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Derek S. Davis, RPh, JD
Derek.Davis@cooperscully.com
972-897-1555

Contributor:
Heidi Fuentes
PharmD Candidate 2018

Inside this issue:

Pharmacy Law & Regulatory News Updates

Companies Selling Unapproved Opioid Cessation Products

The U.S. Food and Drug Administration along with the Federal Trade Commission have posted warning letters to several companies for making claims that their unapproved, opioid cessation products can help with the treatment of opioid addiction and withdrawal. By selling unapproved products and making such false claims these companies are in violation of the Federal Food, Drug and Cosmetic Act. They are also in violation of the Federal Trade Commission Act for deceptive advertising.

The FDA states that health fraud scams like these can pose serious health risks because these products have not been demonstrated to be safe or effective and may keep some patients from seeking appropriate, FDA-approved therapies. The FDA has taken new steps toward making safe and effective medication assisted treatments (MAT) available to those who suffer from opioid use disorder.

The FDA and FTC have given these companies 15 days to respond to each agency with the specific actions they will take to address these concerns. If no corrective action is taken by these companies they could be subject to law enforcement actions such as seizure or injunction.

Opioid Crisis Stats:

- Drug poisoning deaths increased from 17,415 in 2000 to 52,404 in 2015.[1]
- Age adjusted death rate per 100,000 increased from 6.2 to 16.3, most of the increase (7.4) is related to opioid deaths.[1]
- ~53,000 hospitalization occurred for unintentional, opioid-related poisonings in the U.S. in 2014.[2]
- 33,091 persons in the U. S. died from drug overdose involving opioids in 2015.[2]

References: 1) Contribution of Opioid-Involved Poisoning to the Change in Life Expectancy in the United States, 2000-2015. JAMA. 2017; 2) Centers for Disease Control and Prevention. Annual Surveillance Report of Drug-Related Risks and Outcomes – United States, 2017

2018 Compounding Policy Priorities Plan

The U.S. FDA has issued the 2018 Compounding Policy Priorities Plan, which outlines how it will implement certain aspects of the Drug Quality and Security Act (DQSA) that places more oversight on compounders. The law also creates a new category of compounders referred to as outsourcing facilities that will be able to take part in large-scale, nationwide distribution under FDA oversight. The compounding plan comes as a result of the 2012 outbreak of fungal meningitis that resulted after a pharmacy had shipped contaminated compounds all across the country. These policies will assist in minimizing public health risks while continuing to provide access to compounded products to patients who have a medical need for them.

The compounding plan addresses manufacturing standards for outsourcing facilities in which they must follow CGMP requirements, compound in an FDA-registered facility, and report active ingredients used to the FDA. It also sets rules for compounding from bulk substances. 503A facilities can compound drugs in accordance with the FD&C Act using bulk drug

"the FDA has finalized its guidance of mixing, diluting , or repackaging biological products outside the scope of an approved biologics license application"

2018 Compounding Policy Priorities Plan continued...

substances that comply with existing USP or National Formulary Monograph standards, are components of FDA approved drugs, or are listed by the FDA. The plan also places restrictions on compounding drugs that are essentially copies of FDA-approved or commercially available products. The restriction is intended to protect public health as these compounded drugs do not undergo FDA premarket review for safety, effectiveness and quality. The FDA has also addressed how it will work closely with state partners on oversight of compounding activities with its main focus going toward outsourcing facilities and on 503A facilities. In addition, the FDA has finalized its guidance of mixing, diluting , or repackaging biological products outside the scope of an approved biologics license application. It specifically addresses how outsourcing facilities are to assign beyond use dates (BUDs) to repackage biological products that surpass the default BUDs of 24 hours, based on data.

The FDA states that monitoring compliance with the law and taking enforcement action when needed will remain the corner stone of its oversight role. Since the enactment of the DQSA, the FDA has conducted nearly 500 inspections, issued over 180 warning letters to compounders, and oversaw more than 150 recalls that involved compounded drugs.

More information on this plan can be found on the U.S. FDA's website: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm592795.htm

"The stolen information included DEA registration numbers."

Oxycodone Distribution Ring Distributor Sentenced to Prison

Department of Justice

U.S. Attorney's Office

Western District of Washington

Stosh Satkowski, 24, has been sentence to 84 months in prison and 3 years of supervised release by the U.S. District Court in Tacoma for his involvement in a large oxycodone distribution ring. The prescription forgery ring, led by Anthony Ballenger, is responsible for the distribution of hundreds of thousands of oxycodone pills. Satkowski's involvement included recruitment of others who would obtain drugs from pharmacies using forged prescriptions and false identities.

Ballenger was the mastermind behind the whole operation who would steal identity information of medical professionals to forge prescriptions for pain medications. The stolen information included DEA registration numbers. Ballenger was also able to break in to online databases, including government databases, to alter prescribers contact information in order to divert any questions from pharmacies pertaining to the prescriptions back to himself. He even went as far as to pose as the medical professionals when using online prescription -delivery systems to send e-prescriptions to pharmacies. Both Satkowski and Ballenger would then distribute the drugs to their "runners". Ballenger was sentenced to 76 months in prison in June of last year.

Investigation of this case involved the DEA's Tactical Diversion Squad including officers from the Tacoma and Seattle Police Departments and the Washington State Patrol. The U.S. Marshals and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) assisted with the investigation as well.

2017 Report of the Task Force on Long-Term Care Pharmacy Rules

After meeting at NABP Headquarters in August of 2017, the Task Force on Long-Term Care Pharmacy Rules' members reviewed and accepted their charge as follows:

1. Review existing state laws and regulations addressing the practice of long-term care pharmacy.

2. Review current requirements for long-term care pharmacy practice contained within the Controlled Substances Act (CSA) and Code of Federal Regulations (CFR).

3. Recommend, if necessary, amending the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) addressing applicable state regulation of long-term care pharmacy practice.

4. Recommend, if necessary, revisions to the CSA and CFR.

FDA Expands Use of Amgen's Blockbuster Drug

Amgen Inc. has stated that the U.S. Food and Drug Administration approved its drug, Xgeva, to prevent fractures in patients with multiple myeloma. Xgeva had already received approval to treat a condition in which patients have an increased calcium level in their blood and giant cell tumor of the bone. The company had also reacquired sales rights to Xgeva from GSK in a deal that will allow them to right to sell in 48 countries including ones in Asia, South America and Europe.

Medicaid Work Requirements

The Centers for Medicare and Medicaid Services (CMS) will allow states to implement work requirements through section 1115 demonstrations. Section 1115 of the Social Security Act (SSA) allows the secretary of the U.S. Department of Health and Human Services to approve a state Medicaid demonstration if the Secretary deems the demonstration "is likely to assist in promoting the objectives of ... Title XIX". The State Medicaid Director (SMD) Letter #18-002, states it will be able to implement "work and community engagement" requirements for Medicaid enrollees. CMS has claimed that a review of studies found strong evidence that unemployment can be "harmful to health, including higher mortality, poorer general health, poorer mental health, and higher medical consultation and hospital admission rates." It is for this reason that they encourage states to consider a range of activities to include career planning and job support services. Of course there are limitations on the application of work and community engagement requirements such that it can only apply to working-age, non-pregnant adult Medicaid non-disabled beneficiaries.

Xpert Xpress Flu Test

Cepheid announced that it has received U.S. FDA 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver for the Xpert Xpress Flu test. This test will be able to provide rapid detection of Flu A and B RNA in just 20 minutes. The test is indicated to be used with nasopharyngeal swabs or with a nasal swab, which is much less invasive. According to the World Health Organization upper respiratory tract infections are the most common reason for antimicrobial use. Yet, the majority of these infections is viral and should not be treated with antibiotics. "Xpert Xpress Flu provides medically actionable and timely information to clinicians to support improved patient management, and antibiotic and antiviral stewardship," stated Dr. David H. Persing, M.D., Ph.D., Cepheid's Chief Medical and Technology Officer.

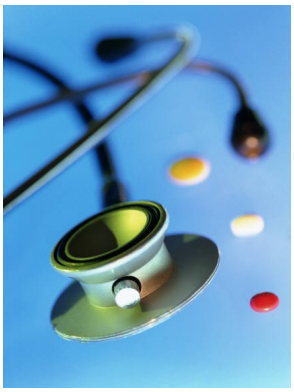
DOJ Recovered $900 Million from FCA Violators

The Justice Department recovered over $900 million from medical product manufacturers having to do with False Claims Act violations in 2017. Some of these major settlements were from Shire Pharmaceuticals for allegations of incentivizing physicians and clinics with kickbacks and perks in exchange for use of its products. They were also accused of making false claims to inflate prices. Ultimately Shire Pharmaceuticals was required to pay $350 million.

"So far more than 590 researchers have registered with the DEA to study Schedule I substances."

DEA Speeds Up Application Process for Research on Schedule I Drugs

The DEA has created a web portal that is dedicated to streamlining the application process for researchers wanting to study Schedule I (CI) substances which are deemed to have no medical use. Researchers looking to conduct studies with CI substances are required to register with the DEA by the Controlled Substances Act. This act also requires them to provide the DEA with information regarding their qualifications, protocols, and the institute where the research is to take place. So far more than 590 researchers have registered with the DEA to study Schedule I substances.



Mid-level Practitioners to Prescribe and Dispense Buprenorphine to Addicts

The DEA has taken a deregulatory measure that will allow nurse practitioners and physician assistants to become DATA-Waived qualifying practitioners. This waiver enables them with the authority to prescribe and dispense the opioid maintenance drug buprenorphine. The authority to prescribe buprenorphine was only allowed to physicians who were registered as both physicians and operators of Narcotic Treatment programs. The hope is that granting authority to mid-level practitioners will provide greater access to treatment options to those in rural areas. The DEA began transitioning mid-level practitioners into DATA-Waived status soon after the Comprehensive Addiction and Recovery Act was passed into law in 2016. Currently almost 5,000 mid-level practitioners are able to provide treatment to opioid addicts.

California State Board of Pharmacy

Statutory Changes to Pharmacy Law: Business and Professions Code Changes

Unless noted otherwise, these provisions have gone into effect January 1, 2018

Section 4044.3 is added

Defines "Remote dispensing site pharmacy" as a licensed pharmacy located in the state that is exclusively overseen and operated by a supervising pharmacy, where pharmaceutical care services are remotely monitored or provided, or both, by a licensed pharmacist through the use of telepharmacy technology.

Section 4044.6

Defines "supervising pharmacy" as the pharmacy, within the state, that exclusively oversees the operations of a remote dispensing site pharmacy.

Section 4044.7 added

Defines "Telepharmacy" as a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs by a remote dispensing site pharmacy. It also provides for related drug regimen review and patient counseling by an electronic method, including, but not limited to, the use of audio, visual, still image capture, and store and forward technology.

Section 4052.10 is added

This new section allows pharmacist to dispense a Schedule II controlled substance as a partial fill if it is requested by the patient or the prescriber. If the pharmacist fills the prescription as a partial fill, the pharmacist will retain the original prescription with a notation for how much of the prescription has been filled and when, until the prescription has been fully dispensed.

Business and Professions Code Changes continued...

Section 4052.10 continued...

Subsequent fills of the prescription have to be at the pharmacy where the original prescription was partially filled until the original prescription is completely dispensed. The full prescription can only be dispensed within 30 days after the date it was written. The prescription will expire 31 days after the date it was written and no more of the drug can be dispensed without a subsequent prescription.

This section shall become operative on July 1, 2018.

Article 8. Telepharmcy Systems and Remote dispensing Site Pharmacies

Section 4130 is added

Allows for a telepharmacy system to be used to dispense prescription drugs and provide related drug regimen review and patient counseling services at a Remote Dispensing Site Pharmacy as defined by the newly added section 4044.3. Remote dispensing site pharmacies are only allowed to be located in a "medically underserved area", which is a location that does not have a pharmacy that serves the general public within 10 miles of the remote dispensing site. A supervising pharmacy may only obtain a remote dispensing site pharmacy license for one such pharmacy.

For a complete list of changes visit:

www.pharmacy.ca.gov/laws_regs/

Texas State Board of Pharmacy

Adopted Rules: Effective Date: January 4, 2018

CHAPTER 291 PHARMACIES

SUBCHAPTER A - ALL CLASSES OF PHARMACIES

§291.3 Required Notifications

The amendments to this section require the pharmacist-in-charge (PIC) to report the date of a fire or other disaster that may adversely affect drugs, medication, or devices within 10 days from the date of the disaster. The PIC must also notify the DEA and the board of any loss of controlled substances or order forms immediately upon discovery.

§291.5 Closing a Pharmacy

The amendment to this section requires the PIC to notify the DEA of any controlled substances being transferred to another registrant (as specified in 21 CFR 1301.52(d)) at least 14 days prior to the closing of a pharmacy.

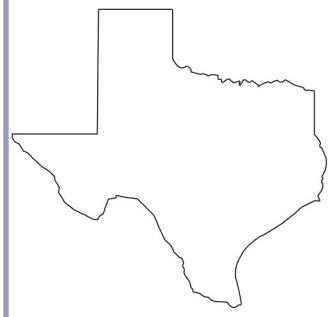
§291.6 Pharmacy License Fees

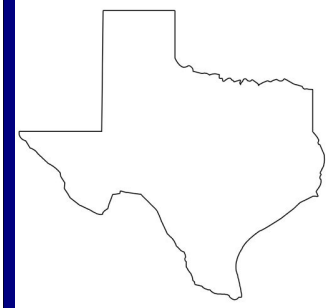
The initial licensing fee is increased from $401 to $459 and the renewal fee is increased from $401 to $456. This section no longer lists additional fees to be collected to fund Texas Online, Office of Patient Safety, Prescription Drug Monitoring Program or other surcharges.

SUBCHAPTER D – INSTITUTIONAL PHARMACY (CLASS C)

§291.74 Operational Standards

The amendment to this section updates the library requirements in order to be consistent with other sections by excluding listed texts such as Facts and Comparisons and Clinical pharmacology as suggestions under general information reference texts. This section also changed by adding that a pharmacist shall perform a drug use review for all medication orders unless it would delay the administration of a drug and therefore cause harm to the patient in an urgent or emergency situation.





For more information on the Texas State Board of Pharmacy rules visit: www.pharmacy.texas.gov

TSBP Adopted Rules continued...

SUBCHAPTER G – SERVICES PROVIDED BY PHARMACIES

§291.121 Remote Pharmacy Services

Amendments updated this section by removing the requirement to include affidavit, statement of contract agreement between provider pharmacy and facility, along with additional documentation for the application and renewal process. It also implements SB 1633 and portions of HB 2561 relating to telepharmacy.

§291.131 Pharmacies Compounding Non-Sterile Preparations and §291.133 Pharmacies Compounding Sterile Preparations.

These sections have been amended to clarify the requirements for written agreements for supplying compounded preparations for office use. These requirements include a statement that addresses acceptable standards of practice for the compounding pharmacy and the practitioner. It also requires that the agreement states that the compounded product can only be administered to the patient and not dispensed to the patient or other entity, unless authorized by§563.054 of the Act. The practitioner or receiving pharmacy should also record the lot number and BUD of a compound administered to a patient.

CHAPTER 295 PHARMACISTS

§295.5 Pharmacist License or Renewal Fees

This amendment increases the initial pharmacist licensing fee from $235 to $284 and increases the renewal fee from $235 to $281. This section will no longer lists additional fees to be collected to fund Texas Online, Office of Patient Safety or other surcharges.

CHAPTER 297 PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

§297.4 Fees

Amendments will increase pharmacy technician registration fees from $45 to $55 for trainees, $72 to $83 for initial registration fee, and $72 to $80 for biennial renewal. This section will no longer list additional surcharges to the registration fees.

§297.7 Exemption from Pharmacy Technician Certification Requirements

This section outlines procedures to petition the board for an exemption to the certification requirements established and is amended to remove the reference to the Pharmacy Technician Certification Board.

§297.8 Continuing Education Requirements

This section has been amended to remove specific reference to the Pharmacy Technician Certification Board. This section has also been amended to clarify continuing education requirements. Technicians still need to complete and report 20 contact hours of approved continuing education with at least one hour related to Texas pharmacy laws or rules. The section also provides a list of the different ways a technician may earn continuing education hours including: Pharmacy related college courses, CPR training, advanced cardiovascular life support courses, attendance at a Texas State Board of Pharmacy Board meeting and more.

CHAPTER 309. SUBSTITUTION OF DRUG PRODUCTS

§309.6 Records

Amendments to this section state if a generic equivalent drug or interchangeable biologic product for a prescription is dispensed the following information must be noted on the original prescription or the pharmacy's data processing system;

1) Substitution instructions given orally by the practitioner or practitioner's agent or include a note that no substitution instructions were given

2) Note the name and strength of the product dispensed on the original prescription

Also, if a prescription is refilled with a generic or interchangeable biological product different than what was previously dispensed, the information required above needs to be recorded on the prescription. All of the aforementioned information must be recorded in patient medication records as well.

Pharmacy Case Law Updates—A brief summary of recent

U.S. ex. Rel. Keen v. Teva Pharmaceuticals USA Inc. No. 15 C 2309 (N.D. Ill. Jan. 4, 2017)

The Relator, who was a former pharmaceutical sales representative for Teva, stated that the drug company had trained its salesforce to use marketing tactics that were misleading in regards to the drug Amrix, brand name for the muscle relaxant cyclobenzaprine. Among these tactics were the promotion of the drug as a treatment to fully stop muscle spasms as well as limiting information related to a possible side effect. The relator also alleged that Teva misguided physicians on the use of Amrix leading to the submission of false claims by pharmacies to federal health programs. Teva filed a motioned to dismiss the complaint. The court concluded that the complaint against Teva's marketing practices does not allege that they led to physicians prescribing Amrix for off-label use and therefore were not submitted as a false claim by any particular pharmacy.

Stevens v. Rite Aid Pharmacy, 851. F.3d 224 (2nd Cir., March 21, 2017) ***UPDATE***

Rite aid appealed the decision of the court that awarded a pharmacist substantial damages amounting to over $1 million after the jury found that the company had violated the ADA for not providing accommodation for his disability. The pharmacist had claimed that he was dismissed because he would not complete immunization training required by the company due to his phobia of needles. The Court of Appeals held that evidence was sufficient to find that immunization administration was an essential job requirement for Rite Aid pharmacists at the time of the pharmacist's dismissal. The court also held that the pharmacist did not provide evidence of a reasonable accommodation that would have allowed him to perform the task at the time he was terminated.

"...the court that awarded a pharmacist substantial damages amounting to over $1 million... "

United States v. Agyekum, 846 F.3d 774 (4th Cir. 2017)

Agyekum challenged the district court's conclusion that his participation in a drug conspiracy qualified as level two enhancements for leadership and abuse of position of trust. Agyekum and his wife owned and operated a pharmacy. She was a licensed pharmacist and he was a licensed pharmacist intern. Their pharmacy was suspected of illegally distributing oxycodone. Upon further investigation Agyekum was arrested and charged with participating in a conspiracy to distribute oxycodone outside of professional practice. The court of appeals held that Agyekums position as the person in charge, a pharmacist intern, and as a de facto manager of the pharmacy was sufficient to support a two-level leadership role enhancement of abusing a position of trust.

Disclaimer :

Much of the information reviewed in this newsletter was derived directly from regulatory services. The authors at Cooper & Scully do not necessarily express the views of these regulators and are simply providing the above information as a courtesy and as a means to inform the reader on current events and developments.

Cooper & Scully
A Professional Corporation

900 Jackson Street, Suite 100
Dallas, Texas 75202

Phone: 214-712-9500
Fax: 214-712-9540
www.cooperscully.com

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