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Board of Registration in Pharmacy

Advisory: Sterile Injectable Dispensing (Including Testosterone)

In accordance with United States Pharmacopeia ("USP") <659> *Packaging and Storage Requirements*, a sterile single-dose vial is designed for use for a single patient as a single injection. Single-dose vials of injectable medications do not have preservatives and are only good for one dose. After that vial has been punctured once, any remaining drug must be discarded.

For example, if testosterone is prescribed as 0.25ml IM weekly for four weeks and the single-dose vial contains 1 ml, the vial would only be considered one dose, not four. Four 1 ml vials should be dispensed and labeled with instructions to discard the remaining contents after each dose. The four vials would be a 28-day supply.

Multiple-dose vials have a preservative to prevent or inhibit microbial growth allowing the vial to be used multiple times. However, USP requires any remaining volume to be discarded 28 days after the initial puncture (*unless otherwise indicated by the manufacturer*). For example, testosterone 0.5 ml IM weekly for four weeks using a 5 ml multiple-dose vial would be considered a 28-day supply. Labeling should include instructions to discard the remaining contents 28 days after the first entry into the vial.

As a reminder, [247 CMR 9.01\(3\)](#) requires pharmacists to comply with all current chapters of USP.

Please direct any questions to: Pharmacy.Admin@mass.gov