

Attachment 15: Medication Container Labeling

The labeling of medications is regulated by both State and Federal law. The exact laws are located in FDCA Section 503(b)(2) (21 U.S.C. § 353(b)(2) and NCGS 106.134.1.

Based on these two regulations, any dispensed medication should contain the following:

- Patient name
- Pharmacy name and address
- “Filled by...” (denoting the pharmacist who actually completed the filling of the medication)
- Rx number and date filled
- Name of prescriber
- Directions for use
- Name (brand and generic) of medication
- Strength of medication
- Discard date also know as the expiration date

In an emergency where mass dispensing is required, it is time prohibitive to label every bottle individually with all of the above information. There are multiple ways to accomplish labeling in a declared emergency. Below are the two types of bottles for bottles that will be issued from DSNS; shown on the following page as Figure 1 and Figure 2. The bottle in Figure 1 (front and side view) is for ciprofloxacin, doxycycline and amoxicillin. The bottle in Figure 2 (multi colored) is what some doxycycline may come in.

These bottles contain most of the required information either attached to the bottle (as on the left) or as sheets of labels to be added to the bottles (as on the right). The patient name, and in some cases directions for use, need to be added to the bottle. Although directions are on the bottle in Figure 1, they are not on the bottle in Figure 2. In addition, the directions only apply to patients who will use the standard directions; children and patients with kidney disease will need alternative directions. In Figure 2, the labels are shown. These labels do not come affixed to the bottle. They come pre-printed on sheets of labels and need to be affixed to the bottles. With both bottles, 2 labels are available. One remains with the bottle and the other is to be affixed to the NAPH form that remains with the health department.

Patient name needs to be added directly to the bottle. This can be done by having the patient use a permanent marker to write on the bottle or writing the name on a self adhesive label and placing it on the bottle. Families are likely to end up with more than one type of antibiotic. In order to avoid confusion and error, the patient name should be on the bottle. Other information, such as the dispensing location and prescriber, could be included on the printed patient information.

It is also acceptable to completely re-label either bottle. A template label is being created and will be distributed soon. This label will contain all information and only name of the patient will need to be added and then the label place on the bottle. A standard Avery self-adhesive label will be used for this template.

Because the bottle for ciprofloxacin, doxycycline and amoxicillin will all look the same, you may wish to color code the bottles. This can be done by using color ink on the labels or attaching a colored sticker to the bottle. Patient information could then be printed on the same color paper. To promote consistency, if your county choose to proceed with color coding, please make every effort to use **RED** for doxycycline, **GREEN** for ciprofloxacin and **YELLOW** for amoxicillin.

Figure 1



Figure 2



**Doxycycline 100 mg
20 TABLETS
Lot # SAMPLE EXP: 00-00
Rx 5220953**

**Doxycycline 100 mg
20 TABLETS
Lot # SAMPLE EXP: 00-00
NDC 66336-449-20**