Attachment B from Medication Samples

Requirements for Medication Dispensing to Ambulatory Patients

Definition

Dispense – means to interpret, evaluate, and implement a prescription medication order or chart order, including the preparation of a medication or device for a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to or use by a patient.

Sample -means any prescription medication given free of charge to any practitioner for any reason except for a bona fide research program.

LABELING REQUIREMENTS FOR DRUGS DISPENSED TO OUTPATIENTS

Labels must contain:

1. Name, address and telephone of dispenser (i.e., Denver Health Medical Center, _____ Department, 777 Bannock St., Denver, CO 80204 (303)436-____)
2. Full name of the patient
3. Name of the medication, strength, and amount dispensed*
4. Directions to the patient regarding how to use the medication
5. Name of the prescribing practitioner
6. Name or initials of the dispensing individual and date dispensed
7. DEA caution labels and/or patient ancillary labels for safe use
8. Pharmacy's identifying serial number+

*will be affixed to containers of unit of use

+applies only to medications dispensed from an outpatient pharmacy

PATIENT ASSISTANCE PROGRAM MEDICATIONS

Patient Assistance Program (PAP) medications dispensed from non-pharmacy areas of the agency must be labeled in compliance with applicable laws and this policy (#1-7 above).

SAMPLE MEDICATIONS

Samples dispensed from non-pharmacy areas of the agency must be labeled in compliance with applicable laws and this policy (#1-7 above).

PACKAGING

All medications dispensed to outpatients will be packaged to conform with the Poison Prevention Packaging Act PPPA (PL 91-601), December 30, 1970. All medications dispensed from a pharmacy and issued from a pharmacy to another area for dispensing will be packaged in accordance with PPPA. Other dispensing areas should not remove the seal from unit of use packaged medications. "Blister pack" medications are considered appropriately

packaged but labeling is incomplete for the purpose of dispensing to patients.

References:

1. CRS 12-42.5: Pharmacists, Pharmacy Businesses, and Pharmaceuticals. Accessed on Feb 1, 2021 at: https://www.colorado.gov/pacific/sites/default/files/atoms/files/Pharmacists%2C%20Pharmacy%20Business%2C%20and%20Pharmaceuticals%20Practice%20Act.pdf
2. 21 CFR Part 203: Prescription Drug Marketing. Accessed on Feb 1, 2021 at: http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr203_02.html
3. CPMG 7356.022: Enforcement of the Drug Sample Distribution Requirements of the Prescription Drug Marketing Act (PDMA). Accessed on Feb 1, 2021 at: https://www.fda.gov/media/85415/download