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Applying for an operating license for a hospital pharmacy

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/392896043/L100008>

Modul	Sachverhalt
Leistungsschlüssel	99004001005000
Leistungsbezeichnung I	Applying for an operating license for a hospital pharmacy
Leistungsbezeichnung II	Applying for an operating license for a hospital pharmacy
Typisierung	2 - Bundesauftragsverwaltung: Regelung, 3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Sachsen-Anhalt
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Erlaubnis (5)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und

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	Führung eines Unternehmens
Lagen Portalverbund	Anmeldepflichten (2010100), Erlaubnisse und Genehmigungen (2010400)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	26.08.2024
Fachlich freigegeben durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/apog/_14.html https://www.gesetze-im-internet.de/apobetro_1987/BjNR005470987.html#BJNR005470987BJNG000301307 https://www.gesetze-im-internet.de/apog/_14.html https://www.gesetze-im-internet.de/apobetro_1987/BjNR005470987.html#BJNR005470987BJNG000301307
Teaser	You need a license to operate a hospital pharmacy. You can apply for this from the local competent authority.
Volltext	If you want to operate a hospital pharmacy as the owner of a hospital, you must apply for a permit to do so. The hospital pharmacy is a functional unit of a hospital. It is responsible for the safe and proper supply of one or more hospitals with medicines and pharmacy-only medical products. It also informs and advises doctors, nursing staff and patients about the medicines and medical devices used. In order to obtain the operating license, you must provide evidence of the prescribed premises and employ a pharmacist who meets the requirements of the Pharmacy Act as a manager. A hospital does not necessarily need its own hospital pharmacy, but can also be supplied by the pharmacy of another hospital or a public pharmacy (hospital-supplying pharmacy) on a contractual basis.

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Erforderliche Unterlagen

- Proof of the rooms required for a hospital pharmacy:
 - Floor plan of the pharmacy operating rooms
 - The size, location, furnishings and function designations of the individual pharmacy operating rooms must be visible
 - For new openings: copy of the building permit from the building supervisory authority
 - Notification of the number of employees, broken down into specialist staff and other staff

The following documents must be submitted by the head of the hospital pharmacy:

- Identity document, proof of nationality if applicable
- Tabular proof of activity after licensure as a pharmacist
- Certificate of licensure (certified copy or transcript)
- Certificate of good conduct, document type 0 for submission to an authority
- Medical certificate of suitability to properly manage a pharmacy (not older than 3 months)
- Declaration of
 - legal capacity
 - any criminal proceedings, professional court proceedings and investigation proceedings as well as the authorization to practice the profession with regard to the reliability check
 - the operation of other pharmacies
 - the complete existence of all contracts and agreements relating to the establishment and operation of the pharmacy
 - the completeness and accuracy of the information

Documents in accordance with the Pharmacy Act must be submitted.

More detailed information on the type and scope is provided by the relevant local authority.

The place and date of the planned new establishment

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	or the name of the pharmacy to be taken over and contact details (telephone, e-mail, address) are mandatory. https://lwva.sachsen-anhalt.de/fileadmin/Bibliothek/Politik_und_Verwaltung/LVWA/LVwA/Familie-Ges-Jug-Vers/Gesundheit_604/Bereich_Pharmazie/Merkblatt_Apothek.pdf https://www.gesetze-im-internet.de/apog/_14.html https://lwva.sachsen-anhalt.de/fileadmin/Bibliothek/Politik_und_Verwaltung/LVWA/LVwA/Familie-Ges-Jug-Vers/Gesundheit_604/Bereich_Pharmazie/Merkblatt_Apothek.pdf https://www.gesetze-im-internet.de/apog/_14.html
Voraussetzungen	• You must employ a pharmacist who fulfills the requirements of the Pharmacy Act • Proof of the rooms required for hospital pharmacies in accordance with the Pharmacy Operating Regulations
Kosten	Gebühr: 750€ - 3.000€ https://www.landesrecht.sachsen-anhalt.de/bsst/document/jlr-GebOST2012rahmen Different regulations in the countries.
Verfahrensablauf	• First, you should contact your competent authority to describe your project and discuss the scope of the documents to be submitted. • Next, submit a complete written application. • Your application will be reviewed by the competent authority. • If necessary, the competent authority will request further documents. • If the requirements of the Pharmacy Act are met, you will be issued an operating license. • Pharmacy operations may only commence after an acceptance inspection by the competent authority. You must submit all essential documents in the original or as a certified copy. You can send the notification including the required documents in advance by e-mail.

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Bearbeitungsdauer	If all application requirements or all documents necessary for the granting of a permit have been submitted, the normal processing period is 4 weeks.
Frist	You may only start operating your hospital pharmacy once the competent authority has granted you permission to do so.
weiterführende Informationen	https://www.abda.de/ueber-uns/bak/ https://www.abda.de/ueber-uns/bak/
Hinweise	
Rechtsbehelf	Action before the administrative court • Objection • objection • Administrative court action At the end of each notification, the competent local court is indicated where you as the applicant can lodge an appeal against a negative notification in most cases.
Kurztext	• Operation of a hospital pharmacy Permit • A hospital pharmacy may only be operated after a permit has been issued • The written application must be submitted by the responsible body of the hospital • The head of the hospital pharmacy must be named in writing • A hospital does not necessarily need its own hospital pharmacy, but can also be supplied by the pharmacy of another hospital or a public pharmacy (hospital-supplying pharmacy) on a contractual basis • Responsible: LVwA
Ansprechpunkt	Please contact the State Administration Office.
Zuständige Stelle	
Formulare	

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Ursprungsportal	Betriebserlaubnis für Krankenhausapotheke beantragen, Applying for an operating license for a hospital pharmacy