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Pharmacy Law & Regulatory News Updates

Department of Justice: Regulatory Steps to address the Opioid Epidemic

Fall 2018

A proposal in Washington consisted of efforts to improve the control of the Drug Enforcement Administration against diversion of dangerous drugs was submitted by Attorney General Jeff Sessions as a final rule. The DEA is given the right to consider the extent of which a drug is diverted for abuse and can set that drug's annual production limits. The production of particular opioid suspected of diversion for misuse at a given year can now be reduced with the authority of the DEA. It is meant to encourage vigilance amongst manufacturers, and help the DEA to adapt their safety efforts to the changes of the opioid crisis. The DEA is required to share notices of production quotas to state attorney general while also allowing for a hearing to resolve state objections against proposed aggregate production quotas of a particular opioid in relation to the need of the country. With this rule, the DEA also becomes more involved in communication and sharing of information with state, and federal organizations such as the Department of Human and Health Services, Food and Drug Administration, Centers for Disease Control, and Centers for Medicare and Medicaid Services.

Opioid Epidemic Statistics:

- Synthetic opioid deaths (i.e. illicit fentanyl) increased from 14.3% (2010) to 45.9% (2016) of opioid related deaths (P <.01) [1].
- CDC reports that more than 115 people die of opioid overdose in the U.S. [2]
- 2.1 M had an opioid use disorder and 11.5 M misused prescription opioids [3]
- $504 B in estimated economic costs [4]

[1] Jones CM, Einstein EB, Compton WM. Changes in Synthetic Opioid Involvement in Drug Overdose Deaths in the United States, 2010-2016. JAMA. 2018;319(17):1819-1821.

[2] CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: US Department of Health and Human Services, CDC; 2017. https://wonder.cdc.gov.

[3] 2016 National Survey on Drug Use and Health

[4] Mortality in the United States, 2016 NCHS Data Brief n. 293, December 2017.

"Right to Try" Act

The Right to Try Act of 2017 was signed into federal law late May 2018 to allow terminally ill patients to use unauthorized medical products according to their respective state regulations. Laws of "right to try" by terminally ill patients have been passed and enacted by Arkansas, Arizona, Alabama, Connecticut, Colorado, California, Florida, Georgia, Iowa, Indiana, Illinois, Idaho, Kentucky, Louisiana, Montana, Missouri, Mississippi, Minnesota, Michigan, Maryland, Maine, North Dakota, North Carolina, New Hampshire, Nevada, Nebraska, Oregon, Oklahoma, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Tennessee, Utah, Virginia, Washington, Wyoming, Wisconsin, and West Virginia. It was designed as an alternative to the expanded access policies of the FDA allowing patients and pharmaceutical sponsors to work directly thus expands access to treatment. Criteria must be met as an eligible patient and as an eligible investigational drug. There is also no liability against all entities involved in providing the drug to the terminally ill patient unless acts of misconduct to care is involved.

Religious Objection and Corresponding Responsibility's Role in Refusal to Fill

"Religious Objection vs. Corresponding Responsibility"

There are a number of situations where a pharmacist may find resistance to fill a prescription with prescribers and patients. More recently, efforts to combat opioid epidemic have brought to light many regulations and laws designed to reduce opioid drug diversion.

The "Corresponding Responsibility" doctrine under the Drug Enforcement Administration rule allows refusal to fill controlled substances at any doubt of legitimate medical purpose (Title 21 C.F.R. §1306.04). Many other states have adapted this rule to their own local policies. A Florida Board of Pharmacy regulation has taken the position that precludes pharmacists from categorically filling all prescription from a particular prescriber and requires the pharmacist to fill prescriptions on a per prescription basis. This raises the concern in Florida, as to how a pharmacist who identifies a suspected pill mill can ensure that the pharmacy does not get entangled in any regulation or criminal prosecutions.

The case of a pharmacist's refusal to fill an Arizona woman's prescription for misoprostol, also known as the abortion pill, is one that may be of similar nature, but of different context. Arizona, along with five others: Arkansas, Georgia, Idaho, Mississippi, and South Dakota, have passed the laws allowing pharmacists to refuse to fill prescriptions due to personal religious and moral beliefs in 2012. At the event of refusal in such a situation, a pharmacist should refer the prescription to another pharmacist or another pharmacy to meet the patient's need on time.

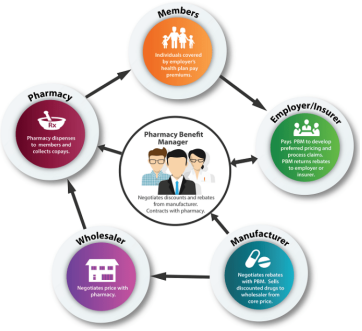
Most states, including Texas and California, have no laws that require pharmacists to fill prescriptions. From a due diligence standpoint, a board may not require a pharmacy to fill prescription. However, pharmacy's participation in esoteric insurance programs may restrict pharmacists from refusing to fill prescription.

Recent Legislative Efforts to Limit Pharmacy Benefit Managers

"PBM contracts can prevent pharmacists from revealing a cheaper option..."

Pharmacy benefit managers or PBMs are middlemen that negotiate drug prices with drug manufacturers for drug plans, agencies, pharmacies, insurers, etc. PBMs can work for an agency or a group that consists of many others related entities; together, they can collect purchasing power that can be used to negotiate drug prices. On the other hand, manufacturers can also provide rebate benefits to PBMs for being included in drug formularies. Notably among these entities are Medicaid and Medicare managed-care plans that handle drug benefits for a large portion of the U.S. population. There are speculations, that this system is leading to an increase in drug prices.

Plans for legislative regulations of PBMs are on the rise to help lower drug prices. One concern is the use of "gag clause" in PBM contracts, these prevent pharmacists from revealing a cheaper option to patients rather than running a prescription through insurance, which may have higher copays than the drug's retail price. In 2018, 18 states have passed similar laws prohibiting "gag clause" and many states considering similar legislation. At least 5 states have passed laws requiring PBMs to be licensed or registered by state administration including a recently signed law by Gov. Asa Hutchison for the state of Arkansas. At least 4 states now required PBMs to disclose transparency reports to show rebates received from manufacturers. Additional regulations are being passed by States against PBMs to increase drug price transparency.



P.A.

Florida puts more limits on Opioid Prescriptions

In an effort to decrease addiction fueling the opioid crisis, Florida physicians registered with the Drug Enforcement Agency (DEA) are now required to check the state's database, Prescription Drug Monitoring Program, for each patient as a routine procedure, similar to pharmacists, before prescribing controlled substances for pain. Effective on July 1 with a deadline of January 31, 2019 for completion, physicians must take a two-hour education class relating to the new law and it must be retaken at every license renewal.

This new law also limits the days that patients can be given medication for acute pain. More specifically, a three-day limit for Schedule II and a seven-day limit prescription when the patient's pain and the absence of an alternative is documented by the provider. Physicians who do not comply to this new law are subject to charges of first degree misdemeanor and/or discipline by the licensing board.

Pharmacists' duty with Prior Authorization

Prior authorization refers to the situation when the prescriber must obtain an insurance preapproval for a specific medication to be covered by the patient's insurance plan. This process is only required for certain drugs and its part of a managed care system of insurance plans, it helps insurance providers better manage costs, utilization and quality of health care for patients.

Recently, Massachusetts Appellate Court reversed the decision of Superior Court about the subject matter, The Appellate Court concluded that pharmacies and its pharmacist have a legal duty to inform both the patient and the prescriber about the requirement of a prior authorization. The pharmacist's role in the patient's healthcare is evolving beyond simple dispensing duties, and this is one example of the growing practice of pharmacy. Details about the case is further discussed in the Pharmacy Law Cases section of this newsletter.

"TO ERR IS HUMAN"

State Efforts to Reduce Pharmacy Errors

The recent rise in pharmacy errors have led to a new legislation by the State of Minnesota, placing work hours limits and addition of breaks for pharmacy personnel. The law states that pharmacy personnel are:

1. Limited to a maximum of 12 hours a day
2. Authorized a 30 minute break after working longer than 6 hours a day
3. Allowed a restroom break every 4 hours

This is an effort to reduce errors especially in retail pharmacies due to fatigue. The director of the Minnesota Board of Pharmacy adds that the increasing responsibilities and volume of prescriptions to pharmacy personnel makes operations inevitable to error, however this provision may help decrease the rate of errors.

For a complete list of changes visit: www.pharmacy.ca.gov/laws_regs/

California State Board of Pharmacy
More Changes to the Business and Professions: Effective Date: January 1. 2018 unless

§4022.6 is added

A designated representative- reverse distributor is described as an individual licensed pursuant to § 4053.2 responsible to supervise a licensed wholesaler only on the act as a reverse distributor. A pharmacist performing the duties of § 4053.2 is not required to obtain this license.

§ 4034.5 is added

An emergency medical services automated drug delivery system or EMSADDS is described as an automated drug delivery system which stores and distributes drugs only for the purpose of restocking a secured emergency pharmaceutical supplies of an emergency medical services agency.

§ 4053.2 is added

This section states the requirements to be licensed as a designated representative-reverse distributor issued by the board. The licensee must protect the public health and safety in handling outdated or non-saleable dangerous drugs and devices. The licensee must be at least 18 years of age and a high school graduate or obtain an equivalent certificate. He or she must also have one year of work experience related to the nature of duties of the license, meet all prerequisites to take the licensure examination as a pharmacist, and completed designated training programs for handing dangerous drugs and devices under the California law, federal law, and the U.S. Pharmacopeia.

§ 4084.1 is added

Any nonprescription diabetes test devices found by a board inspector to have dispute of being purchased directly from the manufacturer or their authorized distributors may be subject to embargo by the board. These products will be processed at the same manner as adulterated, misbranded, or counterfeit drug or device products.

§ 4119.01 is added

This section specifies the conditions that are required for the use of EMSADDS. The conditions include requirements for licensure per location, responsibilities and procedures of maintenance, such as recordkeeping, by authorized personnel.

§ 4127.15 is added

The board may issue a license to a hospital satellite compounding pharmacy. The pharmacy shall provide services that is directly related to the treatment to registered patients who reside in the premises. In addition, pharmacy terms of operation and required documentations are specified for renewal.

§ 4132 is added

This section specifies additional requirements for a pharmacy technician working at a remote dispensing site pharmacy as put forth by the board. The allowable activities that a registered pharmacy technician may perform are stated along with activities that he or she may not perform. The ratio of supervising pharmacist to pharmacy technician is 1:2.

§ 4133 is added

The responsibilities and duties of operation of a telepharmacy system are stated in this section. Specific operational procedures are stated in maintenance of a video and audio communication in pharmacist supervision of activities and patient counseling among others. Records of actions are to be maintained at the remote dispensing site pharmacy for 3 years after the filling of the prescription.

§ 4134 is added

This section states the inspection requirements of a remote dispensing pharmacy that a pharmacist from the supervising pharmacy must perform on a monthly basis. Inspections include review of inventory and reconciliation functions of related to all dangerous drugs including controlled substances designed to prevent any loss of inventory.

§ 4135 is added

A remote dispensing site pharmacy shall utilize an alarm system when closed. It shall close for services when the supervising pharmacy is closed, unless when a pharmacist is present. To provide pharmacy services, the pharmacy must have the telepharmacy system available. The security system shall track entries into the pharmacy, and the pharmacist-in-charge must periodically review the record of entries.

§ 4160.5 is added

A manufacturer of a nonprescription diabetes test device shall list the names of it authorized distributors on its website and provide the information to the board. The board will also post the list on the board's website. Any updates to the list shall be reported to the board. Changes and updates are done within 30 days of notice.

§ 4169.1 is added

Upon discovery, a wholesaler shall notify the board in writing of suspicious orders of controlled substances placed by a California -licensed pharmacy or another wholesaler. Suspicious orders may include orders of unusual size and frequency and/or deviation from normal pattern.

§ 4180.5 is added

This section states the compliance criteria for clinics for licensing, by the board, under § 4180 to two independently owned clinic that share a clinic office space. Among their criteria include distinction of separate maintenance procedures. This section shall be repealed and inoperative on January 1, 2021.

§ 4202.5 is added

The board may issue a designated paramedic license to a licensed paramedic that meets the criteria state in this section. The board shall order a criminal background check for ground of license denial. The board may suspend or revoke the license as specified by the grounds of § 4301.

Texas State Board of Pharmacy
Adopted Rules: Effective Date: June 7, 2018

SUBCHAPTER A- ALL CLASSES OF PHARMACIES

§ 291.9 Prescription Pick Up Locations

The amendments to this section clarify the requirements for prescription pick up locations according to the DEA. The patient can request to have a pharmacy personnel or a common carrier to pick up and/or deliver prescription orders or drugs from specified locations. These locations include the office of the prescriber, residence or place of employment of the patient, or medical facility where the patient is receiving treatment.

SUBCHAPTER B- COMMUNITY PHARMACY (CLASS A)

§ 291.33 Operational Standards

The amendments to this section revised the requirements for the use of automated checking, storage, and distribution devices by Class A pharmacies. The use of automated checking devices for final check is required to be conducted by a licensed pharmacist prior to delivery to the patient or instead, specified checks for accuracy, error, and maintenance must be fulfilled. The use of automated distribution and storage device to deliver previously verified prescriptions to the patient must include the service of counseling and consultation by a Texas licensed pharmacist in addition to maintenance procedures for the devices.

SUBCHAPTER D- INSTITUTIONAL PHARMACY (CLASS C)

§ 291.75 Records

The amendment to this section requires Class C pharmacies to maintain a log of pharmacy personnel initials or identification codes. Initials and identification codes must be unique to the personnel to ensure assertive identification and the log must be maintained at the pharmacy for at least seven years.

§ 291.76 Class C Pharmacies at Freestanding Ambulatory Surgical Centers

The amendments to this section requires Class C pharmacies located in a Freestanding Ambulatory Surgical Center to also maintain a log of pharmacy personnel initials or identifications codes with the same requirements stated in § 291.75.

SUBCHAPTER G- SERVICES PROVIDED BY PHARMACIES

§ 291.121 Remote Pharmacy Services

The amendments to this section clarify the requirements for the delivery at a remote site using telepharmacy systems. Specification with regards to drug regimen review and labeling adhere to § 291.33 prior to delivery of prescription. Schedule II controlled substances may not be dispensed through this system. Drugs dispensed shall only be delivered to the patient or patient's agent at the remote site.

§ 291.125 Centralized Prescription Dispensing

The amendments to this section clarifies the definition of an outsourcing pharmacy, which is " a Class A or C pharmacy that communicates a prescription drug order to a central fill pharmacy to be dispensed by that central fill pharmacy." In addition, requirements of centralized prescription dispensing was updated to require outsourcing by a Class A or C pharmacy dispensing to a central fill pharmacy with a contract or agreement outlining the responsibilities and accountabilities in compliance to federal and state laws and regulations.

SUBCHAPTER H- OTHER CLASSES OF PHARMACY

§291.151 Class F Pharmacies in Free Standing Emergency Medical Care Facility

The amendments to this section require the pharmacist-in-charge to ensure that a pharmacist visits the pharmacy at least once each calendar week. Withdrawal of drugs from the facility must be recorded by an authorized person removing the drugs or devices with specified information documented or can be substituted with the medication order for the patient with all required information. Finally, the pharmacist shall verify the withdrawal as soon as practical, but should not exceed 72 hours from the time of withdrawal. In addition, a rule reference was corrected.

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

"pharmacists' skills and knowledge today, extend to more than dispensing of pills"

Pharmacy Law Cases: Brief Summaries

***Correa v. Schoeck and others*, 33 Mass. L. Rptr. 666 (2016).**
UPDATE: reversed in part, vacated in part, and remanded by ***Correa v. Schoeck and others**, 479 Mass. 686 (2018).*

A Massachusetts Appellate Court reversed and vacated, in part, the decision made by a Superior Court. The claim charged the defendants for wrongful death, punitive damages, pain and suffering alleging that negligence caused the death of the plaintiff's daughter.

The daughter suffered a fatal seizure due to the inability to receive her anti-epileptic prescription medication, Topamax. A prior authorization from the providing physician was needed before the insurance would cover for the high-priced medication. Communication issues between the patient's caregivers, pharmacy, and the provider's office allegedly did not allow for the medication to be filled on time.

Walgreens, the pharmacy involved, moved for a summary judgment claiming that it had no legal duty to plaintiff's daughter, and sought dismissal of the case, the trial court agreed. The plaintiff the claim that Walgreens had the legal duty to notify the provider of the need for the prior authorization of the medication and not relying on the computer system to do so. The court concluded that Walgreens had a limited duty to notify both the patient and the providers of the need for a prior authorization each time the medication was filled. The summary of judgment for Walgreens was reversed to further claims that the pharmacy's duty does not extend to require its own follow up ensuring that the provider received notice or completed the prior authorization process.

Upon Supreme Judicial summary of judgment of the case, the issues of duty of care, pharmacist-patient relationship, specific knowledge, industry practices, and foreseeability were discussed for reconsideration. More notably discussed, pharmacists' skills and knowledge today, extend to more than dispensing of pills. The court noted that the skills and knowledge of the profession parallels that of other healthcare professionals that should have led to the pharmacist notifying the provider of the prior authorization in the case matter. Because of these arguments, the court reversed appellate summary judgment, vacated the dismissal.

Martinez v. Walgreens Company, 2018 WL 3241228.

A U.S. District Court in Texas granted the defendant's motion for summary judgment, this suit revolves around the plaintiff's claim to the theory of common-law negligence with regards to pharmacists' duty to non-patients or a third party.

A different claim was filed by an immediate party for negligence stating that a Walgreens pharmacist was negligent in filling the wrong medication, glyburide/metformin. Plaintiff claimed that the medication allegedly resulted in hypoglycemia that caused a car accident leading to the deaths of the immediate party's family and a third party involved.

The defendant moved for a summary judgment on the grounds that pharmacists do not have duty to non-patients, thus are not liable to third parties. By Texas Law definition, negligence can exists when a duty is established and the breach is committed. Texas courts have not commonly accepted the common-law duty of healthcare providers to third parties. Upon analysis, the Court did not find the pharmacist had a duty to the unconnected third parties regarding the negligent filling of immediate party's prescription. The defendant's motion for summary judgment was granted, the plaintiff's claims and actions were dismissed with prejudice. .

"it is not a constitutional violation to include a limited list of medications to a formulary"

Pharmacy Law Cases: Brief Summaries Continued

Pharmaceutical Care Management Association v. Rutledge, 891 F. 3d 1109, (2018).

Pharmacy Benefit Managers (PBM) Association appealed against a recent Arkansas statute, Act 900. This statute placed a number of restrictions on PBM operations, the most notable regulation in this Act states:

1. Pharmacies must be reimbursed for generic drugs at a price that is equal to or higher than the pharmacies' drug purchase cost as stated by invoices from the wholesaler.
2. PBMs are required to update maximum allowable cost (MAC) list within seven days of an increase in drug acquisition cost.
3. Pharmacies have a "decline-to-dispense" option on transactions that would result in a loss of revenue.

The plaintiff claims that the statute is preempted by the Employee Retirement Income Security Act (ERISA) and Medicare Part D. The Eighth Circuit Court of Appeals granted the appeal acknowledging preemption by ERISA, but not under Medicare Part D preemption. ERISA preempts any state law related to employee benefits plan that is connected to PBM administration and management of pharmacy benefits.

Medicare Part D, however, was initially declared to not preempt the act due to a conflict between state and federal law. However, the decision was reversed due the interference of Act 900's "decline-to-dispense" provisions. This provision interferes with Medicare Part D's pharmacy access standard that protects the patient's convenient access to prescription drugs.

The ERISA ruling was affirmed, Medicare Part D ruling reversed, and the entry of judgement is remanded in plaintiff's favor.

Tuduj v. Johnson, 2018 WL 3689062.

The plaintiff initially filed a suit against collective defendants of the medical care team at a correctional center, where the plaintiff was incarcerated. The plaintiff claims that he was not provided the prescribed medication for his condition due to the medication's exclusion from the pharmacy formulary resulting in damage to his eyes from inadequate medical care for a systemic infection.

The plaintiff filed an objection against a magistrate's order denying the plaintiff's request to amend his complaint to add a certain pharmacy as a defendant against his suit. The plaintiff extends suit against the pharmacy affiliated with the correctional facility under grounds that the pharmacy interfered with the plaintiff's prescribed course of treatment due to its role in the creation a drug formulary. The magistrate noted that no particular "policy, practice, or custom" by the pharmacy caused or contributed to the plaintiff's constitutional claims, and that it is not a constitutional violation to include a limited list of medications to a formulary.

Two motions to seek amendment of the same subject matter were also denied by the same magistrate because the absence of the plaintiff's medication from the pharmacy formulary is not considered unconstitutional.

"In 2009, Tug Valley Pharmacy filled 42,115 hydrocodone prescriptions in a town with a population of only, 3090."

Pharmacy Law Cases: Brief Summaries Continued

Ballengee v. CBS Broadcasting, Inc., S.D. Virginia Case No: 2:17-CV-00212

The plaintiff opened a pharmacy in West Virginia in 2007. From 2008 to 2009, the pharmacy filled 67,388 controlled substance prescriptions primarily written by two clinics. The court later describes these clinics as "pill mills." In 2010 to 2012, Plaintiff and his pharmacy had four lawsuits filed by its customers for negligently filling controlled medications and contributing to their drug dependency.

CBS aired two broadcasts in 2016, the first broadcast made the following representations:

1. The State of West Virginia filed a lawsuit against 11 pharmaceutical distributions for contributing to drug abuse.
2. Another pharmacist that received criminal charges for illegally dispensing drugs.
3. Plaintiff's pharmacy was being sued for negligently filling prescriptions
4. It was filling more than 150 pain prescriptions a day from a single clinic
5. Plaintiff was named in a lawsuit for providing "substandard care."

Plaintiff claimed to have suffered significantly following the first CBS program, he claimed that drug supplier terminated its contract to supply medications to his pharmacy, his pharmacy lost business, causing him to eventually sell his pharmacy and he was unable to find employment with former employer.

CBS aired a second broadcast stating that plaintiff's drug distributor terminated drug supply contract but only after learning about the charges against the plaintiff on CBS.

Plaintiff filed this lawsuit against CBS Broadcasting Inc. asserting defamation, false light invasion of privacy, tortious interference and intentional infliction of emotional distress. Plaintiff argued that defamation arose because:

1. His pharmacy filled 150 to 200 prescriptions a day consisting of both non–pain and pain medications.
2. He had not been charged with criminal charges unlike the other pharmacist stated by CBS.

Defendant filed motion for summary judgement. The court found that CBS's statement did not rise to the level of defamation. To support its ruling the court pointed:

1. Minor inaccuracies do not lead to falsity, since the CBS's statements were substantially true.
2. A reasonable juror would not find charges about the pharmacist to be implied to the plaintiff.

The court also found the claim of tortious interference to be false because CBS had no knowledge of plaintiff's former employer, his current business relations and did find defendant to intentionally harm the plaintiff.

After examination of the pharmacy's opioid dispensing practices, the court found CBS's statements about plaintiff to be substantially accurate. The defendant's motion for summary judgment was granted by the court.

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