

## **(I) Standard: Drug storage and recordkeeping**

**§483.460(I)(1) The facility must store drugs under proper conditions of**

**Guidance §483.460(I)(1)**

Drugs are stored according to manufacturer's recommendations.

### **W377**

sanitation,

### **W378**

temperature,

### **W379**

light,

### **W380**

humidity,

### **W381**

and security.

## **W382**

**§483.460(l)(2) The facility must keep all drugs and biologicals locked except when being prepared for administration.**

## **W383**

**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)**

**§483.460(l)(2) Only authorized persons may have access to the keys to the drug storage area.**

### **Guidance §483.460(l)(2)**

"Authorized persons" is restricted to those who administer the drugs (as allowed by state law) and nursing supervisors (if any). No other personnel should have access to these keys.

## **W384**

**(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)**

**§483.460(l)(2) Clients who have been trained to self-administer drugs in accordance with §483.460(k)(4) may have access to keys to their individual drug supply.**

### **Guidance §483.460(l)(2)**

Drugs that are self-administered do not have to be double locked. The purpose for the double locking is to limit access to scheduled drugs. Since the client is generally the only one who has access to his/her drug supply (with perhaps the exception of a licensed nurse or whoever has overall responsibility for medication administration at the facility and a facility's Director of Nursing Services, who may have access to all of the facility's drug supplies), there is no need to further limit access.

### **W385**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

**§483.460(l)(3) The facility must maintain records of the receipt and disposition of all controlled drugs.**

#### **Guidance §483.460(l)(3)**

The facility must follow state requirements for the control and disposition of controlled drugs.

### **W386**

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

**§483.460(l)(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq., as implemented by 21 CFR Part 308).**

#### **Guidance §483.460(l)(4)**

The facility should follow state requirements for the reconciliation of controlled drugs.

### **W387**

**§483.460(l)(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs**