Kansas State Board of Pharmacy
Minutes of the July 21, 2010
Board Meeting

Kansas Pharmacists Association
1020 SW Fairlawn
Conference Room
Topeka, KS 66604

Wednesday, July 21, 2010

Meeting Called to Order: President Karen Braman called the meeting to order at 10:00 a.m.

Members Present: Karen Braman, R.Ph.,M.S., President; Nancy Kirk, Public Member; Frank Whitchurch, R.Ph. Members present via teleconference: Shirley Arck, Pharm.D., Vice-President; David Schoech, R.Ph. and Mike Coast, R.Ph.

Staff Present: Debra Billingsley, Executive Secretary and Christina Morris, PDMP Director.

Others Present: See Attached List

Introductions were made by everyone in the room. Ms. Braman advised the group that the Board of Pharmacy was continuing public comments and discussion related to the proposed Prescription Drug Monitoring regulations from the June 9, 2010 meeting.

The Joint Legislative Committee on Rules and Regulations had recommended that the Board include a definition of stakeholder in the regulations. A definition had been drafted by Christina Morris and was shared with the group. There were no comments regarding the suggested language.

Christina Morris provided a draft copy of the regulation that deleted the prescriber address data element. There were no comments regarding the deletion.

Ms. Morris indicated that one typo had been corrected and the draft regulation showed the change that was made. There were no comments regarding the correction.

The draft regulation was changed to reflect that the NPI number would be collected from the pharmacy and not the pharmacist because many individual pharmacists do not have an NPI number. The draft also changed any reference

to a “dispenser” because of the definition of the dispenser. These two items were suggested by NACDS and were accepted by the group.

The drug of concern process was discussed. Any drug that is recommended as a drug of concern will be done through the administrative rule and regulation process. Everyone will have adequate notice and a public comment period prior to drugs of concern being added to the Prescription Drug Monitoring program. This process was accepted by the group.

The frequency of pharmacy reporting was discussed. A suggestion was made to require reporting every seven days as this was seen as potentially less administratively burdensome to dispensers. Ms. Morris reminded everyone that NASPER requires a minimum of seven days. Monthly reports were viewed as sufficient in order to track trends and statistical information. David Root of Medco discussed the number of controlleds that are currently shipped into the state by Medco. He reiterated that Medco and other mail order facilities were not asking to be excluded from reporting but would like the Board to allow a seven day process for reporting because these facilities are required to submit to more than 30 different state PMPs, all with different requirements.

It was questioned that since the PMP will have historical Rx data, would receiving the data on a weekly basis vs. a 24-hour basis significantly impact the PMP. Or, if retail claims, which represent approximately 97 percent of controlled substances dispensed, were reported daily, would having mail order controlled substance claims, which represent about 3 percent, reported weekly have a material impact on the PMP? Mr. Root requested the state consider providing waivers. The three states, Oklahoma, Minnesota, and North Dakota that require 24-hour reporting also have a waiver process to allow pharmacies to report on a weekly basis. Oklahoma has daily reporting but their statute exempts non-resident pharmacies from daily reporting and allows them to report every seven days. Everyone recognized the public health problem that the program is addressing but there is a need for flexibility in order to accommodate the various types dispensing providers.

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Doug Lang, Sr. Director of Compliance for Express Scripts (ESI) had provided the Board Office and PMP Advisory Committee a letter in advance of the meeting and attended in person. Mr. Lang requested the state consider allowing mail order pharmacies to submit data on a weekly basis. Mr. Lang described the process ESI goes through each week to submit data to 34 different state PMPs that each have different data reporting requirements. With multiple mail order facilities, ESI has several IT staff involved in pulling the data. The data is then reviewed by the designated pharmacy operational personnel for quality assurance purposes to ensure its accuracy before it is submitted to each state. This process takes 48 – 72 hours. Although most states have monthly, bi-weekly or weekly reporting, ESI is standardizing their process to submit data weekly to each state.

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Ms Braman had just returned from a Harold Rogers meeting and she indicated that the majority of states require either weekly or bi-weekly reporting. The 24 hour reporting has been viewed as too labor intensive by many state PMPs, especially in regard to cleaning rejected claims. Frank Whitchurch noted that one should look at the overall risk of the patient group. The mail order population has a closed relationship with the mail order pharmacy (e.g., there are no cash transactions) and the overall philosophy has been that their risk of abusing or diverting controlled substances is lower than the population obtaining controlled substances from retail pharmacies and paying cash for them. Veterinarians and hospital inpatients were viewed as low risk while retail pharmacy was viewed as higher risk. Applying this same logic, a PBM would be considered low risk.

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The group discussed that retroactive information would have to be submitted, and that when the prescriber or dispenser viewed the individual patient's controlled substance history, they would make their decision to prescribe or dispense a controlled substance based on that patient's last several months of history rather than the last several days.

There were also comments that complying with a weekly report would be the same as providing an end of day report. Christina went through other state exemptions. Minnesota exempts pharmacies based on the number of prescriptions filled in a month. North Dakota also has a waiver process.

The group discussed that the PMP legislation was created nearly three years ago, and although not funded by the State, it is important that we reach a compromise on the reporting requirement so that the program can be implemented. It was also discussed that there is no data on which to make the reporting frequency decision. A compromise of weekly reporting or a waiver process allowing weekly reporting for one or two years would enable the Board to study the issue and make a decision based on the data and impact to the PMP after that time.

After much discussion, it was noted that there are several options for the Board. One is striking "24 hours" and changing it to "within 7 days of dispensing". This would allow pharmacies that wanted to report on a daily basis to do so, but would also enable pharmacies that do not dispense a high volume of controlled substances, or non-resident pharmacies, to dispense weekly. A second option is to permit within 7 days of dispensing but only for a limited amount of time, such as two years, then re-evaluate the need for these pharmacies to report daily. Another suggestion was to keep the 24 hour requirement but add waiver language allowing weekly reporting and revisit after a year or two to determine the impact to the PMP and if the frequency should be changed. Christina Morris will draft the options discussed.

Adjourn: Ms. Braman adjourned the meeting at 11:40 a.m.