

December 29, 2008

Dear Jackie:

I attended the DWAC meeting on behalf of AVDA earlier today. As I had previously indicated, the Department recently issued a Q&A on the new HCCE permit (see attached) that indicated that practitioners in a group practice could "use" drugs purchased by another member of the group practice. There was some ambiguity as to whether the term "use" meant solely administering or whether it also included dispensing. The Department subsequently clarified that as far as vets are concerned, "use" includes administering and dispensing from that stock. This clarification was provided in an e-mail to the Executive Director of the Florida Veterinary Medical Assn, and I followed up to confirm this on a phone call to Greg Jones, a staff member of the Drugs Devices and Cosmetics program (DDC) within the Department of Health. One of the arguments mentioned by Greg Jones is that vets do not fall within the definition of "dispensing practitioner" found in §465.0276, Florida Statutes, because that definition (and the requirements associated with same) only applies to practitioners that dispense drugs for human consumption.

I brought the subject up during the DWAC teleconference call, and the matter was discussed and is now part of the record of that meeting. It was reiterated that one vet in a group practice may buy the drugs which may be used (administered or dispensed) by other vets in the same group practice, so long as the wholesaler invoices those drugs to the name and license # of that individual vet.

Finally, and in an e-mail to Rebecca Poston, Executive Director of the DDC program, she confirmed the Department's position (which had been discussed at the December 4 DWAC meeting) that they will not look into who actually pays for the drugs, so long as the invoicing is correct. This means that a wholesaler can invoice to the name and license # of an individual vet, and be paid with a company check. Please let me know if you have any questions.

In response to the question why must the HCCE permit number appear on distribution documents, §499.0121(6)(a)2., F.S., requires that the name, address and permit or registration number of the person authorized to purchase prescription drugs must be part of the audit trail. The HCCE is the person authorized. Section 499.01(2)(t) basically states that in addition the name and license # of the qualifier must also appear.

As far the responsibilities of drug wholesalers who wish to sell to corporations that have applied for, but have not yet received, a HCCE permit, there was discussion concerning this point, and the Department conceded that many entities that have made application for this permit will not have it come January 1. Staff from the Department indicated that they were aware of the problem and that it was not their intention to start aggressively policing this right away. There was some discussion about listing the names of those entities that have made application on the DOH website so that wholesalers would feel more comfortable selling to them even though they did not yet have a permit number. Although this was left up in the air, it appears based upon the discussion that any wholesaler that has actual notice that the corporation has made application for the HCCE

permit (as for example getting a copy of the application from the company) would have made enough due diligence to avoid a problem with the Department down the road. I know that this is no guarantee, but it is the best I can offer under the circumstances. My advice is that in the interim the invoice be made to the name and license number of a vet in the practice.

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