Q&A from WPSI Webinar: *Demystifying DEA's Role & Implementing a Zero Risk Program*

Speaker: *Dennis A. Wichern, MSc, DEA Special Agent (Ret.)*

Date: Monday, December 16th, 2019

Question: I'm interested in learning the proper way to receive and store Sublocade, ordered on behalf of individual patients, and already paid for through their insurance. Just like any other controlled substance ordered in bulk? There seems to be a little hesitation because of the guideline to not store any patient's controlled medication.

Answer: The "SUPPORT for Patients and Communities Act, Section 3204" which was enacted by Congress on October 24, 2018, and found at https://www.asam.org/docs/default-source/advocacy/hr6_09-28-18-final-opioid-sec-by-sec_bipart-bicam.pdf?sfvrsn=49d048c2_2 states the following: "This provision updates Federal law to allow for implantable or injectable controlled substances for the purposes of maintenance or detoxification treatment to be delivered by a pharmacy to an administering practitioner while maintaining proper controls, such as storage and record keeping."

DEA is expected to issue written guidance in the near future but a safe and conservative recordkeeping method until then would be the following: 1) maintain a ledger/log of all injectable deliveries by receiving date, patient name and date of implant use. 2) Secure the injectable packages in "securely locked cabinet" or safe until their use. 3) Maintain documentation on the date of injectable implant and signature of receiving patient.

I don't see injectable implants ever getting on DEA's radar.

Question: So do you need to email the DEA when you go from 30 to 100 and not just do the waiver increase form online?

Answer: SAMHSA is the only agency that should be notified. Once your year is up you only have to notify SAMHSA at https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php - not DEA, if you want to raise your patient limit to 100.

Question: How would the DEA react if a prescriber unintentionally prescribed to more than their limit? I have a limit of 100 and keep an accurate log but made a clerical error adding and found I hit 101 patients would I likely have a bad outcome from DEA?

Answer: DEA could care less and these types of errors are never an issue. Document in some fashion and keep practicing medicine.

Question: In CA we are working extensively with hospitals to integrate MAT into standard medical practice. Many of the ideas that you have touched on are already standard in a hospital in terms of tracking drug inventory etc. Can you touch on prescribe vs. dispense? Both are important from the hospital setting.

Answer: Those providers that work in a hospital setting or in-patient settings are used to dispensing and administering drugs and should continue to do so because they have the recordkeeping systems and pharmacy operations in place. In-hospital and in-patient settings, dispensing makes more sense than prescribing for induction and treatment.

Office-based opioid treatment providers and small clinics providing out-patient services that are unfamiliar with federal recordkeeping requirements should consider prescribing buprenorphine for induction for simplicity.

Question: Re: Pre-scribing; is Pre-scribing of Long-Acting Stimulant Medication ok in an adult ADHD patient? Asking for a fam med friend.

Answer: Outside my experience and wheelhouse. Generally there is little government focus on ADHD medicines.

Question: Do you have to have a counselling component as part of MAT. Is it a must?

Answer: SAMHSA Tip 63 at https://store.samhsa.gov/system/files/sma18-5063fulldoc.pdf (Section 4-5, page 217) states the following: "The law requires buprenorphine prescribers to be able to refer patients taking OUD medication to counseling and ancillary services. Buprenorphine prescribers may meet this requirement by keeping a list of referrals or by providing counseling themselves."

In HHS's Final Rule found at https://www.deadiversion.usdoj.gov/pubs/docs/SAMHSA_Regulations_275.pdf it states, "HHS believes that in order to ensure quality care, providing behavioral health support services is a key component to delivering effective MAT and encourages all practitioners prescribing covered medications to ensure that their patients receive it. The selection of behavioral health support services is a clinical decision to be made between the practitioner and the patient."

Lastly, on the sample ASAM patient treatment agreement found at https://www.asam.org/docs/default-source/advocacy/sample-treatment-agreement30fa159472bc604ca5b7ff000030b21a.pdf?sfvrsn=bd4675c2_0 , #18, it states, "I understand that treatment of opioid addiction involves more than just taking my medication. I agree to comply with my doctor's recommendations for additional counseling and/or for help with other problems."

Question: Is a particular form of buprenorphine more frequently seen in diversion situations?

Answer: The film form is the most commonly diverted form of buprenorphine. It is often the number one drug found in prisons and worth up to $100 per strip.

Question: Is Dennis available to talk with our team who coaches hospital teams across the state of CA and nationally?

Answer: Yes and he would be honored to assist in any way possible.

Question: Can you post-date a prescription?

Answer: You shouldn't but a more acceptable method is to sign the prescription on the date you examined the patient and write in the body of the prescription the fill date you decide. In other words, write out, "Not to Fill Until xx/xx/20XX."

Question: Could a Dr. in a Jail setting use the 3 day rule for a patient in an emergency situation?

Answer: Yes and that was the intention of the lawmakers. The following paragraph is directly from https://www.deadiversion.usdoj.gov/pubs/advisories/emerg_treat.htm , "The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent the separate registration requirement."

I would still recommend that the doctor get the SAMHSA waiver to increase his or her knowledge and further lower their overall practice risk.

Question: Does cash only apply only to those dispensing or also to docs who do cash only for the visit, but then the patient goes to the pharmacy and uses insurance to fill the Rx?

Answer: No difference between the two and taking cash is not unlawful; however, cash medical practices can often bring increased government scrutiny.

Question: What are the record keeping requirements for Sublocade if it is not purchased by provider?

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