labor contracts. Employment contract. Content and types of employment contracts. The need to conclude an employment contract with employees of pharmacy organizations (licensing requirement). The difference between labor and civil law contracts. <p>Pharmaceutical worker assessment procedures</p> <ul style="list-style-type: none"> ▪ Certification of an employee for compliance with the position held ▪ Certification for the assignment of qualification categories <p>Accreditation of pharmaceutical workers. Unified accounting system for pharmaceutical workers.</p>
3.	Labor rights and obligations. Occupational Safety and Health. Special assessment of the working conditions of pharmaceutical workers.	<p>Labor rights and obligations</p> <ul style="list-style-type: none"> ▪ Changing the terms of the employment contract determined by the parties. Translation, movement. Combination and concurrency. ▪ Job test. ▪ Working hours and rest time. Regulation of labor of certain categories of workers. Protection of labor rights. ▪ Termination of TD. General provisions. ▪ Staff schedule. Payroll and staffing. ▪ Providing pharmaceutical specialists with personal protective equipment <p>Occupational Safety and Health. Special assessment of the working conditions of pharmaceutical workers.</p> <ul style="list-style-type: none"> ▪ Organization of labor protection in a pharmacy organization. Labor protection training. Briefings. ▪ Carrying out a special assessment of working conditions <p>Investigation and registration of accidents at work.</p>
4.	The contract as the main legal form of economic activity in the field of pharmaceutical activity. Supply contract	<p>The contract as the main legal form of economic activity in the field of pharmaceutical activity. Delivery contract.</p> <ul style="list-style-type: none"> ▪ The concept of a supply contract in the Civil Code of the Russian Federation ▪ Unified form of the supply contract. Basic details. <p>Mandatory content of the supply contract. Essential terms of the supply contract.</p>
5.	Legal entities and individual entrepreneurs. Licensing and verification of pharmacy organizations.	<p>Legal entities and individual entrepreneurs.</p> <ul style="list-style-type: none"> ▪ Legal status of YL. Creation of a legal entity. ▪ Reorganization of the legal entity. Liquidation of YL. ▪ Legal status of an individual entrepreneur Creation of IP. Termination of IP activity. ▪ Differences in the activities of legal entities and individual entrepreneurs in the pharmaceutical market. Individual entrepreneurs, legal entities and types of pharmaceutical activities, types of pharmacy organizations

		<p>Licensing of pharmaceutical organizations.</p> <ul style="list-style-type: none"> ▪ Submission of documents, the order of the procedure. Licensing authorities. The decision of the licensing authority. License renewal and other procedures. ▪ Checking the activities of individual entrepreneurs and legal entities. Risky approach when checking the activities of pharmacy organizations. <p>Rights to the results of intellectual activity and means of individualization: general provisions.</p>
6.	A pharmaceutical worker as a person who ensures the observance of the rights of consumers of medicines and other pharmacy products.	<p>A pharmaceutical worker as a person who ensures the observance of the rights of consumers of medicines and other pharmacy products.</p> <ul style="list-style-type: none"> ▪ Rights of consumers of medicines and other pharmacy products. The main categories of consumer rights in the Russian Federation. Legal status of a pharmacy visitor: buyer, consumer, patient? ▪ The right of the buyer to information is the implementation of this right in the process of consulting. ▪ The right of the buyer to information is the realization of this right in the design of the trading floor. Price tag rules. Signage rules. Information about the pharmaceutical organization. Feedback from the consumer. <p>The right of the buyer to a quality product. Rules for returning goods in case of obvious and hidden defects. Return of medicines and other pharmacy products.</p>
7.	Types of responsibility of a pharmaceutical worker	<p>Types of responsibility of a pharmaceutical worker</p> <ul style="list-style-type: none"> ▪ Disciplinary responsibility of a pharmaceutical specialist. ▪ Liability of a pharmaceutical specialist. Preparation of cash documents. ▪ Criminal liability of a pharmaceutical specialist. <p>Administrative responsibility of a pharmaceutical specialist. Basic articles.</p>