

**Texas Department of State Health Services  
Pharmacy Branch  
March 15, 2018**

**Updated Guidelines on the Use of Directly Observed Therapy  
(DOT) Packets for Patient Self-Administration**

In December 2017, the DSHS Pharmacy Branch sought clarification from the Texas State Board of Pharmacy (TSBP) regarding the provision of DOT packets for patient self-administration (i.e. weekend/holiday doses, video DOT, etc.).

The TSBP recommendations are to reclassify DOT packets to fall under physician provision of medications per Texas Occupations Code, Title 3, Chapter 158. This states a physician may provide medications to a patient, free of charge, as part of an indigent pharmaceutical program for adherence to a course of treatment.

When physicians provide medications in this manner, there are labeling requirements that must be met in accordance with Texas Dangerous Drug Act, Section 483.042(a)(2)).

These are:

- The name and address of the medical director or physician who prescribed the drug;
- The date the drug is delivered to the patient;
- The patient's name; and,
- The name, strength and directions for use of the drug(s).

See sample label below:

**Sample Label**

<p>Harris County Public Health Department 123 Main St Houston, TX 77000 713-555-1212</p>
<p>Date: 01/01/2018 Physician: John Watson, MD Patient: Jane Doe Medications: Rifampin 600mg, Isoniazid 300mg, Pyrazinamide 1600mg, Ethambutol 800mg, Pyridoxine 50mg Instructions: Take 2 packets each day</p>

This label must be placed on each Ziploc bag containing the DOT packets with the required information printed or handwritten by the clinician/nurse at the time medication is provided to the patient.

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**Frequently Asked Questions**

**Does this mean we can return to ordering packets for VDOT instead of the individual bottles?**

Yes. DOT packets can be provided to the patient for self-administration as long as the above labeling requirements are met.

**What about weekend/holiday/vacation doses?**

These doses can be provided using DOT packets. Again, make sure the label meets the requirements above. If a small, child-resistant container for weekend doses is needed, you may order amber prescription vials through ITEAMS. Otherwise, you may provide medications in amber-colored bags (not child-resistant) provided by the DSHS Pharmacy Branch.

**Will we see any changes in what DSHS Pharmacy Branch provides to us?**

Yes, beginning March 19, 2018, DOT packets will be sent out in light-resistant, amber zip closure bags instead of clear plastic bags. These bags are not child-resistant, but block ultraviolet light exposure to the medications.

**What about child-resistant closures?**

These new amber zip closure bags will NOT be child-resistant. According to the Consumer Product Safety Commission's guide for Poison Prevention Packaging, "the medical provider has the authority to specify non-complying packaging for his/her patients". Non-complying packaging means not child-resistant. If child-resistant packaging is desired, the amber prescription vials are available for order from the Pharmacy Branch in ITEAMS. For larger items, please contact the DSHS Pharmacy Branch for options.