FZZ-P17 STANDARDNA OPERATIVNA PROCEDURA ZA RUKOVANJE LEKOVIMA KOJI SADRŽE PSIHOAKTIVNE KONTROLISANE SUPSTANCE U AMBULANTNOJ PRAKSI

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Lekovi koji sadrže psihoaktivne kontrolisane supstance podležu strogim zakonskim zahtevima. Standardna operativna procedura (SOP) je razvijena u Domu zdravlja "Novi Sad" sa ciljem da se osigura bezbedno i sledljivo rukovanje ovim lekovima u skladu sa važećim zakonskim zahtevima.

Razvoj procedure se bazirao na propisima Republike Srbije i zahtevima Dobre apotekarske prakse. Definisane su aktivnosti koje se odnose na prijem lekova i kontrolu usklađenosti isporuke sa pratećom dokumentacijom, te način reklamacije u slučaju odstupanja; bezbedno skladištenje; izdavanje kroz posebno trebovanje; i vođenje evidencije. Predviđene su periodične provere usklađenosti stvarnog i evidentiranog stanja zaliha, kao i postupanje u slučaju sumnje na gubitak, neovlašćeni pristup ili zloupotrebu, uključujući prijavljivanje odgovornom licu, vanredni popis uz analizu uzroka, dokumentovanje činjenica i sprovođenje korektivnih i preventivnih mera (npr. ograničavanje ovlašćenja, pojačan nadzor nad evidencijom). SOP obuhvata i rashodovanje lekova te njihovu predaju ovlašćenom operateru za trajno zbrinjavanje opasnog otpada; izradu godišnjeg izveštaja za Ministarstvo zdravlja; definisanje odgovornosti zaposlenih i njihovu obuku; periodične revizije nakon izmena propisa; i praćenje primene kroz interne kontrole i definisane indikatore kvaliteta (usklađenost stvarnog i evidentiranog stanja zaliha, udeo rashodovanih lekova, potpunost dokumentacije i evidencije).

Konačno, uvođenje automatizovanih sistema za izdavanje i skladištenje lekova predstavlja potencijalni pravac za dodatno unapređenje bezbednosti i sledljivosti rukovanja lekovima koji sadrže psihoaktivne kontrolisane supstance.

FZZ-P17 STANDARD OPERATING PROCEDURE FOR HANDLING CONTROLLED DRUGS IN AMBULATORY PRACTICE

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Controlled drugs are subject to strict legal requirements. A standard operating procedure (SOP) was developed at the Health Center "Novi Sad" with the aim of ensuring the safe and traceable handling of these medicines in accordance with applicable legal requirements.

The development of the procedure was based on the Republic of Serbia's rules and the Good Pharmacy Practice requirements. Activities have been defined regarding the receipt of medicines and verification of delivery compliance with accompanying documentation, alongside the complaint report in case of discrepancies; safe storage; dispensing via a separate requisition; and record-keeping. Periodic audits of compliance between actual and recorded inventory levels are envisaged, as well as proceedings for suspected loss, unauthorized access, or misuse, including reporting to the responsible person, an extraordinary inventory with root cause analysis, documentation of the circumstances, and implementation of corrective and preventive measures (e.g., access privilege restrictions, enhanced record monitoring). The SOP also covers the disposal of expired or damaged medicines and their transfer to an authorized operator for the permanent management of hazardous waste; the preparation of an annual report for the Ministry of Health; the definition of employee responsibilities and their training; periodic revisions following regulatory changes; and the monitoring of implementation through internal audits and defined quality indicators (actual and recorded inventory level compliance, disposed medicine proportion, documentation and record completeness).

Finally, the introduction of automated dispensing cabinets represents a potential direction for further improving the safety and traceability of handling controlled drugs.