

Attention: If you or your group practice purchases prescription drugs, you may need to obtain additional permitting.

On May 1, 2008, the Florida Legislature passed HB 7049. In addition to substantially reorganizing Chapter 499, Part I, Florida Statutes, the bill created two new permits under the Drugs, Devices and Cosmetics Program. One of the new permits is called a "Health Care Clinic Establishment Permit." Effective January 1, 2009, certain medical practices may need a Health Care Clinic Establishment Permit (HCCE Permit) to purchase prescription drugs.

Under current law, health care practitioners in a group practice setting must individually order their own prescription drugs under their own license number for dispensing or administering to their own patients. These prescription drugs may only be dispensed or administered by the physician who ordered the drugs.*

Currently, there is no legal mechanism for a group practice to purchase prescription drugs in the name of the group practice for dispensing to any and all of the group's patients. Effective January 1, 2009, however, a practice may do so as long as the practice has an HCCE Permit. This permit is not necessary unless the practice wants to purchase and own the prescription drugs. Physicians who individually purchase prescription drugs for dispensing or administering to their own patients, are NOT required to have an HCCE Permit.

Unfortunately, little else about the new law is clear - the law is vague and ambiguous and its application is uncertain. The Department of Health has been unsuccessful in clarifying the many significant questions raised by this statute. Thus, the FMA is only able to provide the limited information below.

An HCCE Permit is required:

1. for the purchase of a prescription drug
2. by a place of business at one general location
3. owned and operated by a professional corporation (P.A.) or professional limited liability company (P.L.)
4. who desires to purchase and own the prescription drugs in the business entity's name.

If an eligible establishment chooses to obtain a permit, the establishment must designate a "qualifying practitioner" who will be responsible for complying with all legal

and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. The qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment.

If the establishment has more than one location (i.e. satellite offices), a qualifying practitioner must be employed at each location. It is not clear whether each location is required to obtain a separate permit, however, since this is unclear, it would be prudent to obtain a separate HCCE Permit for each location.

* Despite these regulations, it is common for one or more physicians in a group practice to order prescription drugs under their license number which are then dispensed or administered by all members of the practice.