Federal State Budgetary Educational Institution of Higher Education
"Privolzhsky Research Medical University"
Ministry of Health of the Russian Federation

BANK OF ASSESSMENT TOOLS FOR DISCIPLINE

LEGAL ASPECTS OF ORGANIZATION OF PHARMACEUTICAL ACTIVITIES (ADDITIONAL DISCIPLINE)

Training program (specialty): **33.05.01 PHARMACY**

Department: **MANAGEMENT AND ECONOMICS OF PHARMACY AND PHARMACEUTICAL TECHNOLOGY**

Mode of study: **FULL-TIME**

Nizhny Novgorod
2021

1. Bank of assessment tools for the current monitoring of academic performance, mid-term assessment of students in the discipline

This Bank of Assessment Tools (BAT) for the discipline "Legal aspects of organization of pharmaceutical activities (additional discipline)" is an integral appendix to the working program of the discipline "Legal aspects of organization of pharmaceutical activities (additional discipline)". All the details of the approval submitted in the WPD for this discipline apply to this BAT.

2. List of assessment tools

The following assessment tools are used to determine the quality of mastering the academic material by students in the discipline:

No.	Assessment tool	Brief description of the assessment tool	Presentation of the assessment tool in the BAT
1	Test	A system of standardized tasks that allows you to automate the procedure of measuring the level of knowledge and skills of a student	Bank of test tasks
2	Case-task	A problem task in which the student is offered to comprehend a real professionally-oriented situation necessary to solve this problem.	Tasks for solving cases
3	Colloquium	A tool of controlling the mastering of study materials of a topic, section or sections of a discipline, organized as a class in the form of an interview between a teacher and students.	Questions on topics/sections of the discipline

3. A list of competencies indicating the stages of their formation in the process of mastering the educational program and the types of evaluation tools

Code and formulation of competence	Stage of competence formation	Controlled sections of the discipline	Assessment tools
PC-10 Able to carry out measures to control (supervise) the activities of legal entities and individuals licensed for pharmaceutical activities, to comply with mandatory requirements	Entry, Current, Mid-term	**Section 1.** Legal aspects of organization of pharmaceutical activities	Tests Case-tasks Colloquiums

4. The content of the assessment tools of entry, current control

Entry /current control is carried out by the discipline teacher when conducting classes in the form of: test control, organization of a discussion, colloquium.

Assessment tools for current control.

4.1. Bank of test tasks

Choose one correct answer:

№	Test tasks with multiple answers	The code of the competence for the formation of which the test task is aimed
1.	FOR VIOLATION OF THE RULES OF SALE, A PHARMACY ORGANIZATION MAY BE HELD LIABLE Administrative Criminal Disciplinary Material	PC-10
2.	FOR VIOLATION OF LICENSING REQUIREMENTS, A PHARMACY ORGANIZATION MAY BE HELD LIABLE Administrative Criminal Disciplinary Material	PC-10
3.	THE STATE SUPERVISION BODY THAT MONITORS COMPLIANCE WITH THE LEGISLATION ON THE CIRCULATION OF MEDICINES FOR MEDICAL USE IS Roszdravnadzor Ministry of Health of the Russian Federation Rospotrebnadzor Moa	PC-10
4.	THE STATE SUPERVISION BODY THAT CARRIES OUT INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN ORGANIZATIONS ENGAGED IN THE WHOLESALE TRADE OF DRUGS FOR MP IS Roszdravnadzor Ministry of Health of the Russian Federation Rospotrebnadzor Moa	PC-10
5.	IN ACCORDANCE WITH THE FEDERAL LAW OF 26.12.2008 NO. 294-FZ "ON THE PROTECTION OF THE RIGHTS OF LEGAL ENTITIES AND INDIVIDUAL ENTREPRENEURS IN THE IMPLEMENTATION OF STATE CONTROL AND MUNICIPAL CONTROL", THE TYPES OF INSPECTIONS DO NOT INCLUDE: Target	PC-10

	Planned Cameral Documentary	
6.	SCHEDULED INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN PHARMACY ORGANIZATIONS ARE CARRIED OUT no more than 1 time per year no more than 1 time in 2 years at intervals established by the relevant licensing authority no more than 1 time in 3 years	PC-10
7.	SCHEDULED INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN DRUG WHOLESALERS ARE CARRIED OUT no more than 1 time in 2 years no more than 1 time per year at intervals established by the relevant licensing authority no more than 1 time in 3 years	PC-10
8.	ON THE CONDUCT OF A SCHEDULED INSPECTION OF LEGAL ENTITIES, INDIVIDUAL ENTREPRENEURS ARE NOTIFIED BY THE STATE SUPERVISION BODY BEFORE THE START OF ITS CONDUCT NO LATER THAN 3 working days 2 working days 2 calendar days 3 calendar days	PC-10
9.	WHEN CONDUCTING A SCHEDULED ON-SITE INSPECTION, EMPLOYEES OF THE STATE SUPERVISION BODY DO NOT CHECK measures taken by a legal entity or individual entrepreneur to prevent harm to life, health of citizens, harm to animals, plants, the environment, etc. information contained in the documents of a legal entity, individual Entrepreneur; compliance of employees, premises and equipment with the established Requirements Manufactured and sold goods	PC-10
10.	LIABILITY IS PROVIDED FOR VIOLATION OF THE LEGISLATION ON THE CIRCULATION OF MEDICINES Administrative Criminal Material Civil	PC-10
11.	THE VALIDITY PERIOD OF THE REGISTRATION CERTIFICATE FOR A MEDICINAL PRODUCT REGISTERED FOR THE FIRST TIME IN RUSSIA IS (YEARS) 5 7	PC-10

	10 15	
12.	THE VALIDITY PERIOD OF THE REGISTRATION CERTIFICATE FOR THE DRUG AFTER CONFIRMATION OF ITS STATE REGISTRATION IS Indefinite period 5 years 10 years 15 years	PC-10
13.	MEDICINAL PRODUCTS ARE NOT SUBJECT TO STATE REGISTRATION manufactured by pharmacy organizations according to doctors' prescriptions and the requirements of medical organizations Original Reproduced New combinations of previously registered medicines	PC-10
14.	ARE NOT SUBJECT TO STATE REGISTRATION Extemporal drugs Generic drugs Original medicines New combinations of previously registered medicines	PC-10
15.	ACCORDING TO THE LEGISLATION OF THE RUSSIAN FEDERATION, THE CIRCULATION OF MEDICINES DOES NOT INCLUDE: Drug Distribution development, preclinical studies, clinical trials, expertise, state registration, standardization and quality control production, manufacture, storage transportation, import into the territory of the Russian Federation, export from the territory of the Russian Federation, advertising	PC-10
16.	STATE REGISTRATION OF MEDICINES, MAINTENANCE OF THE STATE REGISTER OF MEDICINES ARE WITHIN THE POWERS OF Ministry of Health of the Russian Federation Roszdravnadzor Rospotrebnadzor Drug manufacturing organizations	PC-10
17.	THE STATE SUPERVISION BODY THAT VERIFIES COMPLIANCE WITH LICENSING REQUIREMENTS WHEN CARRYING OUT PHARMACEUTICAL ACTIVITIES IN RETAIL PHARMACEUTICAL ORGANIZATIONS OF PRIVATE OWNERSHIP IS Licensing Authority Ministry of Health of the Russian Federation Roszdravnadzor Rospotrebnadzor	PC-10
18.	THE STATE SUPERVISION BODY, WHICH VERIFIES COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN RETAIL PHARMACEUTICAL ORGANIZATIONS OF MUNICIPAL OWNERSHIP, IS	PC-10

	Licensing Authority Ministry of Health of the Russian Federation Roszdravnadzor Rospotrebnadzor	
19.	THE STATE SUPERVISION BODY THAT VERIFIES COMPLIANCE WITH LICENSING REQUIREMENTS WHEN CARRYING OUT PHARMACEUTICAL ACTIVITIES IN RETAIL PHARMACEUTICAL ORGANIZATIONS SUBORDINATE TO THE EXECUTIVE AUTHORITIES OF THE CONSTITUENT ENTITIES OF THE RUSSIAN FEDERATION IS Licensing Authority Ministry of Health of the Russian Federation Roszdravnadzor Rospotrebnadzor	PC-10
20.	THE STATE SUPERVISION BODY THAT VERIFIES COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN RETAIL PHARMACEUTICAL ORGANIZATIONS SUBORDINATE TO FEDERAL EXECUTIVE BODIES IS Roszdravnadzor Ministry of Health of the Russian Federation Rosselkhoznadzor Rospotrebnadzor	PC-10
21.	THE STATE SUPERVISION BODY THAT VERIFIES COMPLIANCE WITH SANITARY AND EPIDEMIOLOGICAL REQUIREMENTS IN PHARMACEUTICAL ORGANIZATIONS IS Rospotrebnadzor Ministry of Health of the Russian Federation Roszdravnadzor Licensing Authority	PC-10
22.	THE LIST OF ACTIVITIES SUBJECT TO LICENSING SHALL BE APPROVED Federal Law Decree of the Government of the Russian Federation by order of the federal executive body normative legal act of the subject of the Russian Federation	PC-10
23.	99-FZ "ON LICENSING OF CERTAIN TYPES OF ACTIVITIES" LICENSING REQUIREMENTS ARE DEFINED AS A SET OF REQUIREMENTS established by the provisions on licensing of specific types of activities, based on the relevant requirements of the legislation of the Russian Federation and aimed at ensuring the achievement of licensing goals established by regulatory legal acts, and the implementation of which by the licensee is mandatory when carrying out the licensed type of activity corresponding to the norms and rules in the field of circulation of drugs and medical devices established by the Ministry of Health of Russia for premises, equipment, personnel of pharmaceutical organizations and circulation of drugs	PC-10
24.	LICENSING OF PHARMACEUTICAL ACTIVITIES, WITH THE EXCEPTION OF ACTIVITIES CARRIED OUT BY ORGANIZATIONS	PC-10

	OF WHOLESALE TRADE OF DRUGS INTENDED FOR MEDICAL USE, AND PHARMACY ORGANIZATIONS SUBORDINATE TO FEDERAL EXECUTIVE BODIES, STATE ACADEMIES OF SCIENCES, AS WELL AS ACTIVITIES CARRIED OUT BY ORGANIZATIONS IN THE FIELD OF CIRCULATION OF DRUGS INTENDED FOR ANIMALS, CARRIES OUT executive authority of the constituent entity of the Russian Federation Federal Service for Surveillance in Healthcare Federal Service for Veterinary and Phytosanitary Surveillance local self-government body	
25.	LICENSING OF PHARMACEUTICAL ACTIVITIES IN TERMS OF ACTIVITIES CARRIED OUT BY ORGANIZATIONS OF WHOLESALE TRADE OF DRUGS INTENDED FOR MEDICAL USE, AND PHARMACY ORGANIZATIONS SUBORDINATE TO FEDERAL EXECUTIVE BODIES, STATE ACADEMIES OF SCIENCES CARRIES OUT Federal Service for Surveillance in Healthcare Federal Service for Veterinary and Phytosanitary Surveillance executive authority of the constituent entity of the Russian Federation local self-government body	PC-10
26.	ACCORDING TO THE CURRENT "RULES FOR THE SALE OF CERTAIN TYPES OF GOODS ..." THE BUYER MEANS: a citizen who intends to order or purchase, or who orders, acquires or uses goods exclusively for personal, family, household and other needs not related to entrepreneurial activity an organization, regardless of its organizational and legal form, that buys goods for business activities an individual entrepreneur who purchases goods for business activities. a pharmacy organization that purchases goods for sale to the public	PC-10
27.	THE LIST OF GOODS ALLOWED FOR SALE THROUGH PHARMACY ORGANIZATIONS IS ESTABLISHED Federal Law No. 61-FZ "On the Circulation of Medicines" (Article 55) by order of the Ministry of Health and Social Development of the Russian Federation N 553n of 27.07. 2010 year Decree of the Government of the Russian Federation No. 55 of 19.01.1998 Order of the Ministry of Health of the Russian Federation No. 403n of 11.07. 2017 year	PC-10
28.	A SPECIAL PERMIT TO CARRY OUT A SPECIFIC TYPE OF ACTIVITY, SUBJECT TO MANDATORY COMPLIANCE WITH LICENSING REQUIREMENTS, ISSUED BY THE LICENSING AUTHORITY TO A LEGAL ENTITY OR INDIVIDUAL ENTREPRENEUR IS License Certificate of accreditation Certificate Patent	PC-10
29.	THE PHARMACEUTICAL MARKET IS DEFINED AS: a set of existing and potential consumers of medicines, medical devices, services A type of human activity aimed at satisfying needs and requirements	PC-10

	through exchange An effective way to meet the needs of needs Method of formation of the pricing system	
30.	TO OBTAIN A SANITARY-EPIDEMIOLOGICAL CONCLUSION IN A PHARMACY ORGANIZATION, IT IS NOT REQUIRED conclusion of an agreement with a medical organization to conduct a medical examination of employees development of a program of production control over compliance with sanitary rules and the implementation of sanitary and anti-epidemiological measures ensuring that staff have personal medical records and sanitary clothing ensuring the availability of premises and equipment that meet sanitary norms and rules	PC-10
31.	IN ACCORDANCE WITH THE LAW OF THE RUSSIAN FEDERATION "ON PROTECTION OF CONSUMER RIGHTS", THE CONSUMER IS a citizen who intends to order or purchase goods (works, services) exclusively for personal, family, household and other needs a citizen intending to order or purchase goods (works, services) for business purposes a legal entity intending to order or purchase goods (works, services) exclusively for personal, family, household and other needs Those who use the product for its intended purpose	PC-10
32.	THE LAW "ON PROTECTION OF CONSUMER RIGHTS" REGULATES THE RELATIONS ARISING BETWEEN consumers and sellers consumers and manufacturers consumers and suppliers pharmacy staff	PC-10
33.	IN ACCORDANCE WITH THE LAW OF THE RUSSIAN FEDERATION "ON PROTECTION OF CONSUMER RIGHTS", THE SALE OF GOODS is possible if the product can be used before the expiration date Possible before the expiration date is not possible if less than 1/2 of the expiration date is left before the expiration date It is possible if, after the expiration date, the consumer properties of the goods are preserved	PC-10
34.	THE MANUFACTURER IS OBLIGED TO ENSURE THE SAFETY OF THE GOODS DURING the specified service life or shelf life of the goods or within 10 years after handing over to the consumer, if the service life is not established a period of at least 10 years from the date of manufacture the period established by the contract shelf life of the goods	PC-10
35.	FOR GOODS INTENDED FOR LONG-TERM USE, THE MANUFACTURER HAS THE RIGHT TO SET A PERIOD Service Acceptance of claims	PC-10

	Suitability Useful use	
36.	THE RULES FOR THE SALE OF CERTAIN TYPES OF GOODS HAVE BEEN APPROVED Decree of the Government of the Russian Federation No. 55 of 19.01.1998 Federal Law No. 61-FZ of 12.04.2010 Law of the Russian Federation No. 2300-1 of 07.02.1992 Federal Law No. 99-FZ of 04.05.2011	PC-10
37.	IN ACCORDANCE WITH THE RULES FOR THE SALE OF CERTAIN TYPES OF GOODS, MEDICINES OF GOOD QUALITY non-refundable and non-exchangeable Subject to exchange are subject to return to the manufacturer are subject to additional analysis	PC-10
38.	ACCORDING TO THE ESTABLISHED "RULES FOR THE SALE OF CERTAIN TYPES OF GOODS ..." PRE-SALE PREPARATION OF MEDICINES AND MEDICAL DEVICES DOES NOT INCLUDE: Qualitative and quantitative chemical analysis Unpacking checking the quality of goods (by external signs) checking the availability of the necessary information about the product and its manufacturer (supplier)	PC-10
39.	THE BUYER IS NOT ENTITLED TO MAKE CLAIMS FOR DEFECTS IN THE GOODS if the product does not have an expiration date or warranty period, after two years from the date of transfer of the goods to the buyer in the presence of a cash or sales receipt, or other document certifying the purchase in the presence of witness testimony, without the obligation to present documents certifying the purchase If the goods do not have an expiration date, or a warranty period, then within two years from the date of transfer of the goods to the buyer	PC-10
40.	MEDICAL DEVICES PURCHASED AT A PHARMACY ARE SUBJECT TO RETURN OR EXCHANGE, PROVIDED THAT: malfunctions of the device during the warranty period At the request of the buyer within two weeks from the date of purchase within the period set by the seller	PC-10
41.	THE MINIMUM SET OF PREMISES THAT IT IS ADVISABLE TO HAVE TO OPEN A PHARMACY OF FINISHED DOSAGE FORMS DOES NOT INCLUDE Assistant Sales Area Unpacking or isolated area for unpacking goods premises for staff (staff room, manager's office, bathroom, dressing room)	PC-10
42.	THE EQUIPMENT OF THE TRADING FLOOR OF A PHARMACY ORGANIZATION DOES NOT INCLUDE Sanitary clothing storage cabinet a showcase for displaying drugs and other goods allowed for release from	PC-10

	pharmacy organizations, a refrigerated display case or refrigerators for storing thermolabile drugs cabinets for storing drugs and other goods allowed for release from pharmacy organizations cash registers or sales registrar	
43.	IN THE EVENT OF A TEMPORARY SUSPENSION OF ITS ACTIVITIES (FOR SCHEDULED SANITARY DAYS, REPAIRS AND IN OTHER CASES), THE PHARMACY ORGANIZATION IS OBLIGED TO PROVIDE INFORMATION timely information on the date and timing of the suspension of activities timely on the date of suspension of activities timely on the timing of the suspension of activities for a week on the timing of the suspension of activities	PC-10
44.	ACCORDING TO THE REQUIREMENTS OF THE SANITARY REGIME, THE SURFACES OF THE WALLS AND CEILINGS OF THE PRODUCTION PREMISES OF THE PHARMACY MUST BE: allowing wet cleaning with the use of disinfectants, smooth, without violating the integrity of the coating allowing wet cleaning without disinfectants, smooth, without violating the integrity of the coating painted with water-based paint treated with antiseptic and fire-fighting agents	PC-10
45.	THE INSTRUCTION ON THE SANITARY REGIME OF PHARMACY ORGANIZATIONS DOES NOT IMPOSE SANITARY REQUIREMENTS ON bacteriological quality control pharmaceutical staff of pharmacies receiving, transporting and storing purified water and water for injection premises and equipment of pharmacies	PC-10
46.	CONTROL OVER COMPLIANCE BY THE PHARMACY ORGANIZATION WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF ACTIVITIES FOR THE CIRCULATION OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES IS CARRIED OUT on the basis of the order of the head of the licensing body without the order of the head of the licensing body on the basis of the order of the heads of bodies for control over the circulation of narcotic drugs and psychotropic substances without the order of the heads of bodies for control over the circulation of narcotic drugs and psychotropic substances	PC-10
47.	PERSONS ARE ALLOWED TO WORK WITH NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES recognized in accordance with the established procedure as suitable for the performance of work related to the circulation of narcotic drugs and psychotropic substances under the age of 18 having an outstanding or unexpunged conviction for a crime of medium gravity, a serious crime, a particularly serious crime patients with drug addiction, substance abuse and chronic alcoholism	PC-10
48.	THE MAIN TASK OF THE PHARMACY OF A MEDICAL	PC-10

	ORGANIZATION IS provision of departments of a medical organization with medicines and medical devices Making a profit provision of outpatients with medicines providing patients with information on responsible self-medication	
49.	THE EQUIPMENT OF INDUSTRIAL PREMISES AND TRADING FLOORS OF PHARMACIES IS CLEANED daily weekly at least twice a week at least twice a decade	PC-10
50.	ACCORDING TO THE REQUIREMENTS OF THE SANITARY REGIME IN THE PHARMACY ORGANIZATION, THE CHANGE OF TOWELS FOR PERSONAL USE SHOULD BE CARRIED OUT daily 2 times a week 1 time per week 1 time in 2 days	PC-10
51.	TERMS OF MEDICAL EXAMINATION OF A PHARMACIST-TECHNOLOGIST AND PHARMACIST AT LEAST ONCE A (MONTH) 6 18 12 24	PC-10
52.	THE MODE OF OPERATION OF THE PHARMACY ORGANIZATION OF AN INDIVIDUAL ENTREPRENEUR IS ESTABLISHED independently executive authority of the constituent entity of the Russian Federation local self-government body independently in agreement with the licensing authority	PC-10
53.	MEDICINES OF GOOD QUALITY PURCHASED BY CITIZENS non-refundable or non-exchangeable Subject to return and exchange within 14 days are subject to return and exchange within a day Subject to return and exchange within 3 days	PC-10
54.	THE EXCHANGE OF A NON-FOOD PRODUCT OF GOOD QUALITY IS NOT CARRIED OUT IF: The specified product was in use Its presentation and consumer properties have been preserved There is a sales receipt or cash receipt It is possible to refer to witness testimony	PC-10
55.	ON THE SIGN OF THE PHARMACY ORGANIZATION, A MANDATORY INDICATION IS NOT REQUIRED addresses and phone numbers of nearby and on-call pharmacies type of organization location (in accordance with the constituent documents) of the organization	PC-10

	Mode of operation	
56.	AN ORGANIZATION ENGAGED IN WHOLESALE TRADE IN MEDICINES IN ACCORDANCE WITH THE REQUIREMENTS OF THE FEDERAL LAW "ON THE CIRCULATION OF MEDICINES" IS organization of wholesale trade in medicines Pharmacy medical organization pharmacy kiosk	PC-10
57.	THE FEDERAL LAW "ON THE CIRCULATION OF MEDICINES" DEFINES THE ORGANIZATION OF WHOLESALE TRADE IN MEDICINES AS AN ORGANIZATION THAT CARRIES OUT wholesale trade in medicines, their storage, transportation supply of medicines to medical and pharmacy organizations dispensing of medicines to the population and medical organizations production of medicines, their storage, transportation	PC-10
58.	THE FEDERAL LAW "ON THE CIRCULATION OF MEDICINES" DEFINES A PHARMACY ORGANIZATION AS AN ORGANIZATION or a structural subdivision of a medical organization engaged in retail trade in medicines, storage, manufacture and dispensing of medicines for medical use carrying out wholesale trade in medicines, their storage, transportation supplying medicines to medical and pharmacy organizations dispensing medicines to the population and medical organizations	PC-10
59.	ACCORDING TO 323-FZ "ON THE BASICS OF PROTECTING THE HEALTH OF CITIZENS IN THE RUSSIAN FEDERATION", PHARMACEUTICAL ORGANIZATIONS INCLUDE: pharmacy organizations, drug wholesalers drug quality control centers Pharmaceutical Information Centers Control and analytical laboratories	PC-10
60.	THE RULES OF WHOLESALE TRADE IN MEDICINES FOR MEDICAL USE ARE REGULATED BY THE ORDER OF THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION and SR RF No. 1222n of 2010. No 110 2007 No 706n of 2010 No 318 1997	PC-10
61.	THE FEDERAL LAW "ON THE CIRCULATION OF MEDICINES" DOES NOT INCLUDE IN THE LIST OF ORGANIZATIONS ENTITLED TO CARRY OUT PHARMACEUTICAL ACTIVITIES drug quality control centers organization of wholesale trade of medicines pharmacy organizations, veterinary pharmacy organizations individual entrepreneurs who have a license for pharmaceutical activities	PC-10
62.	DRUG WHOLESALERS CANNOT SELL DRUGS OR TRANSFER THEM IN ACCORDANCE WITH THE PROCEDURE ESTABLISHED BY THE LEGISLATION OF THE RUSSIAN FEDERATION individuals for personal, family, home use organizations of wholesale trade of medicines, manufacturers of drugs for	PC-10

	the production of drugs pharmacy organizations, veterinary pharmacy organizations, medical organizations research organizations for research work	
63.	ACCORDING TO ART. 56 OF THE FEDERAL LAW 61-FZ "ON THE CIRCULATION OF MEDICINES" DO NOT HAVE THE RIGHT TO MANUFACTURE MEDICINES medical organizations licensed for pharmaceutical activities, and their separate divisions located in rural settlements in which there are no pharmacy organizations pharmacy organizations licensed to carry out pharmaceutical activities individual entrepreneurs who have a license for pharmaceutical activities Veterinary pharmacy organizations	PC-10
64.	PHARMACEUTICAL ACTIVITIES ARE NOT CARRIED OUT BY ORGANIZATIONS Manufacturers of medicines wholesale trade in medicines pharmacies, individual entrepreneurs medical and their structural subdivisions located in rural areas settlements in which there are no pharmacy organizations	PC-10
65.	ACCORDING TO THE REGULATION ON LICENSING OF PHARMACEUTICAL ACTIVITIES, PHARMACEUTICAL ACTIVITIES DO NOT INCLUDE THE FOLLOWING WORKS AND SERVICES IN THE FIELD OF DRUG CIRCULATION FOR MEDICAL USE: Distribution of medicines Wholesale of medicines for medical use Transportation of medicines (medicinal products for medical use retail, release, manufacture of medicines for medical use	PC-10
66.	THE LICENSING REQUIREMENTS THAT A LICENSE APPLICANT (INDIVIDUAL ENTREPRENEUR) MUST MEET IN ORDER TO CARRY OUT PHARMACEUTICAL ACTIVITIES IN THE FIELD OF DRUG CIRCULATION FOR MEDICAL USE DO NOT INCLUDE THE PRESENCE OF qualification category necessary premises and equipment that meet the established requirements higher pharmaceutical education, work experience in the specialty for at least 3 years Specialist Certificate	PC-10
67.	WHEN A PHARMACY INTERACTS WITH A PHARMACY BELONGING TO IT, THE PHARMACY DOES NOT A consignment note is issued A cash receipt order is issued; Quality documents are provided Revenue is accepted for the goods sold	PC-10
68.	THE CONSIGNMENT NOTE IS ISSUED in Russian language, has the seal of the supplier, the signature of the responsible person in Latin, has the seal of the supplier, the signature of the responsible person	PC-10

	in Russian language, has the seal of the manufacturer of the goods, the signature of the responsible person in Russian language, has the seal of the supplier, the seal of the manufacturer of the goods, the signature of the responsible person	
69.	PERSONS RESPONSIBLE FOR THE RECEIPT, STORAGE, SALE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ARE APPOINTED by order of the director of the pharmacy organization by order of the head of the department of narcotic drugs and psychotropic substances Roszdravnadzor by the licensing authority	PC-10
70.	THE COMMODITY NOMENCLATURE OF A PHARMACY ORGANIZATION IS UNDERSTOOD AS a set of assortment groups; commodity units Anything that is offered to the market for the purpose of use or consumption groups of goods related to each other by similarity all medicines and medical devices in the showcase on the trading floor	PC-10
71.	FOR INFORMATION ABOUT MEDICINES AND OTHER GOODS ALLOWED FOR RELEASE FROM PHARMACY ORGANIZATIONS, SHOWCASES OF VARIOUS TYPES CAN BE USED, WHERE THEY ARE EXHIBITED Over-the-counter medications Prescription medications Medicines that require protection from the effects of light Pharmaceutical substances	PC-10
72.	THE GOODS OF THE PHARMACY ASSORTMENT INCLUDE MEDICINES AND medical devices Food Household chemicals Organic solvents	PC-10
73.	THE MAIN TASK OF THE PHARMACY OF A MEDICAL ORGANIZATION IS provision of departments of a medical organization with medicines and medical devices Making a profit provision of outpatients with medicines providing patients with information on responsible self-medication	PC-10
74.	THERE IS NO MEDICAL ORGANIZATION IN THE PHARMACY Sales Area Material room Assistant Washing	PC-10
75.	PROPERTY, THE SUBJECT OF WHICH IS AN INDIVIDUAL OR LEGAL ENTITY, IS CALLED Private	PC-10

	Municipal State Mixed	
76.	RETAIL TRADE IN MEDICINES CANNOT BE CARRIED OUT pharmacies of a medical organization Pharmacy organizations individual entrepreneurs who have a license for pharmaceutical activities medical organizations licensed for pharmaceutical activities, and their separate divisions (outpatient clinics, FAPs, etc.) located in rural settlements in which there are no pharmacy organizations	PC-10
77.	AN ORGANIZATION, A STRUCTURAL SUBDIVISION OF A MEDICAL ORGANIZATION ENGAGED IN RETAIL TRADE IN MEDICINES, STORAGE, MANUFACTURE AND DISPENSING OF MEDICINES FOR MEDICAL USE IS pharmacy organization pharmacy warehouse pharmacy kiosk pharmacy	PC-10
78.	PHARMACY ORGANIZATIONS DO NOT INCLUDE: Pharmacy warehouses Pharmacies serving the public Pharmacies Pharmacy kiosks	PC-10
79.	THE TYPES OF PHARMACIES APPROVED BY THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION DO NOT INCLUDE A PHARMACY inter-hospital finished dosage forms Production production with the right to manufacture aseptic medicines	PC-10
80.	THE MANUFACTURE OF MEDICINES FOR MEDICAL USE BY PHARMACY ORGANIZATIONS IS CARRIED OUT ACCORDING TO prescriptions for drugs, according to the requirements of medical organizations prescriptions for veterinary drugs requirements of veterinary organizations the request of the visitor to the pharmacy on the basis of the bottle with the label presented to him previously used drugs manufactured in a pharmacy;	PC-10
81.	THE NOMENCLATURE OF PHARMACEUTICAL SPECIALTIES FOR PERSONS WITH HIGHER PHARMACEUTICAL EDUCATION DOES NOT INCLUDE Clinical Pharmacy Management and Economics of Pharmacy pharmaceutical technology pharmaceutical chemistry and pharmacognosy	PC-10
82.	THE POSITIONS APPROVED FOR PHARMACEUTICAL WORKERS WITH HIGHER PHARMACEUTICAL EDUCATION DO NOT	PC-10

	INCLUDE pharmacist pharmacist, pharmacist-trainee Senior Pharmacist pharmacist-analyst	
83.	LABOR RELATIONS OF ALL EMPLOYEES AND EMPLOYERS ARE REGULATED Labor Code of the Russian Federation Civil Code of the Russian Federation Civil Procedure Code of the Russian Federation Code of Administrative Offenses of the Russian Federation	PC-10
84.	RECRUITMENT TO THE POSITION IS FORMALIZED employment contract contract for work a contract for the provision of services for a fee employment contract	PC-10
85.	AN EMPLOYMENT CONTRACT IS CONCLUDED IN THE FORM OF Writing Oral which is established by agreement of the parties which is set by the employer	PC-10
86.	THE EMPLOYEE HAS THE RIGHT TO TERMINATE THE EMPLOYMENT CONTRACT BY NOTIFYING THE EMPLOYER in writing, no later than 2 weeks in advance in writing, no later than 2 months in advance orally, no later than 2 months in advance orally, no later than 2 weeks in advance	PC-10
87.	THE DISCIPLINARY SANCTIONS THAT THE EMPLOYER HAS THE RIGHT TO APPLY FOR COMMITTING A DISCIPLINARY OFFENSE DO NOT INCLUDE transfer to lower-paid work for up to three months remark reprimand dismissal on relevant grounds	PC-10
88.	THE DOCUMENT REGULATING LABOR, SOCIO-ECONOMIC AND PROFESSIONAL RELATIONS BETWEEN THE EMPLOYER AND EMPLOYEES AT THE ENTERPRISE, INSTITUTION, ORGANIZATION IS Collective bargaining agreement Commercial contract application Employment contract	PC-10
89.	FOR DAMAGE CAUSED TO THE EMPLOYER, UNLESS OTHERWISE PROVIDED BY THE LABOR CODE OF THE RUSSIAN FEDERATION OR OTHER FEDERAL LAWS, THE EMPLOYEE SHALL BE LIABLE WITHIN THE LIMITS OF your average monthly earnings of his salary	PC-10

	of his official salary minimum wage	
90.	MATERIAL LIABILITY IN THE FULL AMOUNT OF THE DAMAGE CAUSED MAY BE IMPOSED ON THE EMPLOYEE IN THE CASES PROVIDED FOR: The Labor Code of the Russian Federation and other federal laws only the Labor Code of the Russian Federation only the Civil Code of the Russian Federation The Labor Code of the Russian Federation and the Civil Code of the Russian Federation	PC-10
91.	TO HARMFUL PRODUCTION FACTORS ACCORDING TO ART. 209 OF THE LABOR CODE OF THE RUSSIAN FEDERATION INCLUDES PRODUCTION FACTORS, THE IMPACT OF WHICH ON THE EMPLOYEE CAN LEAD TO illness of the employee work-related injury decrease in the productivity of an individual employee decrease in the professional skills of employees	PC-10
92.	TO HAZARDOUS PRODUCTION FACTORS ACCORDING TO ART. 209 OF THE LABOR CODE OF THE RUSSIAN FEDERATION INCLUDES PRODUCTION FACTORS, THE IMPACT OF WHICH ON THE EMPLOYEE CAN LEAD TO work-related injury illness of the employee decrease in the productivity of an individual employee decrease in the professional skills of employees	PC-10
93.	RESPONSIBILITIES FOR ENSURING SAFE CONDITIONS AND LABOR PROTECTION ARE ASSIGNED TO: Employer Board of Directors Parent organization committees (commissions) on labor protection	PC-10
94.	MEDICAL EXAMINATIONS OF EMPLOYEES OF PHARMACY ORGANIZATIONS ARE CARRIED OUT AT INTERVALS OF 1 TIME IN per year 2 years 3 years At 4 years old	PC-10
95.	MEDICAL EXAMINATIONS OF EMPLOYEES OF PHARMACY ORGANIZATIONS ARE CARRIED OUT AT THE EXPENSE OF Employer Worker of the municipal budget Compulsory Medical Insurance Fund	PC-10
96.	THE SPECIAL ASSESSMENT OF WORKING CONDITIONS DOES NOT INCLUDE: assessment of timely payment of wages to employees identification, research and measurement of harmful/hazardous industries.	PC-10

	Factors assignment of working conditions according to the degree of harmfulness / danger to the class (subclass) of working conditions registration of the results of a special assessment of working conditions	
97.	OCCUPATIONAL SAFETY TRAINING AND TESTING OF KNOWLEDGE OF OCCUPATIONAL SAFETY REQUIREMENTS ARE SUBJECT TO: All employees of the organization Only the head Only responsible for labor protection only employees engaged in work with harmful and dangerous working conditions	PC-10
98.	INTRODUCTORY BRIEFING IS CONDUCTED WITH ALL newly hired, temporary workers, business travelers, students who arrived for practice, etc. employees at least once every six months employees with the introduction of new instructions on labor protection employees in the performance of one-time work not related to direct duties in the specialty	PC-10
99.	INITIAL ON-THE-JOB TRAINING IS CONDUCTED WITH ALL newly hired, temporary workers, business travelers, students who arrived for practice, etc. when applying for a job employees at least once every six months employees with the introduction of new instructions on labor protection employees in the performance of one-time work not related to direct duties in the specialty	PC-10
100.	INITIAL BRIEFING WITH THE EMPLOYEE IS CARRIED OUT BY Employee's immediate supervisor Head of the organization Head of Human Resources Department Human Resources Specialist	PC-10

4.2. Bank of case-tasks for solving cases

№	Situational task	The code of the competence for the formation of which the task is directed
1.	**A pharmacy located in the city has submitted an application to the licensing commission for a license for activities related to the circulation of narcotic drugs and psychotropic substances (NA and PV). During the inspection by the licensing commission, the following was revealed: the pharmacy has a license for pharmaceutical activities; located on the ground floor of a non-residential building, the windows do not have bars, but are equipped with blinds that are not inferior in strength to metal grilles; there is an agreement with a legal entity licensed to carry out private security activities; for storage of HC and PV there is a separate room without windows with a metal door and a wooden**	PC-10

	cabinet; The head of the organization did not issue a referral to medical organizations for a preliminary (periodic) medical examination (examination) and a mandatory psychiatric examination in accordance with the established procedure, as a result of which the employee did not receive the relevant certificates. However, an order was issued for his admission to work with the NS and PV. 1) Is it possible to issue a license to a pharmacy for activities related to the circulation of narcotic drugs and psychotropic substances in this situation? Identify non-compliance. 2) Who has the right to issue a license for activities related to the trafficking of NA and PV and their precursors? 3) What drugs are classified as NA and PV? 4) Which organizations have the right to carry out various activities related to the trafficking of NA and PV and their precursors? 5) Who has the right to work with NA and PV and under what conditions? 6) What are the requirements for the storage of NA and PV? 7) What are the requirements for the release of NA and PV? 8) Accounting for NA and PV in the pharmacy. Argue the answers with the relevant regulatory documents.	
2.	**When checking the activities of the pharmacy kiosk of the municipal unitary enterprise "Pharmacy No. 1", the control and supervisory organization found the following. Onthe showcase are exhibited drugs: almagel-A susp. 170 ml, Corinfar** table. p / o 10mg No. 30, panangin table. p / o No. 50, **lidaza (**lyophilisate for the preparation of the solution d / in. 64 UE, 5 ml No. 10**), cerucal** table. 10mg No. 50, **Levomekol 40g, tincture of peony evading 50ml, formic alcohol 50ml, Fotil ch. cap. 20/5mg 5ml, mercazolil table. 5mg No. 50, diphenhydramine table. 50mg No. 10, No-shpa table. 40mg No. 20, no-shpa r-r d / in. 20mg/ml 2ml No. 5, grass celandine 75g, etc. When checking the storage conditions, the absence of a refrigerator was found, the temperature at the place of storage of the medicine was 23 ° C. When asked to present documents confirming the quality of the drugs, the kiosk pharmacist replied that they exist, but are stored in the pharmacy. The answer to the requirement to present a license for pharmaceutical activities and a specialist certificate was the same. When checking the documents in the pharmacy, it turned out that the pharmacist did not have a specialist certificate, she was hired under a contract agreement.** 1) Conduct an audit analysis: comment on the results and identify violations. What licensing requirements were violated? 2) What forms of state control (supervision), municipal control, according to the Federal Law of the Russian Federation of 26.12.2008 No. 294-FZ "On the Protection of the Rights of Legal Entities and Individual Entrepreneurs in the Exercise of State Control (Supervision) and Municipal Control", exist? Describe the procedure for their implementation. 3) What rights do legal entities and individual entrepreneurs have in the exercise of state control (supervision), municipal control? 4) Who has the right to carry out the process of licensing pharmaceutical activities? What is the procedure for obtaining the above licenses? 5) Violation of what requirements are classified as gross and non-gross violations? When answering each of the questions, it is necessary to make references to the relevant regulatory legal documents.	PC-10
3.	**Pharmacy N is municipally owned, serves the population and medical organizations. It has 3 departments: production, department of stocks and dispensing of medicines of the Ministry of Defense, department of dispensing medicines to the population. In addition, the pharmacy received a license to work with narcotic drugs and psychotropic substances (NA and PV). In the pharmacy at night there was a theft of goods. Actions of the manager in this**	PC-10

	situation. 1) How should the safety of goods be ensured? 2) With which organizations does this pharmacy have the right to conclude a security contract? 3) What types of liability are there? 4) List the stages of conducting and documenting the verification of compliance of the actual availability of goods with accounting data. 5) What will be the composition of the inventory commission in this case? 6) What will be the procedure for compensation for damage to the pharmacy in the event of a shortage of goods based on the results of the inventory and its documentation? 7) Who has the right to work with NA and PV? 8) How should the storage room for HC and PV be organized in this pharmacy? Argue the answer with the relevant regulatory legal documentation.	
4.	**On November 15, 2012, the municipal unitary enterprise "CRA No. 5" from the Moscow Region received requirements for finished medicines, including a solution *of morphine hydrochloride 1.0 N50*. The pharmacy has a license for pharmaceutical activities with the right to work with narcotic drugs and psychotropic substances (NA and PV), issued by the Commission for Licensing of Pharmaceutical Activities of the Constituent Entity of the Russian Federation on January 10, 2012.** 1) Does the pharmacy have the right to fulfill the application of a medical organization (MO) in this situation? 2) Do all pharmacies have the right to work with NA and PV? How is the permit for the right to work of a pharmacy with NA and PV documented? 3) What types of work include activities for the turnover of NA and PV? 4) What are the licensing requirements for obtaining a license for the right to work with NA and PV? 5) How is the process of applying for NA and PV carried out in this pharmacy organization? 6) What documents reflecting the transactions on the turnover of NA and PV should be available in the pharmacy organization? 7) What documents need to be checked when accepting NA and PV at the pharmacy? 8) How is the process of storing NA and PV in the MO carried out? Argue the answer with the relevant regulatory documentation.	PC-10
5.	**The licensing authority sent a commission for a routine inspection of compliance with licensing requirements to the pharmacy of PharmPlus LLC. As a result of the inspection, it was established: prescription drugs are stored in the windows, the pharmacist of the JSC has expired the validity of the specialist's certificate, at the time of the inspection, the temperature regime in the refrigerator where the LP "Grippferon" was stored (on the packaging of the drug it is indicated "Store at a temperature of 2** 0 C **to 8** 0 C**", "Dispensing without a prescription"), was violated (15^{0}C).** 1. What are the licensing requirements for the implementation of pharmaceutical activities by a pharmacy organization? 2. Who has the right to engage in pharmaceutical activities? 3. How long can the verification of licensing requirements last? 4. What violations are gross violations of licensing requirements? 5. Can a decision be made to suspend the license, by whom and for how long? 6. Can this JSC be held administratively liable (which one)? 7. Can LP Grippferon be put on display?	PC-10
6.	**When checking the activities of the pharmacy, the licensing commission established the following: drugs of the List of SD and poisonous are stored on racks; prescriptions for diphenhydramine (table) are left in the pharmacy and stored for 1 month; there are no duly executed price tags for medicines and**	PC-10

	other goods allowed for release from pharmacies (only the price is indicated);phenobarbital for a course of treatment for up to 1 month is often dispensed by prescription with the inscription "For special purposes", signed and personal seal of the doctor; The pharmacist-analyst has not improved his qualifications for 6 years. The director explained the latter by the fact that the employee has reached retirement age and it is inappropriate to send him to advanced training courses at the expense of the pharmacy. In addition, there was no instruction on the procedure for registering the collection of information on the side effects of the drug, adverse reactions during its use, on the facts and circumstances that pose a threat to the life and health of citizens and medical workers and the transfer of information about them to Roszdravnadzor. 1) Who has the right to inspect pharmaceutical organizations? 2) What types of inspections of legal entities are there? Give them a brief description. 3) What is the peculiarity of conducting a prosecutor's check of a pharmaceutical organization? 4) What is the procedure for checking licensing requirements and conditions? 5) List the basic rights of legal entities in the implementation of their verification. 6) Conduct a validation analysis; comment on the results; Identify violations. 7) Which violations of licensing requirements can be classified as gross and which as non-gross. 8) Who in the pharmacy organization is obliged to collect information about the side effects of the drug, adverse reactions when it is used, about the facts and circumstances that pose a threat to the life and health of citizens and medical workers and transmit information about them to Roszdravnadzor? What other information must be transmitted to the specified structure? Argue the answer with the relevant regulatory documentation.	
7.	**As a result of the inspection of the pharmacy organization conducted by the Federal Antimonopoly Service, a violation of pricing for medicines included in the list of vital and essential drugs was revealed. The violation consisted in the fact that the audited organization calculated the retail price from the actual selling price of the manufacturer with VAT. The pharmacy organization itself is on the general taxation system.** 1) Describe the scheme of formation of retail (selling price) for finished medicines. Specify the peculiarity of pricing for vital and essential medicines. 2) Analyze the result of the inspection. Who is right in this situation? 3) Calculate the wholesale and retail cost of the drug "X" (for the pharmacy organization of Nizhny Novgorod), if it is known that the actual release of the manufacturer without VAT = 150 rubles, with VAT = 165 rubles, the organization of wholesale trade is also on the general system of taxation. 4) How would the retail price for this drug be calculated if the pharmacy organization were a payer of a single tax on imputed income (imputed income)? 5) Which organizations can pay imputed? The procedure for paying this type of tax. 6) What other control and supervisory organizations, in addition to the FAS, have the right to verify the correctness of pricing in pharmaceutical organizations?	PC-10
8.	**The patient turned to the pharmacy with a request to let him go without a prescription package of Solpadein tablets No. 12 (8 mg of codeine per 1 tablet), 2 packs of Nurofen Plus tablets table. p / o No. 12 (10 mg of codeine per 1 tablet), Tempalgin table. p / o No. 20, No-shpy table. 40mg No. 6 and Baralgetas table. 500mg No. 10. The pharmacist did not release all the drugs, referring to the current vacation rules. Another visitor demanded a refund for an over-the-counter drug sold the day before in the same pharmacy, arguing that after reading the instructions for the drug again, he realized that it was not suitable for him. The pharmacist refused to return.**	PC-10

	1) Did the pharmacist do the right thing in the first case? Which of the following drugs can be dispensed without a prescription? How do you explain the refusal of vacation to the patient? 2) What are the conditions and procedure for storing these drugs? Requirements for storage facilities. 3) What are the rules for prescribing and dispensing these drugs? 4) List the goods that the pharmacy organization has the right to sell. For the sale of what goods should it obtain additional permission and in what form? 5) Did the pharmacist do the right thing in the second case? 6) What is the consumer entitled to, according to the Federal Law of the Russian Federation of 07.02.1992 No. 2300-1 "On Protection of Consumer Rights"? Argue the answer with the relevant regulatory documents.	
9.	**The prescription prescribes a solution of atropine sulfate for oral administration. The prescription is certified by the signature and personal seal of the doctor. The highest single dose is exceeded 100 times. Taking a prescription, the pharmacist noticed that today this is the third prescription incorrectly written by this doctor.** 1) What is the pharmaceutical examination of a prescription? 2) What group of drugs does atropine sulfate belong to and what other lists of drugs exist? 3) How should a prescription be issued if a doctor prescribes a drug in a dose exceeding the highest single dose. 4) What types of prescription forms are there? List for each of them: basic and additional details, validity and storage. 5) What drugs can be prescribed on each prescription form? 6) What are the specifics of prescriptions for medical devices? 7) How is it necessary to organize the process of storing drugs in a pharmacy organization? Argue the answer with the relevant regulatory documentation.	PC-10
10.	**On the 10th day of the current month, goods packed in boxes were delivered to the pharmacy by road of a wholesale pharmaceutical organization. When accepting the goods in terms of the number of units and quality, a shortage of 5 packages of the D / in solution was found. 50mg 2ml No. 10 "Pipolfen" at a price of 563 rubles. At the same time, the pharmacy received a batch of narcotic drugs and psychotropic substances (HC and PV), during the inspection of which no violations were found. Laying out these drugs in their storage areas, the pharmacist accidentally dropped one package on the floor, breaking one ampoule, which he immediately reported to the head of the pharmacy.** 1) How are the economic ties between the pharmacy and the wholesale pharmaceutical organization formalized? 2) How and by whom should the goods be accepted at the time of receipt? 3) What are the indicators of acceptance quality control of incoming medicines? 4) Your actions, as a materially responsible person, in case of discrepancies in the acceptance of goods, documentation. 5) In what documents, and in what expression (meter) should the received goods be capitalized? 6) Where should the received medicines be stored? 7) List the actions of the head of the pharmacy in case of detection of battle, damage to medicines related to NA and PV. 8) How is the process of write-off and destruction of various categories of medicines in a pharmaceutical organization? Argue the answer with the relevant regulatory documents.	PC-10
11.	**The pharmacy of the regional clinical hospital, serving 1400 beds, received a requirement for ethyl alcohol from the surgical department for January of this year. The estimated number of patients for the current year in this department**	PC-10

	is 1100 people. The approximate standard for the consumption of ethyl alcohol for the surgical department per 1 treated patient (per year) is 225 g. 1) Determine the approximate consumption rate of the surgical department in ethyl alcohol for the year and January of this year. 2) What are the norms for the release of ethyl alcohol from the pharmacy to the departments of a medical organization? Argue the answer with the relevant regulatory documentation. 3) What are the rules for prescribing requirements for medicines and other pharmaceutical products to the pharmacy of a medical organization. 4) What are the requirements for the organization of the storage room for ethyl alcohol? Argue the answer with the relevant regulatory documentation. 5) List the safety requirements when working with ethyl alcohol. 6) What is the responsibility of pharmacy officials for the safety of ethyl alcohol? Argue the answer with the relevant regulatory documentation. 7) List all the main accounting documents on the turnover of ethyl alcohol in the pharmacy organization. Name the employees responsible for their registration. Argue the answer with the relevant regulatory documentation.	
12.	**In April of this year, the pharmacy released to the population on preferential prescriptions of medicines in the amount of 45.5 thousand rubles, which amounted to 16% of the total turnover.** 1) Which pharmacies have the right to dispense medicines on preferential prescriptions? 2) How is the preferential leave financed? How is the pharmacy paid for drugs released on preferential prescriptions? 3) List the population groups and categories of diseases, in the outpatient treatment of which drugs are released on preferential terms. 4) What about thespecifics of prescribing preferential prescriptions, the procedure for their registration and shelf life in a pharmacy? 5) How should the process of storing different groups of preferential drugs be organized? 6) How is the wholesale and retail price of drugs included in the list of vital and essential drugs formed? Argue the answer with the relevant regulatory documentation.	PC-10
13.	**The pharmacy received the following goods: rubber heating pads, alcohol iodine solution 5% 10 ml, clonidine tab. No. 10, promedol, solution for injection 1% 1.0. You, as a financially responsible person, need to place the received goods in storage locations.** 1) In accordance with what principles of storage will you do this? 2) What regulatory documents should be followed when organizing the storage of received goods? 3) To which groups do these goods belong in terms of storage conditions? 4) How should their storage be organized? Justify the distribution of the received goods to storage locations. 5) For the turnover of which of these drugs is the pharmacy organization obliged to obtain an additional permit? 6) Conditions for the release of the above drugs from the pharmacy. 7) Rules for accounting for the above drugs in a pharmacy. Argue the answer with the relevant regulatory documentation.	PC-10
14.	**In the surgical department of the medical organization (MO) N**, a **special room for storing narcotic drugs and psychotropic substances (NA and PV) is equipped. Applications for NA and PV are drawn up by the head nurse of the department and signed by the chief physician. In the course of her work, the newly appointed head nurse faced the following situation: from her department during night duty (and in her absence), a nurse from the therapeutic department was taken one package of narcotic drugs, without the appropriate order of the head of the organization.** 1) What requirements in the field of turnover of NA and PV were violated by	PC-10

	this MO? 2) Who is responsible for the process of organizing activities related to the turnover of NA and PV in the Ministry of Defense? 3) What is the liability for the above violations? 4) How should a senior nurse behave in this situation? 5) Describe the process of obtaining medicines and medical devices from the pharmacy of a medical organization to its branches. 6) What are the requirements for the registration of the invoice requirement? How many copies of it should be issued, and for how long should it be stored in the Ministry of Defense? 7) What are the functions of the pharmacy of a medical organization? 8) What are the main methods used in the process of analyzing and calculating the need for MO in medicines and medical devices? Argue the answer with the relevant regulatory documentation.	
15.	**The head of the pharmacy of the Ministry of Defense has work experience in this specialty, general experience and experience of continuous work in health care institutions for 10 years, expressed a desire to be certified for the assignment of a qualification category.** 1) What regulatory document approved the regulation on the certification of pharmacists and pharmacists? Where should a pharmacist, pharmacist go for certification? 2) In what specialties is the certification of pharmacists, pharmacists carried out? 3) Who is allowed to be certified for the assignment of a qualification category, the procedure for its implementation? 4) What are the requirements for each of the qualification categories? 5) What category can be assigned to the head of the pharmacy? 6) List all the necessary documents that must be submitted to the certification commission in this case. 7) What type of needs, according to existing theories, is predominant for a given employee? List the main methods and ways of motivation.	PC-10
16.	**During the sterilization of solutions for injections in the pharmacy of the Moscow Region, an accident occurred: when opening the steam sterilizer (autoclave), glass bottles exploded and a pharmacy nurse was injured by glass fragments, who was instructed by the head of the pharmacy, due to the pharmacist's illness, to sterilize solutions for injection.** 1) Which of the officials is responsible for the state of labor protection? 2) How is theinvestigation of accidents at work carried out? 3) List the requirements forpremises for the manufacture of medicines under aseptic conditions. 4) What should be the equipment and equipment of workplaces in the premises for the manufacture of medicines? 5) Who has the right to sterilize manufactured medicines? 6) What should be the actions of the leader in this situation? 7) Which of the officials will be held accountable in this situation? 8) Is the injured employee entitled to material compensation in this situation? Argue the answer with the relevant regulatory documentation.	PC-10
17.	**As of 31.12.2013, the actual average number of personnel in the pharmaceutical organizationN** was 303 people (planned 323 people), including administrative and managerial personnel - 50 people (planned - 50 people), economic service personnel - 15 people (planned - 20 people), pharmaceutical **personnel - pharmacist - 114 people (planned - 120 people), medium pharmaceutical - 124 people (planned - 133 people). Throughout the year 5 people were hired (15 people are planned). At the same time, 10 people resigned, one of whom was dismissed for violation of labor discipline.** 1) How is the analysis of the availability of labor resources in a pharmacy organization carried out?	PC-10

	2) Analyze the movement of labor resources in the above example, calculating the provision of the organization with labor resources and determining the qualitative indicators: the turnover rate for admission, the turnover rate for retirement, the turnover rate for personnel. 3) What is the analysis of the use of working time? Give the formula for calculating the working time fund. 4) Explain the procedure for calculating and paying wages. 5) What tax deductions are provided by law for individuals? 6) What documents must be accepted and executed when hiring a pharmaceutical specialist? Argue the answer with the relevant regulatory documentation.	
18.	**Pharmacist Ivanova A.N., who is 3 months pregnant, went on another paid vacation for two weeks. After a week of vacation, she was asked to go to work in connection with a routine inventory at the pharmacy. At the same time, it was assumed that the inventory would take place at night.** 1) How legitimate is this situation? What could the pharmacist do in this case, based on the current labor legislation? 2) Does the manager, in case of refusal of the pharmacist to go to work, have the right to apply any punishment to him? 3) Which organizations monitor the observance of employee rights in the Russian Federation? 4) What is night work? What are the features of its payment? 5) What are the normal working hours? What other types of working time are there? 6) What is "inventory"? What are its tasks, types, and timing? Imagine an inventory algorithm. 7) List the documents to be processed in the inventory process.	PC-10
19.	**The pharmacist, who resigned at his own request, was delayed by the director of the pharmacy "Medicines for You" the issuance of a work book, since upon dismissal he did not return the gown issued to him.** 1) Is the head of the pharmacy right in this situation? What documents should be filed and stored in a pharmaceutical organization for each of the employees? Their shelf life. 2) Terms of issuance of the work book, calculation of dismissal. 3) The procedure for terminating an employment contract at the initiative of the employee (at his own request). 4) The employee's right to withdraw his application. What day is considered the day of dismissal? 5) What should the employer do if the employee was absent from work on the day of dismissal? 6) What is the responsibility of the employer (pharmacy) to the pharmacist in this situation? 7) Can the director of a pharmacy be held financially liable? Foundation. 8) What are the norms for issuing and accounting for sanitary clothing in a pharmacy. Argue the answer with the relevant regulatory documents.	PC-10
20.	**The accountant of the pharmacy accrued wear and tear on the equipment used for sterilization of medicines as of 01.01.2015 after 2 years of its operation, using the linear method, while taking the initial cost as a basis.** 1) What was the main mistake made by the accountant? 2) By what criteria will the property be classified as fixed assets? 3) What other methods of calculating depreciation of fixed assets are used in pharmacies? 4) What is the classification of pharmacy household products? 5) List the measures for labor protection in pharmacies, paying special attention to the operation of pressure devices. 6) The procedure for investigating accidents in a pharmacy organization.	PC-10
21.	**Evaluate the legitimacy of the administration's actions in each of the**	PC-10

	situations below from the standpoint of the Labor Code of the Russian Federation and give answers to questions. **а) When hiring a pharmacist, the director of the pharmacy "Cherry Orchard" asked her to write her autobiography, then found out that she had a child of 2 years old and refused to hire her, although the pharmacy had a vacant pharmacist rate.** **б) The director of the pharmacy hired a pharmacist for taking prescriptions and dispensing medicines with a probationary period of 1 month. From the first days of work, it became clear that the pharmacist did not know the basic requirements of the current documents regulating the procedure for taking prescriptions and dispensing medicines, and was rude to visitors and colleagues. After 2 weeks (in agreement with the trade union organization of the pharmacy), she was dismissed. Did the director of pharmacies have the right to dismiss an employee before the end of the probationary period. List the categories of workers who, in accordance with the Labor Code of the Russian Federation, are prohibited from establishing a probationary period when hiring.** 1) What documents are required when applying for a job? 2) What are the qualification requirements for a pharmacist? 3) Does the employer have the right to dismiss an employee before the end of the probationary period? 4) What are the grounds for dismissal of the employee? 5) List the categories of workers who are prohibited from establishing a probationary period when hiring. 6) Does a transfer to another workplace apply to transfers to another position? **7)** Can it be carried out without the consent of the employee?	
22.	**During the inspection of the activities of the pharmacy kiosk of the municipal unitary enterprise "Apteka 1", conducted jointly by the Inspectorate for the Protection of Consumer Rights, the Labor Inspectorate, the Commission for Licensing of Pharmaceutical Activities and the Tax Inspectorate, the following was established:** 1) The following drugs were exhibited in the showcase: Almagel A, Nikodin, Corinfar, Panangin, Saridon, Lidase, Cerucal, Lorinden-A ointment, peony tincture, formic alcohol, otipax, Maerkazolil, diphenhydramine in table., No-shpa in table. and ampoules, grass celandine, etc. 2) When checking the storage conditions, the absence of a refrigerator was found, the temperature at the place of storage of the drug is 230C. 3) A pharmacist was working at the kiosk that day. When asked to present documents confirming the quality of the drugs, the kiosk pharmacist replied that they exist, but are stored in the pharmacy. On the proposal to present a license for pharmaceutical activities and a specialist certificate, the answer was the same. 4) When checking the documents in the pharmacy, it turned out that the pharmacist did not have a specialist certificate, she was hired under a contract agreement. 5) At the time of the inspection, the electricity was turned off, and the pharmacist dispensed medicines without punching checks on the cash register.	PC-10
23.	**The management of the pharmaceutical organizationN decided to conduct an advertising campaign in order to stimulate the sale of products. The turnover of the organization in the pre-advertising period amounted to 60 thousand rubles The advertising department justified the need for five publications in a pharmaceutical newspaper and four broadcasts of a radio commercial in the amount of 3 thousand rubles As a result, 2 thousand rubles were allocated, the money was used for 3 broadcasts and 3 publications. After carrying out promotional activities, the turnover amounted to 66 thousand rubles.** 1) Give a description of the concept of "pharmaceutical advertising". What is its purpose?	PC-10

	2) What should not be contained in the advertising of medicines? 3) Give a classification of the means of advertising. Give them a brief description. 4) How is the phased planning of the budget of advertising and information activities in a pharmaceutical organization carried out? 5) What expenditure items does the advertising budget contain? 6) How is the effectiveness of information and advertising activities of pharmaceutical organizations assessed? 7) What liability is provided for by the legislation of the Russian Federation for violations in the field of advertising, consumer protection and rules for the sale of certain types of goods? Argue the answer with the relevant regulatory documentation.	
24.	**A fine was imposed on one of the pharmacies of the "Your Doctor" network for the fact that the pharmacist of this pharmacy took a sample of the drug from the medical representative of the pharmaceutical company X. In another pharmacy of the same network, the manager made a remark to a visitor who photographed the windows.** 1) Is it legal to impose a fine on the first pharmacy? 2) Is the head of the second pharmacy right? 3) List the rights of the consumer in the field of obtaining proper information about the pharmaceutical organization and the product sold by it. 4) What are the rights of consumers when dispensing drugs from a pharmacy organization? 5) What is the liability for violation of these rights? 6) What restrictions are imposed by the legislation of the Russian Federation in the field of advertising of medicines? 7) Give examples of outdoor and indoor advertising in a pharmacy organization. Argue the answer with the relevant regulatory documentation.	PC-10
25.	**The administration of the pharmacy decided to form a closed joint-stock company on its basis and began to prepare constituent documents, the pharmacy staff was not informed about this. Rumors began to spread around the pharmacy about the sale of the pharmacy to unknown people and the dismissal of all employees. Finally, a delegation of employees led by an informal leader - the head of one of the departments of the department - came to the director of the pharmacy with a threat to start a strike. Head. The pharmacy was surprised, and then explained to the employees the benefits of the changes, that they would all be the owners of the pharmacy, and denied the rumors. The conflict was avoided.** 1) What is the mistake in the behavior of the pharmacy administration? 2) Reveal the essence of the concepts of "Formal" and "Informal" structure of the organization. 3) What are some examples of sources of conflict in pharmaceutical organizations? 4) What measures can be taken to prevent them? 5) What are the requirements for management decisions? 6) Stages of development of management decisions?	PC-10
26.	**A pharmacist was hired at the Municipal Unitary Enterprise "Apteka" to carry out information work from August 1 of this year with a probationary period of 1 month. On September 3 of this year, the employee was dismissed under Art. 71 of the Labor Code of the Russian Federation, as he did not pass the test. In November of this year, the district court of N ruled to reinstate the pharmacist at work with the payment of average earnings for the entire period of forced absenteeism and with compensation to the employee for monetary compensation for moral damage in the amount of 5 thousand rubles.** 1) What is the violation of the labor legislation of the head of the pharmacy? 2) Testing when applying for a job: the purpose of the test, its duration, design.	PC-10

	3) Categories of workers for whom the test is not established. Test result. 4) then compensates for the damage caused to the employee? What is it? 5) What financial responsibility is imposed in this case on the manager? Foundation. 6) Information activities of the pharmacy. Consumers of pharmaceutical information, methods of working with different groups of consumers of pharmaceutical information. 7) List the responsibilities of the pharmacist for information work.	
27.	**An advertisement for the dietary supplement "Fulflex" was placed in the television space. The advertiser recommended treatment for gout. The FAS banned the broadcast of the video and fined the manufacturer's company.** 1) Give the concept of unfair competition. 2) What inconsistencies with the Federal Law "On Advertising" were identified by the FAS in this case? 3) What types of unfair competition are found in the pharmaceutical market? 4) Terms of advertising for prescription and over-the-counter drugs. 5) What additional inscriptions when advertising dietary supplements should be on the screene?	PC-10
28.	**In the manufacture of chloramphenicol alcohol solution 1% 25 ml, the pharmacist found that in the tare with the label "Laevomycetinum", which had just arrived from the material room, there was, in his opinion, another substance that resembled anestezinin in appearance and taste.** 1) What should a pharmacist do in this situation? 2) What kind of control must be subjected to medicines coming from the material room to the assistant room, and who should carry out this control? How is it documented and how should the tare be issued? 3) What types of intra-pharmacy control are you required to own as a pharmacist for quality control of medicines in a pharmacy? 4) How and where should the workplace of a pharmacist-technologist and a pharmacist-analyst be organized? 5) What types of control can be subjected to medicines manufactured in a pharmacy, including injectables, purified water, medicinal plant materials? 6) What preventive measures are you required to carry out in the pharmacy to ensure the quality of medicines prepared in the pharmacy? 7) At the expense of what indicators in the pharmacy are the costs of quality control of medicines written off?	PC-10
29.	**As a result of the inspection carried out by the inspector of Roszdravnadzor in the wholesale pharmaceutical organization, it was found that a batch of the drug "Herceptin, lyophilized powder for the preparation of solution for infusions of 440 mg (fl.) was prepared for sale. / complete with solvent series N3555 / B2055 (on the packages the manufacturer is indicated F. Hoffman-La Roche Ltd., Switzerland, Jenentek Inc., USA), in respect of which the Federal Service for Surveillance in Health and Social Development reported by letter as falsified. The drug in the amount of 10 packages was seized and destroyed in the presence of the inspector.** **Conduct a full legal analysis of this situation and answer the questions posed with references to the relevant legislation:** 1) What types of violations and in what area of legislation took place? 2) What legal consequences can occur for a wholesale organization? 3) What is the procedure for the destruction of drugs in this situation? 4) What liability can the perpetrators incur? 5) Rights of legal entities and individual entrepreneurs in the exercise of state control and supervision.	PC-10
30.	**The head of the pharmacy of the health care facility has work experience in this specialty, general experience and 10 years of continuous work experience in health care institutions, expressed a desire to be certified for the assignment of a qualification category.**	PC-10

	1) What regulatory document approved the Regulation on the certification of pharmacists? 2) Where should the pharmacist go? What documents do I need to prepare? 3) In what specialties is the certification of pharmacists, pharmacists carried out? 4) Who is allowed to be certified for the assignment of a qualification category, the procedure for its implementation? 5) What category can be assigned to the head of the pharmacy? 6) The procedure for drug provision of LLU in modern conditions. **7)** Modern problems of drug provision for inpatients.	

4.3. Questions for colloquiums

1. The structure and procedure for the functioning of the state system for monitoring the safety, efficiency and quality of drugs and medical devices.
2. Types of regulatory documentation for standardization.
3. Requirements for organizations involved in the provision of medicines to the population to comply with the Law of the Russian Federation "On the Circulation of Medicines".
4. The main regulatory legal acts regulating the activities of pharmaceutical organizations.
5. Bodies exercising quality control of drugs and medical devices, their goals, objectives.
6. Features of the control of drugs and medical devices in comparison with the quality control of other consumer goods and industrial and technical purposes.
7. Types of control: state, departmental, arbitration.
8. Methods of control: documentary; commodity analysis of drugs and medical devices; pharmaceutical analysis of drugs and medical devices; intra-pharmacy control of drugs.
9. The Law of the Russian Federation "On Protection of Consumer Rights", responsibility for information on the quality of products sold.
10. Documentation confirming the quality of drugs, medical devices and parapharmaceutical products.
11. Pharmaceutical order in pharmacy organizations. Licensing of activities in the field of circulation of medicines.
12. Features of control over the organization of drug provision of the population and medical institutions.
13. Falsification of medicines, methods of its detection.
14. Measures taken in relation to falsified, poor-quality and counterfeit medicines.
15. Pricing policy and pricing features in the pharmaceutical market. Analysis of the level and dynamics of prices.
16. Legal support of pharmaceutical activities. Labor rights and obligations of employees.
17. Employment contract: parties, content, duration, procedure for conclusion, guarantees.
18. The procedure for hiring, employment record, probationary period.
19. Transfers, grounds for termination of the employment contract. Reasons and procedure for termination. Payment of severance pay.
20. Collective agreement: content, procedure for conclusion, actions, changes, control of execution.
21. Working time. Duration of work at night.
22. Part-time and substitution. The order of registration.
23. Work on holidays and weekends. Overwork. Payment procedure.
24. Time tracking. The right to rest. Duration of leave, procedure for granting, types of leave. Warranties and indemnities. Benefits.
25. Liability. Contract. Procedure for compensation for damages. Labor discipline: obligations of the parties, ensuring labor discipline, incentives and penalties.
26. Internal labor regulations. Performance discipline.

27. Labor disputes: bodies and procedure for consideration, deadlines for appeal, execution of decisions.

28. Occupational health and safety: rules, requirements, provision, instruction, control, responsibilities of administration and employees.

29. Registration of termination of the contract (dismissal of the employee). Statute of limitations for termination of employment. The procedure for applying for employment under the contract system Probationary period. Transfer to another job.

30. Registration of termination of the contract (dismissal of the employee).

31. Reference and information support of pharmaceutical activities.

32. Purpose and basic requirements for pharmaceutical information.

33. Information and legal support of activities in the field of circulation of medicines.

34. Determination of the category of consumers of pharmaceutical information.

35. Study of the information needs of various groups of consumers of pharmaceutical information.

36. The concept of quality and quality management. International quality standards.

37. Quality standards in pharmaceutical activities. Rules of good pharmacy practice.

38. Functional and process approach in the management of a pharmaceutical organization. Basic processes.

39. Quality assurance system. Model of the quality management system.

40. Quality Commissioner in a pharmacy organization.

5. The content of the assessment tools of mid-term assessment

Mid-term assessment is carried out in the form of a credit.

5.1 The list of control tasks and other materials necessary for the assessment of knowledge, skills and work experience

5.1.1. Questions for the credit in the discipline

1. The structure and procedure for the functioning of the state system for monitoring the safety, efficiency and quality of drugs and medical devices.

2. Types of regulatory documentation for standardization.

3. Requirements for organizations involved in the provision of medicines to the population to comply with the Law of the Russian Federation "On the Circulation of Medicines".

4. The main regulatory legal acts regulating the activities of pharmaceutical organizations.

5. Bodies exercising quality control of drugs and medical devices, their goals, objectives.

6. Features of the control of drugs and medical devices in comparison with the quality control of other consumer goods and industrial and technical purposes.

7. Types of control: state, departmental, arbitration.

8. Methods of control: documentary; commodity analysis of drugs and medical devices; pharmaceutical analysis of drugs and medical devices; intra-pharmacy control of drugs.

9. The Law of the Russian Federation "On Protection of Consumer Rights", responsibility for information on the quality of products sold.

10. Documentation confirming the quality of drugs, medical devices and parapharmaceutical products.

11. Pharmaceutical order in pharmacy organizations. Licensing of activities in the field of circulation of medicines.

12. Features of control over the organization of drug provision of the population and medical institutions.

13. Falsification of medicines, methods of its detection.

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40. Quality Commissioner in a pharmacy organization.

6. Criteria for evaluating learning outcomes

For the credit:

Learning outcomes	**Evaluation criteria**	
	Not passed	**Passed**
Completeness of knowledge	The level of knowledge is below the minimum requirements. There were bad mistakes.	The level of knowledge in the volume corresponding to the training program. Minor mistakes may be made
Availability of skills	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes.	Basic skills are demonstrated. Typical tasks have been solved, all tasks have been completed. Minor mistakes may be made.

Availability of skills (possession of experience)	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes.	Basic skills in solving standard tasks are demonstrated. Minor mistakes may be made.
Motivation (personal attitude)	Educational activity and motivation are poorly expressed, there is no willingness to solve the tasks qualitatively	Educational activity and motivation are manifested, readiness to perform assigned tasks is demonstrated.
Characteristics of competence formation*	The competence is not fully formed. The available knowledge and skills are not enough to solve practical (professional) tasks. Repeated training is required	The competence developed meets the requirements. The available knowledge, skills and motivation are generally sufficient to solve practical (professional) tasks.
The level of competence formation	Low	Medium/High

For the exam:

Learning outcomes	**Assessment of competence developed**			
	unsatisfactory	**satisfactory**	**good**	**excellent**
Completeness of knowledge	The level of knowledge is below the minimum requirements. There were bad mistakes	The minimum acceptable level of knowledge. A lot of light mistakes were made	The level of knowledge in the volume corresponding to the training program. A few light mistakes were made	The level of knowledge in the volume corresponding to the training program, without errors
Availability of skills	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	Basic skills are demonstrated. Typical problems with light mistakes have been solved. All tasks have been completed, but not in full.	All basic skills are demonstrated. All the main tasks have been solved with light mistakes. All tasks have been completed, in full, but some of them with shortcomings	All the basic skills were demonstrated, all the main tasks were solved with some minor shortcomings, all the tasks were completed in full
Availability of skills (possession of experience)	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	There is a minimal set of skills for solving standard tasks with some shortcomings	Basic skills in solving standard tasks with some shortcomings are demonstrated	Skills in solving non-standard tasks without mistakes and shortcomings are demonstrated
Characteristics of competence formation*	The competence is not fully formed. The available knowledge and skills are not	The formation of competence meets the minimum	The formation of competence generally meets the	The formation of competence fully meets the requirements. The

Learning outcomes	Assessment of competence developed			
	unsatisfactory	**satisfactory**	**good**	**excellent**
	enough to solve professional tasks. Repeated training is required	requirements. The available knowledge and abilities are generally sufficient to solve professional tasks, but additional practice is required for most practical tasks	requirements, but there are shortcomings. The available knowledge, skills and motivation are generally sufficient to solve professional tasks, but additional practice is required for some professional tasks	available knowledge, skills and motivation are fully sufficient to solve complex professional tasks
The level of competence formation*	Low	Below average	Intermediate	High

For testing:
Mark "5" (Excellent) - points (100-90%)
Mark "4" (Good) - points (89-80%)
Mark "3" (Satisfactory) - points (79-70%)
Mark "2" (Unsatisfactory) - less than 70%

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