Commission SBAR Communication

Agenda Item/Title: 6.6 Use of DEA registration numbers in hospital settings

Date SBAR Communication Prepared: August 21, 2018

Reviewer: Tracy West, Deputy Director

Link to Action Plan:

☐ **Action** ☒ **Information** ☐ **Follow-up** ☐ **Report only**

Situation:
Commission members have received questions recently on proper use of DEA registration numbers in hospital settings.

Background:
The Commission received advice from AAG, Christopher Gerard on this topic.

DEA allows practitioners working in a hospital or other institutional setting to use the hospital or facility DEA registration number but does require an additional internal code added to the end to identify individual prescribing practices when necessary.

Assessment:
An article was published in the April 2018 newsletter on this topic, No. 1283 Practitioner DEA Registrations, which detailed the DEA's position and how licensees can comply with the DEA's requirements.

Recommendation:
The Commission should give staff guidance on additional publication or educational opportunities they would like to see.

Follow-up Action:

April 2018

News

Washington State Pharmacy Quality Assurance Commission

Published to promote compliance of pharmacy and drug law

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www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission.aspx

No. 1280 New Inspection Process

The Washington State Pharmacy Quality Assurance Commission is excited to inform you that a new process for pharmacy inspections started on March 1, 2018. Pharmacy inspections will now follow a notice of deficiency/plan of correction model, rather than the point-based classification previously used. The new inspection rules require all pharmacies to conduct an annual self-inspection in March or within 30 days of naming a new pharmacist-in-charge. The self-inspections are done on worksheets provided by the Commission.

When the pharmacist investigators arrive, they will review your self-inspection as part of their inspection process. If deficiencies are noted during the inspection, you will receive an inspection report noting deficiencies, also known as a **statement of deficiency,** within 14 days following the inspection. If you receive an inspection report noting deficiencies, you then have options on what your next steps will be.

Information on these changes is on the Commission's Inspections web page. The web page includes all the necessary self-inspection worksheets that pharmacies will need to complete. Additionally, training videos of recorded webinars are available, which the Commission strongly encourages you to view. There are six training videos that last between one and a half and 10 minutes.

The Commission encourages all pharmacists, interns, and pharmacy technicians to sign up for the email distribution list. To sign up, click on the green "Subscribe" link at the bottom of any page on the Washington State Department of Health (DOH) website or the Commission website, including the Inspections web page.

If you have questions, please contact your pharmacist investigator or Commission staff.

No. 1281 Pharmacist Required Suicide Screening, Referral, and Lethal Means Training

In 2016, the Washington State Legislature recognized that Washington's suicide rate was 14% higher than the national average. One of the most immediate ways to reduce the tragedy of suicide is through suicide awareness and prevention education, coupled with the safe storage of lethal means commonly used in suicides, such as firearms and prescription medication (Revised Code of Washington 43.70.442).

Reminder, Washington Administrative Code (WAC) 246-861-105 Suicide prevention education requires all pharmacists to complete an approved three-hour suicide prevention education in suicide screening, referral, and content related to imminent harm via lethal means. Licensed pharmacists must complete the one-time training by the end of the first full continuing education (CE) reporting period (12 months) after January 1, 2017, or during the first full (12-month) CE reporting period after initial licensure, whichever is later. The list of DOH-approved courses are on the DOH website under Suicide Prevention Training for Health Professionals. Online and in-person courses are available.

Your suicide educational hours will count toward the 15 CE hours required for renewal. Please retain your certificate of completion because these hours will not appear on your CPE Monitor® e-Profile report.

Pharmacists play a key role in suicide prevention, both by identifying people at risk and counseling on how to safely store and dispose of unused and unwanted drugs. If you forget to take the course within the timeline required, the Commission encourages you to take the training as soon as possible. This is not just because it is the law, but because pharmacists can make an important difference in this public health crisis.

No. 1282 Automated Drug Dispensing Devices

Compliance With WAC 246-874-020 Through WAC 246-874-070 Required by April 7, 2018

The Commission adopted rule language establishing standards for the use of automated drug dispensing devices (ADDDs). The rules went into effect on April 7, 2017. They outline the requirements for installation and use of ADDDs in various facilities, identified in Chapter 246-874 WAC. Additionally, the rules do not require facilities to obtain approval from the Commission before using ADDDs. Pharmacies and nonresident pharmacies must submit a list of physical address

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National Pharmacy Compliance News

April 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

Continued from page 1

locations where they manage or service ADDDs. They must do so on a form provided by DOH. This form is on the Commission's website.

Per WAC 246-874-020, pharmacies approved by the Commission to use ADDDs before April 7, 2017, were given one year to come into compliance with the new rule, which includes submitting the list of physical locations mentioned above. The form to submit this information can be found here or on the Commission's Applications and Forms page.

No. 1283 Practitioner DEA Registrations

A pharmacist working under a collaborative drug therapy agreement (CDTA) may prescribe controlled substance (CS) prescriptions under the following conditions:

1. The scope of the CDTA must permit this activity; and
2. The pharmacist must have a Drug Enforcement Administration (DEA) registration.

Recently, there has been some confusion regarding obtaining DEA registrations. Pharmacists acting with prescriptive authority to prescribe CS must have their own unique DEA registration issued by DEA. There is a variation to this if pharmacists are acting with prescriptive authority in hospitals or other institutional settings.

DEA permits practitioners with appropriate prescriptive authority working within a hospital or other institution to use the hospital DEA registration with an **additional** internal code added to the end of the registration. Internal codes for each practitioner are assigned and maintained by the hospital or other institution. The internal code serves as a unique identifier for that practitioner. For example:

> Hospital DEA: AB1234567 – ***012*** (emphasis indicates internal code unique identifier)

You can read more about general DEA registrations at *https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm.* For more information on this specific topic, scroll down the web page to the section titled "Practitioner's Use of a Hospital's DEA Registration Number."

No. 1284 Opioid Use – A National Epidemic

New Opioid Rules Coming Soon

The opioid epidemic is not exclusive to Washington State. It is a national epidemic that state and federal governments are attempting to solve. In 2017, the Washington State Legislature passed Engrossed Substitute House Bill 1427 (ESHB 1427) (Chapter 297, Laws of 2017) to do just that. By January 1, 2019, the health care provider disciplinary boards and commissions that formed the Opioid Task Force will adopt rules implementing ESHB 1427, which will affect the way opioids are prescribed, monitored, and dispensed.

What does ESHB 1427 and the evolving landscape mean for you?

1. Components of the draft rules as created by the voting members of the Opioid Task Force need your feedback and input on how the proposals will affect your practice. Please provide feedback to the task force at opioidprescribing@doh.wa.gov, as well as to the Commission at WSPQAC@doh.wa.gov.
2. Things to consider as you review the conceptual rules from the Opioid Task Force:
   a. How would this affect your practice? The proposal restricts the quantities of opioids prescribed based on the type of pain, such as acute, subacute, episodic, or chronic. However, what if the diagnosis is not required to be noted on the prescription? As part of the health care team and medication experts, is the time taken to extract the information from the electronic medical record system vital to aid pharmacists in ensuring that dispensed opioid pain medication is both safe and appropriate for each patient? Or is there no value, but only an added inconvenience for the prescriber?
   b. Do pharmacists currently think the CE and certification offerings are sufficient to meet pharmacist management of opioid patients? Please review the Food and Drug Administration's Opioid Analgesic Risk Evaluation and Mitigation Strategy, an education blueprint for health care providers involved in the treatment and monitoring of patients with pain. **(Send comments on conceptual rules 246-XXX-X50.)**
   c. How frequently are pharmacists reviewing the prescription monitoring program database when dispensing an opioid prescription? What are your barriers to review? **(Send comments on conceptual rules 246-XXX-X91.)**
   d. Please provide comments on the challenges you experience in dispensing partial fills of opioid prescriptions.

No. 1285 Congratulations Tim Lynch, PharmD, RPh

Dr Tim Lynch, PharmD, RPh, Commission chair, received the 2018 Distinguished Alumni Award in Pharmacy Practice from the University of Washington School of Pharmacy.

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Subject: Attorney-Client Privileged - DEA Registrations for Pharmacists Prescribing under a CDTA for inpatients

Good Afternoon,

Please find below advice related to whether pharmacists have to be individually registered with the DEA when operating under a CDTA for hospital inpatients. This information is being sent to all Commission members.

This advice is subject to attorney-client privilege and should not be disseminated unless the Commission waives this privilege through action at an open public meeting. I hope it is helpful and please feel free to contact me directly (and *not* through "Reply All") with any questions.

To my knowledge, an article communicating the substance of this information will be provided in the next newsletter.

Attorney-Client Privileged

Issue

The Commission has asked for advice on whether pharmacists have to be individually registered with the DEA when operating under a CDTA for hospital inpatients.

Short Answer

A reading of the applicable federal regulations indicates a pharmacist who is prescribing a controlled substance under a CDTA for hospital inpatients could utilize the hospital's DEA registration to prescribe controlled substances in lieu of obtaining their own DEA registration. The hospital would be under an obligation to ensure the pharmacist is assigned a specific internal code number that identifies the pharmacist as the prescriber. As this is a DEA regulation, the DEA's interpretation would be given the most deference and consultation with the DEA may be warranted.

Analysis

Federal law requires a practitioner who dispenses a controlled substance to obtain a DEA registration. 21 U.S.C.A. § 822(a)(2). A pharmacist is a practitioner for the purposes of determining whether a DEA registration is necessary. 21 U.S.C.A. §802(21). In addition, the federal definition of dispense includes, among other things, writing a prescription. 21 U.S.C.A. § 802(10). Consequently, as a starting point, a pharmacist who is prescribing controlled substance pursuant to a CDTA would need to register separately with the DEA.

The federal statute does allow the Attorney General, by regulation, to waive the DEA registration requirement. 21 U.S.C.A. § 822(d). One such exemption applies to the employees of hospitals. 21 C.F.R. § 1301.22. This does allow an "individual practitioner" (which would include a pharmacist) who is an employee of a hospital to utilize a hospital's DEA registration when prescribing controlled substances in lieu of being registered themselves. 21 C.F.R. § 1301.22(c). While there are a number of criteria that apply, one does require the use of a specific internal code number for each individual practitioner utilizing the hospital's DEA registration to prescribe controlled substances. 21 C.F.R. § 1301.22(c)(5). This is a specific internal code number only must be made available at all times "to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. 21 C.F.R. § 1301.22(c)(6).

Based on the analysis above, a pharmacist who is prescribing a controlled substance under a CDTA for hospital inpatients could utilize the hospital's DEA registration to prescribe controlled substances, in lieu of obtaining their own DEA registration. The hospital would be under an obligation to ensure the pharmacist is assigned a specific internal code number that identifies the pharmacist as the prescriber. The practitioner and hospital would also have to ensure the other criteria listed in the regulations are met.

Best,

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