

GROUP 4 (PHARMACY) BOARD DIRECTOR REPORT

February 2011

1.) Board Meetings Scheduled & Held

<u>Board</u>	<u>Scheduled</u>	<u>Held</u>	<u>Date</u>	<u>Reason Cancelled</u>
Pharmacy (Board)	February 14, 2011	Scheduled and Held		

2.) # of Out-of-State License Verifications Processed & Walk-ins Served

<u>Board</u>	<u># Processed</u>	<u># Walk-ins</u>
Pharmacy	3	18

3.) # of Complaints and Petitions for Summary Suspensions Filed by OAG

<u>Board</u>	<u># of Complaints</u>	<u># of Petitions for Summary Suspensions</u>
Pharmacy	7	0

4.) # of Full Board & ALJ Hearings and Personal Appearances (Disciplinary & Appeal)

<u>Board</u>	<u># of Full Board</u>	<u># of ALJ</u>	<u>Separate ALJ Day?</u>
Pharmacy	17	no	no
INSPECT	0	no	no
CSR Applications	0	no	no
EDI	0	no	no

5.) # of Discipline Actions Taken During Previous Month

<u>Board</u>	<u># put on Probation</u>	<u># of NPD</u>	<u># Suspended</u>	<u># Reinstated</u>
Pharmacy	3	3	3	1

<u># of Surrender</u>	<u># of Revocation</u>	<u># CE Audit Suspensions</u>
0	0	0

6.) Concerns & Additional Information

- **Staffing/HR:** Now that our Diversion Officer position has been filled by Eric Pearcy, we are moving forward on posting his vacant Compliance Officer Position for the Southern District of Indiana. The position has been posted and will remain open until March 1, 2011. I anticipate receiving resumes of candidates some time towards the end of the first week of march and scheduling interviews the second and third week of March. I'd like to have someone in the position by the beginning of April if possible. A tablet PC, a blackberry, and the assigned Car have already been secured.

This is a repeat from last month, but bears reiteration: I will also be advocating in the coming months for the creation of two new positions within the Board of Pharmacy. One position that I would call a Pharmacy "**Regulatory Affairs Coordinator,**" and the other "**Board of Pharmacy Assistant Counsel.**" The role of the attorney would be to assist in everything from rulemaking, legislative research, interpretation of law questions related to Board or licensee questions, Compliance Team/law enforcement guidance (i.e. – what does the law say we have the authority to do or not do), INSPECT related matters (including contracts, MOUs, HIPAA/Privacy matters, etc.), and in managing our litigation process. The role of Regulatory Affairs coordinator would be directed to assisting the director, the Board, licensees, and other State of Indiana agencies in navigating the complex regulatory structure that governs life sciences in the State of Indiana. This person would assist with complex licensing discussions with IEDC, companies like Medco, and large distributors or PBMS like Cardinal Health or Walgreens. This individual would also assist with strategic planning and identifying areas where the Board needs to address policies, rules, or statutes that impede pharmacy business or effective oversight of pharmacy in Indiana. For example, this individual would help oversee the approval of automated pharmacy systems, development and approval of prescription pads, and assist with stakeholder communications (all the meetings with IEDC, etc.).

The only change in the position noted above is with respect to the attorney position. Between Josh Klatte and I we think we may have come up with a way to fund the position within our existing budget restraints, but it would require money and positions around. It would require moving staff within existing positions. We are in the process of preparing a memorandum to executive staff to address the possibility of making these changes and putting a request in to State personnel.

- **IT Update & Issues:** We are currently working with IT to prepare our renewals for Pharmacist Interns. They renew from March 1, 2011 – April 30, 2011 and expire on March 1, 2011. Unfortunately, because of the manner in which we require them to do renewal (and with the frequency with which they change addresses because of school and summer jobs), we will be mailing their renewals to them. Fortunately, this is a small number, so it will not have a major impact and will probably save us more money, time, and energy overall as opposed to other methods. Please note, b/c of the requirements for intern renewals, they are not capable of renewing online (we have to receive documentation from their respective schools).

We are also continuing to use the functionality of the sharepoint site, our board website, and facebook page to exchange data amongst staff, the compliance team, and the Board. We recently started scheduling inspections through shared calendars between the administrative staff and compliance staff. Also, we have made several major upgrades to our external facing website. We have made all of our electronic inspection templates available, and we have also updated multiple applications and instructions for different license types. Amy Phillips also built out instructions and an application for a “new” license type. The license is not new but the manner in which we allow it to be applied for is – we now allow people to specifically apply for remote locations to their existing pharmacies (allowed by law already but not contemplated or discussed in any of our applications or instructions). This has come about because of increased use and approval of new technologies available in the healthcare sector (another instance where are laws and regs are not keeping pace with the changes taking place in practice).

In conjunction with the INSPECT launch of RxWatch we are also beefing up our data collection vis a vis reporting thefts and losses and filing complaints. We have upgraded our links and directions for this functionality. We are also revising questions within the eMobile Inspection system to continue collecting better data. We hopefully will soon be at a point where all pharmacies in the State of Indiana have been inspected using the new system.

One new functionality we would like to explore is to allow our licensees to sign up to receive emails each time we update certain sections of our site – i.e., the announcements page (which we update approximately once a month but plan to update more frequently as we roll out new services like the newsletter and renewal announcements).

- **Abandon Rate:** Our abandoned call rate for the month of February was 2% (a repeat of the month of January – showing strong consistency and performance for the group that I attribute to achieving balanced staffing and improved coverage, especially with the addition of our newest case manager who is now up to speed on all things pharmacy). Again, we tied for first place in the agency among all groups for the month (two months in a row now). We are still experiencing slightly lower than average call volume at this time. I am not sure whether this is attributed to more proactive outreach, which in turn is stifling calls, or the fact that we are not currently in a renewal cycle for any of our license types (which will soon change starting in March).
- **Legal/Legislative:** Like January, February was an extremely busy month for pharmacy based legislation. We have been tracking multiple bills including (but not limited to): unused medications, pharmacy take back, immunizations, collaborative practice, drug substitution, criminal background checks, communications requirements, scheduling and/or tracking of PSE, scheduling of spice, etc.

We participated heavily in the pharmacy take back bill and provided testimony on the impact and need for take back legislation. The Take Back Bill was one of the bills that the Board crafted. We are starting to work with the Unwanted Meds Task Force in

anticipation of the bill passing and being authorized to implement rules. I reported to the Board at the February meeting that the bill successfully passed out of the House and is now awaiting assignment to committee and a hearing in the Senate.

- **Economic Development:** We are still working with Advion BioSciences and Stericycle to address their licensing needs and timelines. Both are projects that IEDC has asked that we continue to be involved in and will have job implications for Central Indiana. Stericycle is seeking to do a major expansion, but is struggling with satisfying the licensing requirements based on their business model (the licensing requirements are outdated and don't fit their business specifically but are still required for them to meet – they are working with us to find a good middle ground that the State and Board can be comfortable with). Advion is willing to be licensed but just has expedited inspection needs and application review needs based on its business timeline and that of its client (the good news – they have proactively sought out our assistance and asked all the right questions to ensure they meet all requirements). I don't anticipate any problems but may need to relax inspection timelines in conjunction with their obtaining a DEA Registration and going through their inspection.
- **Board President Meeting:** The new Board President, Bill Cover, and I met on February 21st, to go over material that was presented at the February meeting and material that will be presented at the upcoming March Meeting. Bill specifically outlined some priorities he'd like to see the Board address over the next year. Rulemaking specifically, the transfer of prescriptions rule and others relating to remote/order entry and telepharmacy. Our ability to move these types of rules forward has been complicated by the fact that they are not process rules but substantive practice rules that involve substantial detail and research that we are not necessarily equipped to do at the current staffing level without additional resources and competency (i.e., they are not changing a fee or requiring more CE or specifying approved providers).
- **Update on Boxes:** We are pretty much in the same as last month vis a vis the remaining boxes (litigation files and old renewals from the back storage room), but we have made additional progress in completing the indexing process (which moves us one step closer to destruction). The next step in the process will be receiving approval for destruction from Maureen and ICPR or shipping the remaining scanned and indexed boxes off to ICPR for destruction at a predetermined date by them. We have approximately ten boxes left (some of which included a recent box of new license files). We still anticipate being finished by the end of first quarter.
- **Renewal Issues/Update:** We start renewals for our Pharmacist Interns on March 1, 2011 and they expire on May 1st. Our call volume and mail volume should increase, but not substantially since this is one of our smaller groups of renewals. However, it will occur at approximately the same time as we are starting to receive applications from new graduates.

- **Outreach:** During the month of February, I participated in the following meetings, presentations, or workgroups that involved the Board of Pharmacy or had contact with media on the following issues:
 1. IPA Board Meeting & Legislative Day
 2. Meet w/Officials from Stericycle about considering new ways to license expansions of their existing VAWD Accredited sites and what the Board would be willing to consider.
 3. Meet w/the Medical Board re: Prescription Pad Standards and Renewal
 4. Channel 6 Story on Cass County Animal Shelter
 5. Indystar Story on Pharmacy Robberies
 6. We will be issuing our first newsletter on March 1, 2011, and issue it monthly thereafter. It will be posted on our external website as well as on our facebook page and via GovDelivery.
 7. Visited with Pharmacy Personnel from IU Health and Riley Hospital to discuss piloting new technology that relates to sterile compounding. Specifically, it would require the Board to change the way it interprets pharmacists final check, direct supervision, and the scope of responsibility for technicians.
 8. Met w/representatives from Pearl IRB for a discussion of their services available to Board Licensees.
 9. Arranged a training presentation sterile fields and products available to do 797 compliant compounding for the Compliance Staff at the February Board Meeting. This is important and relevant b/c the Compliance Team is now enforcing this requirement during inspections at pharmacy locations that do sterile compounding.
- **Dept. of Health/Medicaid Workgroups:** I did not have meetings with these groups during the month of February.
- **Misc:** A substantial part of my time the last week and a half of February was spent on completing the Employment Restrictions Survey. I struggled with the sections concerning facilities in particular.

At our February Meeting we also meet with Gabrielle Owens and Michael Minglin from the Consumer Protection Division of the Attorney General's Office to discuss the Board's concerns with the lack of involvement of the Board in determining which complaints merit charges and action. This is an issue we will continue to work with the Attorney General's Office. The Board has requested we obtain, as required by statute, ongoing updated lists of complaints filed with the Attorney General's Office. I am working on drafting a letter to this end to deliver and be signed by the Board President.