

99603003261000

Notification of the prescription of a substitution drug Acceptance

Heruntergeladen am 06.06.2025

<https://fimportal.de/xzufi-services/118247108/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99603003261000
Leistungsbezeichnung I	Notification of the prescription of a substitution drug Acceptance
Leistungsbezeichnung II	Report the prescription of a substitution drug to the substitution register
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Prüfung und Nachweise für Sachkunde und Sicherheit (2120300)

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	14.04.2025
Fachlich freigegeben durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/btmg_1981/_13.html https://www.gesetze-im-internet.de/btmvv_1998/_5b.html
Teaser	As a doctor, you must report to the substitution register if you prescribe substitution medication to opioid-dependent persons. You can request your access data from the Federal Institute for Drugs and Medical Devices (BfArM) for the first online notification.
Volltext	Opioid addicts can benefit from substitution therapy. The Federal Opium Agency of the Federal Institute for Drugs and Medical Devices (BfArM) maintains a corresponding data register for prescribed substitution drugs. If you as a doctor prescribe substitution substances for opioid-dependent persons, you must report this to the BfArM's substitution register. The purpose of the substitution register is to help detect and prevent multiple treatments as early as possible. In addition, the BfArM compiles statistical evaluations based on the data for the responsible state authorities. You can submit a report to the substitution register via an online service of the BfArM. If you are submitting a report via the online service for the first time, you must apply for access data from the BfArM in advance.
Erforderliche Unterlagen	If you submit your notification in writing: • Form "Notification to the Substitution Register"
Voraussetzungen	• You are a doctor. • You carry out or intend to carry out substitution treatment.
Kosten	There are no costs.

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Verfahrensablauf

You can report the prescription of substitution substances in writing or online. To use the online service of the Federal Institute for Drugs and Medical Devices (BfArM), you must apply for access data in advance. You can do this either online or informally by post.

Apply for access data online:

- Go to the website of the federal portal and open the online application. This will guide you step by step through the necessary information.
- You will need an electronic ID document such as the online function of your ID card and a BundID account.
- Submit the application.
- The BfArM will check your details.
- The BfArM will notify you if you need to submit additional information or documents.
- The BfArM will send you the access data and a PIN by post, whereby the access data and PIN will be sent in 2 separate letters.

Apply for access data by post:

- Compose an informal letter with the following details:
 - Your full name,
 - Your date of birth,
 - Your full business address
 - Address of the facility where you carry out the substitution treatment,
 - Your work telephone number,
 - your narcotics number (BtM number).
 - Sign the informal application and send it by post to the Federal Opium Agency of the BfArM.
 - The BfArM will check your details.
 - The BfArM will notify you if you need to submit additional information or documents.
 - The BfArM will send you the access data and a PIN in 2 separate letters by post.

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If you have lost your access data or suspect unauthorized access, you can request new access data from the BfArM.

Report the prescription of a substitution product online:

- Call up the BfArM form server.
- Log in with your personal access data and PIN.
- Enter all the required information in the data fields provided.
- Check the data you have entered.
- Send the notification of prescribed substitution substances.

Report the prescription of a substitution substance in writing:

- Complete the "Notification to the substitution register" form in full.
- Send the form to the BfArM.

Bearbeitungsdauer	7 Tag(e)
Frist	If you prescribe substitution substances for opioid-dependent persons, you must report this immediately to the BfArM substitution register.
weiterführende Informationen	https://www.bfarm.de/DE/Bundesopiumstelle/Substitutionsregister/onlineMeldeVerfahren.html
Hinweise	There are no indications or special features.
Rechtsbehelf	No legal remedy is provided for.
Kurztext	• Doctors must report prescriptions of substitution substances to the substitution register • Notification to the substitution register possible by post or online • Access data and PIN for online reporting procedure must be requested in advance from the Federal Opium Agency of the Federal Institute for Drugs and Medical

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	Devices (BfArM) • online or by post
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Meldung über die Verschreibung eines Substitutionsmittels Entgegennahme, Notification of the prescription of a substitution drug Acceptance