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PUBLIC MEETING NOTICE:	**CONTROLLED SUBSTANCE COMMITTEE**
DATE AND TIME:	**Wednesday, July 29, 2015 at 9:00 a.m.**
PLACE:	**Buena Vista Conference Center, Dining Room, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720**
APPROVED:	December 2, 2015

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Philip Kim, M.D., Medical Representative
Art Jankowski, VMD, Veterinary Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative
Stephen Ruggles, PA-C, PA Representative
Mark Hanna, Public Representative

MEMBERS ABSENT

Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Alex Zarow, R.Ph., Pharmacy Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances
Christine Mast, Administrative Specialist III
Eileen Kelly, Deputy Attorney General
David Mangler, Director, Division of Professional Regulation
Samantha Nettesheim, Pharmacist Administrator
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Amy Bixler
Lucy Somer
Jamie Mack
Deborah Hamilton
Roopa Bher
Mark Thompson
Karyl Ratay
Tejal Patel

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:04 am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Ruggles, seconded by Dr. Jankowski, to approve the minutes from the May 27, 2015 meeting. The motion was unanimously carried.

PRESIDENT'S REPORT

No Report

UNFINISHED BUSINESS

Public Hearing – Proposed Regulatory changes 11.0

Ms. Kelly explained the purpose of the hearing to the committee and the attending public. She asked the committee members and staff to introduce themselves for the record. Having received written comment she entered the following as exhibits: Exhibit #1 News Journal Public Notice, Exhibit #2 Delaware State News Public Notice, Exhibit #3 Written comment received from Cynthia Denemark R.Ph., Division of Medicaid and Medical Assistance, Exhibit # Written comment received from Karyl T Rattay MD, MS, Director Division of Public Health. The committee reviewed the written comment received. Dr. Kremer asked for public comment.

Dr. Karyl Rattay provided the following comment. She congratulated the committee for their work on this issue. She provided the committee with statistical information regarding opioid addition and subsequent overdose deaths. She suggested to the committee that the PMP should be required to be queried every 6 months; Acute Care should be included in the regulations and PMP Risk Behavior reporting should be provided every 3 months to practitioners.

Mr. Mark Thompson, Medical Society of Delaware provided the following comment. The Medical Society of Delaware generally supports the proposed regulations. Mr. Thompson mentioned that the following would be beneficial. 9.2 should better define Acute and Chronic Pain and define Risk Assessment and tools that may be used. 9.5.2 Clarification and examples or "as available added". 9.5.10 should provide detailed language and possibly a 2 phased approach. Finally, 9.8 we would suggest consideration of a second care provider.

With no more public comment Ms. Kelly requested that Deliberations of Proposed Rules and Regulations changes be added to the next agenda. This concluded the hearing.

Non-Photo ID Cards – Ms. Kelly and Mr. Dryden will continue working on possible solutions to be presented during the next meeting.

NEW BUSINESS

Review of Consent Agreement – Dr. Ganesh R Balu, a motion was made by Dr. Kremer, seconded by Ms. Baler, to accept the agreement with the correction to strike #24 on page 5. The motion unanimously carried.

Request to lift Suspension – Jean Binley, a motion was made by Dr. Kremer, seconded by Dr. Jankowski to table the request for more information in adherence to the order. The motion unanimously carried.

Review of Consent Agreement – John T Pearson, a motion was made by Mr. Hanna, seconded by Dr. Kim to approve the consent agreement. The motion unanimously carried.

Investigative Study Prescription Monitoring Program (PMP) Reporting – Mr. Dryden provided a handout from Lauren Bellow, Clinical Research Administrator of SunPro CSEOP, Pediatric Research Center of Southern Florida. There is a study at A.I. Dupont Children's Hospital where pediatric patients are participating in a double blind study. Some are given schedule II drugs and others a placebo. The PMP statute requires all schedule II drugs to be reported. The reporting process using the NDC# presents an issue with a double blind study. When only reporting the schedule II and not the placebo a practitioner could be misguided in the assumption that the patient is receiving schedule II drugs but not aware they

are in an approved study versus someone who is given the placebo and not reported at all. Concern was expressed with reporting and jeopardizing the study. Other states were reviewed for possible solutions to this issue. A motion was made by Dr. Kim, seconded by Ms. Baker to approve the process for studies conducted to report the schedule II drugs accurately after the study is completed and remove the placebo patients to prevent confusion. The motion unanimously carried.

DIRECTOR'S REPORT

Mr. Dryden reported that the Controlled Substance renewals have been completed. Mr. Dryden also provided guidance to pharmacists on the law regarding dispensing of syringes. The statute states that a pharmacist may dispense a syringe without a prescription only in the case that a prescriptive medication is used. There has been some confusion regarding the statute and some pharmacists believed that syringe exchange was allowed but, it is not acceptable practice by statute.

There have been nursing statutes changes regarding collaborators for Advanced Nurse Practitioners therefore, the Office of Controlled Substances will no longer require this information be provided for registration applications.

Mr. Dryden will be attending the National Association of State Controlled Substance Authorities (NASCSA) conference in October as an Executive Officer and Presenter.

Case/Diversion Review

None

PMP Review

Ms. Nettesheim provided the committee a handout with statistical data for the Prescription Monitoring Program (PMP). She attended the National Association of Boards of Pharmacy (NABP) for the PMP Interconnect annual sub-committee meeting. Ms. Nettesheim has been completing the project for mandatory PMP registration for new applicants and practitioners who have not registered. Ms. Nettesheim noted that the PMP reached over 100k in queries for the April – June 2015 period. Ms. Nettesheim also attended a meeting with the Department of Corrections to discuss the possible utilization of the PMP within the corrections environment.

Dr. Philip Kim expressed the positive benefits of utilizing the PMP, treating patients with pain and preventing the abuse of controlled substances. He suggested in improvements in the ease of use and readability of the reports. He also stated that exporting data to the EMR would be beneficial to have available.

Current Event Review

DEA Operation Spans Four States, Leads to 280 Arrests Related to Prescription Drug Diversion and Abuse

Drug Enforcement Administration (DEA), in collaboration with federal prosecutors, has announced the conclusion of a 15-month operation that resulted in 280 arrests across four states, including arrests of 22 doctors and pharmacists. Known as Operation Pilluted, the effort resulted in arrests across Arkansas, Alabama, Louisiana, and Mississippi and targeted DEA registrants who were identified as being involved in illegally prescribing, obtaining, and distributing dangerous and addictive controlled substances, including opioid painkillers. Operation Pilluted was led by the DEA New Orleans Field Division and utilized intelligence data provided by state and local law enforcement, and complaints made by citizens. In addition to the arrest of 22 doctors and pharmacists, DEA issued two immediate suspension orders and obtained the voluntary surrender for cause of an additional 40 DEA Registrations, according to a news release posted to the DEA website. DEA is pursuing administrative actions which may result in the revocation of additional DEA registrations.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage

chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention (PDF). Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

FDA Takes Action Against More Than 1,050 Websites Selling Counterfeit Prescription Drugs and Medical Devices

As part of the eighth annual International Internet Week of Action (IIWA), Food and Drug Administration (FDA), in collaboration with international regulatory and law enforcement agencies, took action against more than 1,050 websites that illegally sell potentially dangerous, unapproved prescription medicines and medical devices to consumers. Specifically, from June 9-16, 2015, FDA sent warning letters to nearly 400 website operators, and inspectors screened and seized illegal drug products and medical devices received through international mail facilities in Chicago, IL, Miami, FL, and New York, NY. Over 800 packages were detained and referred to appropriate FDA offices for follow-up. Parcels found in violation of the Federal Food, Drug, and Cosmetic Act will be refused entry into the country, according to an FDA.

Drug Overdoses Doubled Over the Last 14 Years, Half Are Related to Prescription Drugs, Indicates New Report

Drug overdoses are now the leading cause of injury deaths in the United States, and half of those injuries, 22,000 per year, are related to prescription drugs, according to a new report from the Trust for America's Health and the Robert Wood Johnson Foundation. The Facts Hurt provides a report card for states based on 10 "leading evidence-based strategies," or indicators that can help reduce injuries. Indicators related to reducing the rate of prescription drug overdose include whether or not a state requires mandatory use of a prescription monitoring program, and whether the state has laws in place to expand access to naloxone, the drug that can reverse the effects of an opioid overdose.

Dispensers Get Four More Months to Meet DSCSA Provisions

Food and Drug Administration (FDA) has granted dispensers an additional four months to comply with provisions of the Drug Supply Chain Security Act (DSCSA) that call for tracking and tracing drug packages across the drug supply chain. As some dispensers indicated that electronic systems for tracking product information would not be operational by the original July 1, 2015 deadline, dispensers now have until November 1, 2015, explains FDA in a guidance document (PDF). Specifically, "FDA does not intend to take action against dispensers who, prior to November 1, 2015, accept ownership of product without receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act," states the agency. FDA also notes that "this compliance policy does not extend to transactions in which dispensers must provide the subsequent owner with product tracing information, including transaction history, as required by section 582(d)(1)(A)(ii). If a dispenser has not received product tracing information prior to or at the time it takes ownership of a product, FDA recommends that the dispenser work with the previous owner to receive this information. FDA believes that product tracing information serves as an important tool for dispensers to meet their obligation under section 582(d)(4) to identify suspect product, quarantine the product, and investigate whether that product is illegitimate." Drug manufacturers, wholesale distributors, and repackagers were still expected to meet the original July 1 deadline.

NABP, Alliance for Safe Online Pharmacies Warn Public About Rogue Online Pharmacies in USP Blog

The majority of online drug sellers operate illegally and sell counterfeit medications that can contain toxins such as floor wax and road tar, warn NABP and the Alliance for Safe Online Pharmacies

(ASOP). In a post on Quality Matters, the blog of the United States Pharmacopeial Convention (USP), NABP Executive Director Carmen A. Catizone, MS, RPh, DPh, and ASOP Executive Director Libby Baney, JD, explain the proliferation of rogue Internet pharmacies and the many dangers they pose. In the blog post, Catizone and Baney also detail the programs that both organizations launched to raise awareness of these dangers and to steer consumers toward safe online sources of medication.

Pharmacy Robberies Still Climbing in Some States, Reports Drug Topics
During the first five months of 2015, Indiana has had 68 pharmacy robberies, the most out of any other state, reports Drug Topics. The online publication, geared toward pharmacists, used Drug Enforcement Administration data to compile a report of the 20 states hit hardest by pharmacy robberies. After Indiana follows Wisconsin, with 32 robberies so far in 2015, more than it experienced in all of 2014. Nationwide, there have been 382 armed pharmacy robberies from January to June 2015.

FDA Advises Caution Against Codeine for Treating Colds in Kids
FDA is evaluating the safety of using medicines containing codeine to treat children under 18 for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for children, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds and to not use codeine for teens 12 to 18 who have asthma or other chronic breathing problems.

Prescription Opioid Abuse Key Indicator for Future Heroin Abuse
People who abuse prescription opioid painkillers are 40 times more likely to abuse heroin, reports the July edition of CDC Vital Signs. Researchers from Centers for Disease Control and Prevention (CDC) and FDA looked at the factors behind America's heroin epidemic and found that prescription opioid abuse is the strongest risk factor for a heroin use disorder, indicates a press release. Additionally, 45% of people who currently abuse heroin were addicted to opioid painkillers in the past. The report suggests several ways to help solve the problem. Prescription monitoring programs (PMPs), which are used to track an individual's controlled substance prescription drug history, should be widely available and easy to use. Health care providers should prescribe the lowest effective dose of opioid painkiller and only in a quantity that is needed, and they should also be able to connect patients with treatment programs as necessary, advises CDC in the report.

COMMITTEE REPORTS

Medical Examiner's Report
No report.
DEA Report
No report
Substance Abuse Report
No Report
Law Enforcement Report
No report
Regulatory Committee Report
No report
Legislative Committee Report
No report

INSPECTION REPORT

Ms. McCreary reported that she continues to complete routine inspections. She is also working with the DEA regarding findings related to controlled substance issues.

COMMITTEE CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD
None

PUBLIC COMMENTS
None

EXECUTIVE SESSION
None

NEXT SCHEDULED MEETING
A motion to reschedule the next Controlled Substance Committee meeting was made by Mr. Von Goerres seconded by Ms. Baker to move the meeting to September 23, 2015. The motion carried unanimously.

The next regular meeting will be held on September 23, 2015 at 9:00 am at the Buena Vista Conference Center, Buck Library.

ADJOURNMENT
A motion was made by Dr. Kremer, seconded by Mr. Von Goerres, to adjourn the meeting at 10:57 am. The motion unanimously carried.

Respectfully submitted,

Christine Mast
Administrative Specialist III
Office of Controlled Substances