

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

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POLICY GUIDELINE TABLET-SPLITTING

The issue of dispensing of tablets that are "scored" has been addressed many times over the years. Clearly, these products are designed to be broken, and prescribers, pharmacists and patients alike can have confidence that the dosage delivered will be sufficiently accurate to achieve desired therapeutic results. Of course, pharmacists must be careful to clearly label prescriptions to ensure that the proper dosage is taken by the patient or administered by a caregiver.

The splitting of "unscored" tablets poses a number of related concerns. These include, but may not be limited to:

- Manufacturers may not guarantee that a drug is uniformly dispersed throughout the dosage form. Splitting such a product may not deliver comparable doses.
- Many new dosage forms are designed for sustained-release, continuous release, delayed release, etc. cutting these dosage forms may inappropriately alter their pharmacokinetic characteristics.
- Likewise, the concerns noted above might apply to "coated" tablets.
- ➤ Cutting a tablet not manufactured with a "score" may cause the product to crumble, or otherwise break in an uneven fashion. If pharmacists dispense products that do not deliver an accurate dosage, they might be considered to have dispensed an adulterated or misbranded product, or to have practiced in a negligent fashion.

We know that some pharmacists have dispensed whole tablets and instructed patients to cut them in half. If this is the choice of a prescriber and a patient is willing, a pharmacist might not be subject to some of the above noted concerns. However, not all patients are either willing or capable of cutting tablets.

Clearly, this issue is complex. What some might see as a short-term cost saving might otherwise result in higher costs to respond to therapeutic failures, etc. While there is nothing in current laws or regulations that would prohibit the cutting of unscored tablets in all cases, I hope the considerations we have identified provide guidance to pharmacists. In all cases, professionals must apply their judgment to best serve their patients. As we have often noted, corporate or other pressures are not a defense in professional misconduct proceedings.