

**Appendix to the Order of
the Ministry of Public
Health and Social
Development of the Kyrgyz
Republic dated
" 25 " 03 2021 city
of
№ 318 _____**

**COMPETENCE CATALOG
BY SPECIALTY
"ORGANIZATION OF PHARMACEUTICAL WORK"
POSTGRADUATE LEVEL**

Catalog of competencies in the specialty "Organization of Pharmaceutical business " was developed by a working group consisting of:

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The competence catalog was discussed by employees of the I. K. Akhunbaev State Medical University and specialists of the Ministry of Health and Social Development of the Kyrgyz Republic, Department of Medicines and Medical

Devices, Members of the professional association "Pharmaceutical Union of Kyrgyzstan", representatives of pharmaceutical organizations. **The catalog is reviewed:**

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EXPLANATORY NOTE

Over the past decades, the role of the pharmacist in the healthcare system has changed significantly: from the simple preparation and delivery of medicines to the pharmacist who provides the full range of pharmaceutical services. In accordance with the standards of the world health organization (who), International pharmaceutical Federation (IFF, FIP) the duties of the pharmacist include: implementation of the selection, procurement, storage, delivery, distribution, issuance and use of high-quality, safe, Effective medicines, wherever they delivered wherever it operates, with the aim of improving the health of patients. To do this, the specialist must have knowledge and skills in organizing and regulating the provision of high-quality pharmaceutical services.

Currently, the sphere of pharmaceutical activity is undergoing changes due to the entry of the Kyrgyz Republic into the EAEU. In this regard, the head of a pharmaceutical organization – a manager-needs knowledge in the regulatory field and the ability to apply it in practice, both as a specialist of the regulatory body and as an employee of a pharmacy providing services. Also, most pharmaceutical organizations are represented mainly by business structures, the main purpose of which is to generate profit, but taking into account the fact that this activity remains socially responsible and socially significant.

According to the Decree of the Government "On medical postgraduate education in the Kyrgyz Republic" dated July 31, 2007 No. 303, graduates of the Faculty of Pharmacy are provided for postgraduate education on a voluntary basis (residency).

1. GENERAL PROVISIONS

Residency in the specialty "Organization of pharmaceutical business" provides for professional training of a specialist who has deep theoretical and practical

knowledge and is ready to carry out professional activities. The term of study is 1 year, the degree of study is full - time.

1.1. The purpose of the residency is to train a qualified pharmaceutical business manager who has a system of universal and professional competencies, is capable and ready for independent professional activity control-resolving and organizational and managerial.

1.2. Residency tasks:

- develop in-depth knowledge of the residency sections that form the competencies of a pharmaceutical business manager who is able to successfully solve professional tasks;
- develop skills in mastering the latest technologies and techniques in the field of professional interests;
- prepare a pharmaceutical business manager who has an analytical mindset and is able to manage pharmaceutical organizations and their divisions engaged in the field of drug circulation.

2. SPECIALIST'S COMPETENCIES

The competence of a specialist characterizes its potential ability to use the acquired knowledge, skills, and practical experience in professional and social activities.

The Catalog of postgraduate training competencies (residency) in the specialty "Organization of Pharmaceutical business" (hereinafter referred to as the Catalog) provides a list of specific competencies (knowledge and skills), a list of practical skills that a resident should master during the residency under the guidance of a mentor or independently. When developing the Catalog, we used the recommendations of WHO, FIP, the experience of foreign countries, such as Austria, Great Britain, USA, Switzerland, the Russian Federation, and regulatory legal acts of the Kyrgyz Republic regulating activities in the field of drug circulation.

2.1. In this Catalog, competencies are divided into two groups: general and professional. They must be mastered by a specialist in accordance with the requirements of the order of the Ministry of Health to R No. 691 of 04.10.2018 " On approval of requirements for the structure of the basic professional educational program of postgraduate medical education (residency) in the Kyrgyz Republic".

2.2. General competencies reflect the needs of society and the individual to general cultural, social and personal qualities of the graduate, knowledge

and ability to apply instrumental competencies upon completion of the residency program.

Professional competencies reflect the demands of the labor market regarding the readiness of a specialist to perform tasks and professional activities and related labor functions from professional standards (if any) for the appropriate level of professional qualification.

The results of mastering the residency program are determined by the competencies acquired by the specialist, i.e. his ability to apply knowledge, skills and personal qualities in accordance with the tasks of professional activity. **2.3.**

Purpose of the document.

This one The catalog should become part нормативных of the regulations for postgraduate training and, therefore, be valid for all postgraduate training programs of the residency program in the specialty "Organization of Pharmaceutical Business".

2.4. Based on the Catalog data:

Defined by:

The purpose and content of postgraduate training in residency in the specialty; the levels of professional competencies, knowledge and practical skills of a specialist. **Being developed:**

- Work programs
- Criteria for evaluating the quality of specialist training
- Standard requirements for certification of a specialist
- Standards of professional activity of a specialist **Being organized:**
- professional orientation of medical university graduates;
- postgraduate training; **Held**
- Attestation of internships.

2.5. The main users of this Catalog are: - medical educational organizations that implement programs of higher postgraduate pharmaceutical education;

- pharmaceutical organizations that have licenses for pharmaceutical activities;
- professional pharmaceutical associations;
- residents;
- authorized body of executive power that performs the functions of developing state policy and regulatory regulation in the field of healthcare;
- other stakeholders.

3. REGION PROFESSIONAL ACTIVITY OF A PHARMACIST-MANAGER

The areas of professional activity of a pharmaceutical specialist-manager who has completed a residency program are: - healthcare (in the sphere of circulation of medicines, medical devices and other pharmacy products).),
- administrative, managerial and office activities (in the sphere of circulation of medicines),
- education and science (in the field of scientific research) - other areas of activity related to health protection.

3.1. Types of professional activities for which graduates of the residency program in the specialty "Organization of pharmaceutical business" are prepared»:

- control and authorization system;
- organizational and managerial information.

3.2. Tasks of professional activity of a graduate of the residency program in the specialty "Organization of pharmaceutical business" in the field of: organizational and managerial activities:

- participation in the development of legislative and regulatory acts of executive authorities in the field of drug circulation; - organization and management of activities of pharmaceutical organizations and their structural divisions;
- conducting inspections of compliance and compliance with license requirements;
- organization and management of legal turnover of narcotic drugs, psychotropic substances and precursors;
- conducting state registration of medicinal products;
- creating favorable working conditions in pharmaceutical organizations and their structural divisions, taking into account the requirements of occupational safety and health; **pharmaceutical activities:**
- managing the activities of an organization engaged in wholesale and retail sales of medicinal products;
- implementation of drug provision for citizens who are eligible for social assistance, who are on an inpatient or outpatient basis.
treatment;
- providing advice to specialists of medical and pharmaceutical organizations, the public on the choice and rational use of medicines and medical devices.
products;
- provision of storage conditions for medicines and other pharmacy products;
- conducting operational and managerial accounting of the movement of commodity values; **marketing activities:**

- conducting market research of existing and potential consumers of the pharmaceutical market;
- application of basic principles of satisfaction of needs of consumers in pharmacy products and services;
- application of merchandising technology in the work of pharmacies;
- financial and economic activities:**
- planning the organization of strategic and ongoing activities of pharmaceutical organizations and structural divisions;
- assessment of the competitiveness of pharmaceutical organizations' activities; conducting economic and financial analyses, identifying risks in the activities of pharmaceutical organizations.

4. REQUIREMENTS FOR THE PLANNED RESULTS OF MASTERING THE EDUCATIONAL PROGRAMS PROVIDED BY RESIDENCY DISCIPLINES AND PRACTICES

As a result of mastering the ordinator program, the graduate should develop general and professional competencies: - readiness for abstract thinking, analysis, synthesis (OK-1);

- the willingness of the management team, tolerant to perceive social, ethnic, religious and cultural differences (OK-2); - willingness to participate in teaching activities in the programs of secondary and higher medical and pharmaceutical education and additional professional programs for persons with secondary vocational or higher pharmaceutical education (OK-3).

control and permitting activities:

- readiness to implement procedures for import of medicines into the Kyrgyz Republic and export of medicines from the Kyrgyz Republic (PC -1);
- readiness to conduct procedures for the withdrawal from civil circulation of counterfeit, substandard, counterfeit medicines and their destruction (PC-2);
- readiness to carry out the procedures provided for in the state registration of medicinal products (PC-3); **organizational and management activities:**
- readiness to apply the basic principles of professional management (PC -4);
- readiness to organize pharmaceutical activities (PC-5); - readiness to evaluate economic and financial indicators used in the field of drug circulation (PC-6); - readiness to organize technological processes in the production and manufacture of medicines (PC-7);
- readiness for the organization of quality control of medicines (QA – organizations of quality control of medicines (IIK – 8).

To indicate the level of competence that needs to be achieved by the end of training in this discipline, the following gradation is used::

Level 1-indicates that a specialist can independently carry out pharmaceutical activities in the field of control and organizational and managerial activities to solve professional problems.

Level 2-indicates that the specialist is well-versed in matters of professional activity and can perform certain functions.

**Thematic cycles of internships in the specialty
"Organization of pharmaceutical work»**

n/a number	Cycle names	Duration (week)
1.	State regulation of public health protection and circulation of medicines	6
2.	Pharmaceutical management and marketing	13
3.	Economics of pharmaceutical organizations	5
4.	Organization of drug supply	4
5.	Medical and pharmaceutical commodity science	4
6.	Pharmaco economics	5
7.	Clinical pharmacology and fundamentals of pharmaceutical consulting	4
7.	Pedagogy and Psychology	3
6.	Checkpoint	2
7.	Certification	2
	Total:	48

5. LIST OF MANIPULATIONS/SKILLS

Ординатор-А graduate resident in the specialty " Organization of pharmaceutical business "(position-manager of pharmaceutical business) must possess the following skills (work out during internship in healthcare institutions that regulate issues in the field of drug circulation and pharmaceutical organizations that have a license for pharmaceutical activities):

	Skills	Number of tasks performed together with	Number of self-completed tasks
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		mentor	
1.	Carry out the procedure for registration and issuance of a document authorizing the import of medicines and medical devices	3	2
2.	<p>Carry out the procedures provided for in the state registration of medicinal products in the Kyrgyz Republic:</p> <ul style="list-style-type: none"> - acceptance of the application for registration of medicinal products and the registration dossier (RD); - verification of completeness of documents; - preparation of an invoice for payment; - after payment by the applicant, transfer RD for pharmaceutical and pharmacological examination; -send samples of the drugs to the Central control and analytical laboratory (CCAL) for analysis according to the normative document (ND) quality; - if you have comments of experts, to prepare a request and send to the applicant; - received response to request to transfer to the experts; - preparation of materials for submission to the meeting of the Expert Council; - the minutes of the meeting; - in case of positive decision: the draft 	2	

	<p>order permitting of drugs for medical use, design registration certificate.</p> <ul style="list-style-type: none"> - if the decision is negative, prepare a letter of refusal to register. 		
3.	<p>Conduct an assessment of the quality of medicines;</p> <ul style="list-style-type: none"> - accepting applications with documents for conducting an assessment of the quality of medicines sent by the applicant in the "on-line " mode; - checking the completeness of the submitted 	2	documents.

	<p>documents;</p> <ul style="list-style-type: none"> - identification batch of drugs in the warehouse of the applicant, <p>a certificate of identification;</p> <ul style="list-style-type: none"> - selection of samples of medicinal products (registration act of sampling for analysis by the accredited testing laboratory); - analysis of information in the submitted documents, as well as marking drug regulatory compliance document quality; <p>-participation in the decision and issuing a conclusion on the quality of drugs;</p> <ul style="list-style-type: none"> - preparation of defective and counterfeit drugs to be placed on the website DLS and MI. 		
4.	<p>Possess the skills of organizing acceptance quality control of received medicines and MI in pharmacy institutions:</p> <ul style="list-style-type: none"> - checking the compliance of received medicines with the data specified in the accompanying documents (quantity, name, series, expiration date, document confirming the quality of medicines); - checking the availability of Registration of medicinal products in information базax databases on suspension or withdrawal from circulation of received medicinal products; - visual inspection, checking the integrity of packaging and labeling compliance with established requirements; - registration of medicinal products. 	5	2

5.	Possess algorithms of actions in case of detection of falsified, substandard and counterfeit medicines and other goods allowed for release from pharmacies and organize their destruction.	1	
6.	Own methods of forming logistics channels, managing the channel of commodity movement for supplying medical and pharmaceutical organizations with medicines, medical devices and other goods allowed for vacation;	1	
7.	Master the rules of prescription and over-the-counter drug dispensation from a pharmacy;	5	2
8.	Possess the skills of HR records management;	2	
9.	Possess skills in resolving conflict situations with pharmacy visitors;	2	
10.	Possess skills in occupational health, safety and fire safety and documentation of their implementation;	2	1
11.	Possess skills in selecting, equipping and operating premises, taking into account the type and scope of activities and current sanitary and hygienic standards; training and passing licensing procedures;	1	
12.	Master the methods of ABC / XYZ analysis;	2	

13.	Master the methods and methods of organizing контроля quality control of medicines at the level of production, distribution, and storage.	1	
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Characteristics of post-graduate training institutions/organizations

1. Department of Medicines and Medical Devices Main tasks:

- implementation of the State policy on providing the population and healthcare organizations with medicines and medical devices;
- organization of a management and monitoring system for providing the population with safe, effective, high-quality medicines and medical devices;
- determination of directions and organization of research activities to improve the methods of management, control and standardization of medicines and medical devices.

2. Neman Pharm Limited Liability Company»

The Neman-Pharm pharmacy chain was founded in 1995. Neman-Pharm cooperates with the world's leading pharmaceutical companies. The logistic company's system meets modern standards. It consists of more than 200 pharmacies in all regions of Kyrgyzstan. It has a wholesale and retail link, an office where managers work in all areas of the company's activities: registration of drugs and MI; quality assessment of drugs licensing of pharmacies; import of drugs, including narcotic and psychotropic drugs, etc.

3. Farmamir Limited Liability Company»

The pharmacy chain "Farmamir" was founded in 1998 and is one of the leaders in the pharmaceutical market. Pharmamir cooperates with the world's leading pharmaceutical companies. It consists of more than 150 pharmacies in all regions of Kyrgyzstan. It has a wholesale and retail link, an office where managers work in all areas of the company's activities: registration of medicines and MI; evaluation of the quality of medicines licensing of pharmacies; import of medicines, etc.

6. REGULATIONS ON THE EXAMINATION/ATTESTATION.

The purpose of the exam / attestation is to determine the level of knowledge and practical skills of residents who have been trained in the specialty "Organization of pharmaceutical business" in accordance with the competence catalog.

The composition of the examination commission is determined by the Ministry of Health and Social Development of the Kyrgyz Republic:

Exam Board tasks/attestation commission:

1. organization of the exam/attestation;
2. conducting an exam/attestation and reporting the result;
3. review and correct exam questions no as needed if necessary;
4. formation of exam questions and bringing them to the residents no later than 1 month before the exam.

Filing an appeal. The appeal must be submitted after the exam on the sameday.

Exam structure:

- 1 Part: a test exam with multiple choice answers.
- 2 part: a structured oral exam based on a discussion of practical skills with minimal criteria for results determined in advance (from 30 to 60 minutes).

Admission to the exam.

Graduate of the postgraduate educational program in the specialty "Organization of pharmaceutical business". **Exam/attestation evaluation criteria:**

The assessment of each part of the exam, as well as the final assessment, is given with a note "passed" or "did not pass". The exam was successful if both parts of the exam were passed.

LITERATURE:

1. Resolution Government of the Kyrgyz Republic "On Medical Postgraduate Education in the Kyrgyz Republic" dated July 31, 2007 No. 303.
2. Order of the Ministry of Health of the Kyrgyz Republic No. 691 dated 04.10.2018 " On approval of requirements for the structure of the main professional educational program of postgraduate medical education (residency) in the Kyrgyz Republic".
3. International Standards of the World Federation of Medical Education (WFME) for Improving the Quality of Postgraduate Medical Education (WFME, 2015), the World Health Organization (WHO) and the International Pharmaceutical Federation (IFF).
4. Development of pharmaceutical practice: focus on the patient. - B.: 2008. -112 C. CitiHope International, Inc.
5. Federal State Educational Standard of Higher Education in Residential Specialties, Russian Federation.

Postgraduate medical education
About the approval of the catalog of competencies of the
specialty " Organization of pharmaceutical activities"
to the draft order
approval sheet

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Arjuib will present the project

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