

unfair to those who must pay individual registration fees and suggested that before registration fees are increased that DEA require all prescribers of controlled substances to be individually registered. Two commenters noted that it is expensive to license multiple practitioners in a practice and that a fee increase would encourage practitioners to forego licensure of all practitioners especially in large practices. One also noted that it would be beneficial if practitioners could work under an umbrella license for the whole clinic.

The Controlled Substances Act requires that every person who manufactures, distributes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance obtain an annual registration. 21 U.S.C. 822(a)(1) and 822(a)(2). However, the Controlled Substances Act also provides for certain exceptions, including "an agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment." 21 U.S.C. 822(c)(1).

More specifically, "an individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances" may be exempted from securing his or her own registration but may "when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself." 21 CFR 1301.22. That is, within a group practice, for example, one DEA-registered physician may take the responsibility for ordering a stock of controlled substances from which other physicians in the practice could dispense. However, only the DEA-registered physician would be authorized to issue prescriptions for controlled substances. That is, prescriptions written under a particular DEA number may *only* be written by the physician possessing that registration number.

Additionally, an individual practitioner who is an agent or employee of a hospital or other institution also may administer, dispense, or prescribe controlled substances under the registration of the

hospital or other institution which is registered in lieu of being registered him/herself (much like a pharmacist operates under the pharmacy's DEA registration). However, such registration is permissible only if: (1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice; (2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing; (3) The hospital or other institution by which he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction; (4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution; (5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized; and (6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner (21 CFR 1301.22). Other registrants would include pharmacies wishing to verify the identity and authority of individual practitioners to prescribe controlled substances. Note, state laws differ with regard to clinic registration and the use of "umbrella" registration numbers for employees of such clinics.

A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person (21 U.S.C. 822(e)).

C. Allocation of Fee Based on Usage

Four commenters raised issues related to allocation of the registration fee according to usage of controlled substances. Three commenters wrote that, because veterinarians use a limited amount of controlled substances, they should not be expected to be equal partners with other practitioners in funding the DCP. Another commenter stated that, as staff write only 12 controlled substances prescriptions per year, the fee increase would dramatically increase the cost of each of these prescriptions per unit.

The Controlled Substances Act mandates that "every person" who manufactures, distributes or dispenses

any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance obtain an annual registration (21 U.S.C. 822(a)(1) and 822(a)(2)). This statute mandates such registration irrespective of the extent such persons handle controlled substances. Accordingly, DEA may not alter the fee structure to account for the extent to which registrants handle controlled substances.

VIII. Enforcement of Controlled Substances Act

Several commenters expressed concern that Internet pharmaceutical companies selling veterinary products at discounted prices are undermining veterinarian revenue, with one commenter alleging that Internet and catalog pharmacies sell prescription medications directly to consumers without a prescription from a veterinarian. Three commenters wrote that it is "not in my profession[s] best interest to pay such exuberant fees * * * while the internet companies undercut the veterinarian." Another commenter stated that Internet pharmacies selling controlled substances to consumers without a prescription should be fined severely.

The mission of the Diversion Control Program, as outlined above, is to prevent the diversion of licit controlled substances in conformance with the Controlled Substances Act. All manufacturers, distributors and dispensers of controlled substances are required to obtain a registration with the DEA (21 U.S.C. 822(a)(1) and 822(a)(2)). This requirement includes Internet-based pharmaceutical companies that dispense controlled substances. No dispenser, including Internet-based companies, is permitted to dispense controlled substances without the prescription of a registered physician or other appropriate practitioner. DEA investigates and prosecutes violations of the Controlled Substances Act, including the dispensing of controlled substances without a legal prescription from an authorized and registered practitioner.

Four commenters, three from the same institution, objected to the ability of Internet pharmaceutical companies to sell veterinary products directly to consumers thus affecting sales directly through the veterinary clinics. Commenters expressed concern that clients were purchasing veterinary pharmaceutical supplies through the Internet companies when veterinarians "must write prescriptions," thus eroding pharmaceutical sales by veterinarians and undermining the