**NABP Interactive Compliance Officer/Legal Counsel Forum December 1-2, 2015**

Attended by Jennifer Tiffany and Laura Steffensmeier

Takeaways from session on Drug Supply Chain Security Act

* MA—they are registered 503B facilities located both in-state and out-of-state. They are not allowing facilities to be licensed as both a pharmacy and a 503B facility. They allow for provisional registrations wherein the facility can make product but the product cannot leave the facility until the FDA has inspected.
* IL —they see 503B facilities as manufacturers and, therefore, are not doing a unique state licensure as an outsourcing facility.
* OR—requiring annual reporting from 503B facilities.
* NM—allow facilities to be licensed as both a pharmacy and a 503B, but require that everything be kept separate.
* NC—also has “dual use” licensees; pharmacy license for patient-specific prescriptions and outsourcing license for non-patient-specific compounds
* TN—Changed their definition of “wholesaler” to match federal law. This was done in light of DSCSA.
* 2 preemption issues with law
  + Traceability—states cannot have regulations that are more or less stringent than the federal standards and the regulations cannot conflict in any way
  + Wholesale licensure—state laws regarding wholesale licensure must be made consistent with the federal law within 26 months.
* Law requires that states perform an inspection for initial wholesale licensure. States are permitted to accept inspections from other states or third parties, such as NABP.
* Recommendation to ask wholesalers on license applications/renewals what wholesalers they purchase from. This may be helpful info if there is a situation where there are fraudulent transactions occurring between several wholesalers.
* FDA maintains a database of wholesalers and all wholesalers must report to FDA. One idea is to find out who is licensed in your state that is not on the list. These entities can be inspected or reported to NABP/FDA.
* Under the new law, pharmacies can no longer transfer drugs to other pharmacies—they can only transfer to a practitioner. A pharmacy to pharmacy transfer can occur only in the event of an emergency, and a drug shortage is not considered an emergency. There was a lengthy discussion about whether the MatchRX business model is legal under the new law, given that pharmacy to pharmacy transfer is severely restricted.
* States need to consider possession laws if they choose not to license 3PLs. Otherwise, 3PLs may be unlawfully be possessing prescription drugs and controlled substances. The majority of 3PLs distribute drugs on behalf of manufacturers. 3PLs are not required to pass transaction data because the 3PL never takes ownership of the drugs. (FedEx, UPS, and USPS would qualify as 3PLs.)
* “Intracompany Distributions” are a big hole in the DSCSA because they don’t qualify as needing to produce and maintain transaction records.
* There is a 10 year implementation of the DSCSA.

Takeaways from NC Dental session:

* The next issue for the lower courts to tackle is what constitutes active supervision.
* Another issue that will likely be addressed is whether damages would be available against licensing boards—the speaker thought if a court addressed this issue, it would determine damages are not appropriate.
* The speaker encouraged states to look at their coverage for damages, to ensure insurance policies are appropriate.
* OK instituted a process whereby every disciplinary case is reviewed by the attorney general’s office for supervision purposes—the consensus of the ground was this was unnecessary and maybe even unconstitutional.
* IL Boards are advisory only so they feel comfortable that they won’t face similar NC Dental-type issues.

Takeaways from Diversion and Fraud Prevention session:

* Gangs and Mexican drug cartels are finding it easier to recruit individuals to obtain employment as a pharmacy technician and have the technician divert controlled substances than to attempt a robbery or night break in.
* Seeing more pharmacies unlawfully making money by signing insurance logs that a patient picked up a high dollar prescription, when they never did. Then the pharmacy puts the drug back in stock but they don’t reverse the insurance claim.
* Several states have a dedicated Compliance Officer that just investigates diversion cases. (New Mexico rotates this position among their C.O.s every 4 months.)

Takeaways from Multistate Pharmacy Inspection Blueprint session:

* Ohio BOP uses Lenovo laptops during their inspections and have a digital inspection form. “Matrix Inspector” software is used. Ohio BOP worked with a software developer for a year to create the product.
* On Connecticut’s BOP website their USP 795 and 797 inspection checklists are available.
* Indiana also uses an electronic inspection report.
* NABP has a Multistate Pharmacy Inspection Blueprint for both USP 795 and 797, and they are providing these sample forms to help each state build their own unique form.

Takeaways from Multi-Topic sessions:

* NABP does have a Model Act that can be a good resource.
* During inspections, encourage states to ask pharmacies if they ship out-of-state.
* Some states have a non-drug pharmacy license that essentially has recordkeeping regulations. An alternative suggestion is to put recordkeeping rules in the pharmacist chapter.