DPH LABELING GUIDELINES FOR SAMPLE PRESCRIPTION DRUGS

Regulations permit practitioners to dispense up to a 30 day supply of Schedule VI sample medications. Larger supplies of sample medications, up to 90 days, may be dispensed as part of a manufacturer's indigent drug program. Samples of Schedule II, III, IV or V medications are limited to a single dose or to a quantity needed for immediate treatment.

Labeling Requirements

Practitioners must label all sample medications dispensed to patients, including those provided as part of an indigent patient drug program (see M.G.L. c. 94C §22 and 105 CMR 700.010). Labels must contain the information described below; however, the method of labeling the medications may vary. For example, sample medications may be placed in a larger container such as an envelope with the required information written or typed on the front. Alternatively, the label may be a piece of paper affixed to the sample packaging or to a container holding the samples. The label may also be inserted inside a container holding the drug samples. This container may be a plastic or paper bag, an envelope or a box. However, the regulations specify that a container must hold only one type of drug sample. Thus, different drugs and their accompanying labels may not be mixed in a single container.

The following information must appear on the label provided to the patient:

- Practitioner’s name and address
- Date of dispensing
- Name of the patient

In addition, the following information must be on the label if not included on the manufacturer's packaging of the sample medication. Physicians may use a combination of written information, labeling and counseling to provide this information.

- Name, Dosage form and strength of the sample medication
- Clear, simple and brief directions for use and any necessary cautionary statements
- Date on which medication will expire

Pharmaceutical companies may assist prescribers by providing pre-printed labels. Below are model labels prepared by the Department.

Manufacturer's Logo (if desired) **Practitioner's name/address** **Patient's Name** **Date Dispensed**

If not on the manufacturer's package, include:

Drug Name **Cautionary Statements** **Dosage Form and Strength** **Expiration Date** **Directions for Use**

For further information, contact the Drug Control Program at (617) 983-6700.