I. OVERVIEW

A. Objectives

1. After this program, attendees should be able to:
   a. Describe the legal holdings for recent judicial decisions affecting pharmacy.
   b. Describe the Utah judicial decisions that govern pharmacists’ liability for negligence.
   c. List the most common problems that Utah DOPL inspectors find in Utah pharmacies.
   d. Implement steps to enhance compliance with Utah pharmacy laws and regulations.
   e. List means pharmacists can use to keep track of legislative and regulatory changes in laws affecting pharmacists.
   f. Describe the rights and obligations of pharmacists when DOPL inspects or investigates pharmacies.
   g. Describe most recent changes in Utah laws and regulations affecting pharmacists.

II. RECENT LEGAL CASES AFFECTING PHARMACY

A. Defamation—Physician against Pharmacy


   RELIEF SOUGHT: Physician sued pharmacy for slander because its employees made false statements about his medical reputation and ethics.

   ISSUE: Did the physician provide enough evidence to survive a motion for summary judgment for the slander claims.

   FACTS AND PROCEDURAL HISTORY: Walgreens filed a motion for summary judgment asking the court to dismiss physician’s claims as a matter of law.

   REASONING: Under Florida law, a plaintiff must prove the following to prevail in a suit for slander: “(a) a false and defamatory statement concerning another; (b) an unprivileged publication to a third party; (c) fault amounting
to at least negligence on the part of the publisher; and (d) either actionability of the statement irrespective of special harm or the existence of special harm caused by the publication.” Malice is also “an essential element” of a claim. Malice is presumed if a false statement “suggests someone has committed a dishonest or illegal act.” Proof must include the specific person speaking, to whom the statement was made, and a time frame.

A statement is privileged if it is: 1) made in good faith; 2) with an interest to be upheld; 3) published on a proper occasion; and 4) published in a proper manner.” Here Walgreens’ pharmacists were in the proper location (the pharmacy) and made by pharmacists at the time prescriptions were with the apparent purpose to provide information about a physician who prescribed their medications. Florida case law held that pharmacists cannot satisfy their duty to provide competent advice to patients by “a robotic compliance with the instructions of the prescribing physician.” Furthermore, the statements were about specific prescriptions, not simple generalizations. Thus, the statements were made in good faith to further a legitimate interest.

Walgreens pharmacists’ statements were protected by privilege and plaintiff failed to show any malice.

**HOLDING:** Court granted summary judgment to Walgreens and dismissed the claims for slander.

### B. Duty to Refrain From Dispensing Refills Too Often


**RELIEF SOUGHT:** Patient’s widow appealed dismissal of her claims against pharmacy and pharmacist for filling controlled substances prescription too often, which she claimed resulted in her husband’s death.

**ISSUE:** Did the pharmacy and pharmacists have a duty to inquire into or refuse to fill prescriptions being prescribed too often.

**FACTS AND PROCEDURAL HISTORY:** Physician treated patient for “stress syndrome” and prescribed alprazolam, hydrocodone/acetaminophen or oxycodone/acetaminophen. Widow claimed the pharmacy filled 30 or more prescriptions without any questions despite their being issued too quickly based on the time the patient would have consumed the medication. Patient died of “combined drug intoxication of Alprazolam and Hydrocodone.”

Widow claimed defendants owed her husband a duty to: (i) use proper care in filling prescriptions; (ii) exercise care of a reasonably prudent pharmacist; (iii) not dispense prescriptions that were unreasonable on their face or in light of the circumstances; (iv) warn, under the circumstances; (v) comply with
pharmacy’s policies and procedures; (vi) comply with applicable laws and regulations; and (vii) not subject her husband to unreasonable risk of harm from their foreseeable conduct.

Pharmacy filed a motion for summary judgment asserting under prior Florida case law that pharmacists owed no duty to the patient other than correctly filling valid and lawful prescriptions.

**REASONING:** The court explained that the question of whether a duty exists is a question of law for the court to determine. In this case, the defendants had a duty to “use due and proper care in filling a prescription that extends beyond simply following the prescribing physician’s directions...” We refuse to interpret a pharmacist’s duty to use ‘due and proper care in filling the prescription’ as being satisfied by ‘robotic compliance’ with the instructions of the prescribing physician.” Here the pharmacy filled “numerous prescriptions that were so close together that Pharmacy should have been on notice that Mr. Porter was receiving too may pills.”

Plaintiff alleged sufficient facts to create a factual question for the jury to determine whether defendants violated its duty to the patient.

**HOLDING:** Court reversed summary judgment in favor of pharmacy and remanded the case for trial.

**C. Refusal to Fill Prescriptions**


**RELIEF SOUGHT:** Physician and patients sued mail order pharmacies for failing to fill HGH prescriptions the physician wrote.

**FACTS AND PROCEDURAL HISTORY:** Endocrinologist prescribed HGH for patients that they allege were “evaluated and determined to be medically necessary.” Pharmacies began refusing to fill the prescription in 2010. Defendants claimed they refused to fill the prescriptions because they were concerned that filling them would have been a violation of the Food, Drug and Cosmetic Act, 21 U.S.C. § 333(e) because they would have been knowingly distributing HGH for uses that were not approved by the FDA. Another Express Script pharmacy previously entered into a deferred prosecution agreement related to distribution of HGH. The refusal to fill was based on policies established to comply with that agreement. Furthermore, pharmacies claimed their due diligence showed the prescriptions were for off-label use or that the physician associated with organizations that advocated such use.
REASONING: Plaintiffs’ claims were based in large part on the Indiana pharmacy law sections that said pharmacists must exercise “professional judgment in the best interest of the patient’s health” and have a duty to honor all prescriptions from a prescriber licensed under the laws of another state after taking reasonable steps to make sure a prescription complies with the laws of that state. The court rejected plaintiffs’ arguments and explained that the law in question did not create a private cause of action, but was part of a broad regulatory scheme with enforcement mechanisms to regulate the profession of pharmacy.

HOLDING: Court dismissed plaintiffs’ claims as a matter of law with prejudice.

D. Refusal to fill without payment—Is there a duty to fill?


RELIEF SOUGHT: Pharmacy moved to dismiss claims by estate of deceased patient that sued pharmacy claiming its delay in providing anticoagulation medications while insurance payment was held up caused patient’s death.

ISSUE: Does a pharmacy have a duty to dispense drugs without payment after telling a patient the pharmacy has the drugs in stock?

FACTS AND PROCEDURAL HISTORY: Patient was in a car accident and suffered a broken leg, among other injuries. After surgery, patient’s medical providers prescribed Lovenox and Coumadin upon discharge from the hospital. The hospital pharmacy could not provide the medications, but a CVS employee told patient the pharmacy had the medications and would provide them. However, when the pharmacy tried to fill the medications, there was a problem with insurance approval and the prescriptions would be available after a short time. The pharmacy dispensed all other prescribed medications. The patient died several days later from complications due to not receiving the medications. The patient also sued the workers’ compensation insurance carrier.

Pharmacy filed a motion to dismiss arguing that a pharmacy has no duty to dispense medications without payment. Plaintiff argued that CVS voluntarily undertook a duty to provide the medications. The plaintiff never alleged the employee said CVS would supply the medications regardless of payment. A
“retail pharmacy like CVS understandably requires payment for medications it dispenses.”

HOLDING: Court granted pharmacy’s motion to dismiss.

E. DEA—Duty to Verify Prescriber DEA Registration


RELIEF SOUGHT: In two separate DEA actions against pharmacies, each pharmacy appealed the decision of an administrative law judge (“ALJ”) to deny applications for DEA registration.

ISSUE: Does a pharmacy have a duty to verify the DEA registration of prescribers under the DEA corresponding liability regulation?

FACTS AND PROCEDURAL HISTORY: In *JM Pharmacy*, the DEA claimed two pharmacies filled more than 170 prescriptions for a physician whose DEA registration had been revoked. The other case, *Farmacia Yani*, involved allegations that the pharmacy filled more than 200 prescriptions for controlled substances for a physician whose DEA registration had been revoked. The ALJ denied the pharmacies’ applications for registration. Among other findings, the ALJ explained the pharmacies could have checked the prescribers’ registration on the DEA diversion website, contacted the local DEA office, or contracted with a private service to obtain DEA verifications.

REASONING: The DEA Administrator (“Administrator”) reviewed the ALJ’s decision and particularly, the corresponding liability section of the DEA regulations, which reads:

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall
be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

The Administrator noted that under this section, the pharmacist must act knowingly or intentionally. Moreover, there is no requirement in the Controlled Substances Act or DEA regulations that requires a pharmacist to verify a prescriber’s DEA registration before dispensing a controlled substance prescription. To meet this requirement, the pharmacist must have knowledge or reason to know a prescription is not valid.

The Administrator explained the pharmacists violated a duty to periodically check whether a prescriber has retained authority to practice medicine and dispense controlled substances. The Administrator further noted that the DEA must provide some guidance on the scope of this duty before the DEA will do anything more than give “nominal weight” to such a duty.

**HOLDING:** The Administrator concluded that a pharmacist must have knowledge that a prescription is not valid, but also mentioned an amorphous duty to verify DEA registration. Ultimately, the Administrator denied registration in the JM Pharmacy case because it had falsified its application for registration. In the Farmacia Yani case, the Administrator afforded minimal weight to the failure to verify DEA registrations and held the DEA application in abeyance for six months until the pharmacy personnel completed a course on controlled substances dispensing and corresponding liability.

F. Employment—American with Disabilities Act (“ADA”)


**RELIEF SOUGHT:** Pharmacist who claimed he had trypanophobia (needle phobia) sued pharmacy for damages based on allegation pharmacy violated ADA and the New York State Human Rights Law (“NYSHRL”).

**ISSUE:**

1. Did pharmacy violate the ADA when it fired a pharmacist who would not give immunizations because of his fear of needles?

2. Is so, what damages was the pharmacist entitled to?

**FACTS AND PROCEDURAL HISTORY:** Pharmacist Christopher Stevens was a pharmacist at Eckerd Pharmacy in upstate New York. Rite Aid purchased the pharmacy in 2007. Rite Aid required all pharmacists to undergo mandatory immunization training. Stevens had never undergone such training. Stevens provided human resources department and district
managers with letters from physician stating that he has trypanophobia. Stevens contended that it would be unsafe for him to provide immunizations to patients. Rite Aid warned Stevens that he would be terminated if he did not undergo immunization training. Stevens refused. Stevens was fired days later in August 2011. Stevens filed a complaint with the EEOC. During the investigation, Rite Aid admitted that Stevens was fired because he refused to administer flu shots.

Rite Aid argued that trypanophobia was not a disability defined by the ADA and firing was on a “legitimate, nondiscriminatory” basis.

The jury found that Rite Aid violated ADA and state law requiring employers to provide reasonable accommodations and prohibit termination due to disability.

VERDICT: Jury found Rite Aid:

(i) Violated the ADA because it discharged pharmacist because of a disability;

(ii) Violated the ADA by not providing reasonable accommodation for his disability;

(iii) Retaliated against pharmacist because of his ADA claim; and

(iv) Violated NYSHRL by discharging pharmacist because of his disability, failing to provide reasonable accommodation, and retaliating against him for his claim.

Jury awarded $2.6 million in damages. See details below.


RELIEF SOUGHT: Pharmacy filed motions for judgment as a matter of law seeking to overturn jury verdict, or, in the alternative, seeking a new trial.

ISSUES:

1. Was there sufficient evidence for the jury to render its verdict on the various violations of the ADA and the NYSHRL?

2. Was the jury’s award proper?

FACTS AND PROCEDURAL HISTORY: After a jury found Rite Aid violated the ADA and the NYSHRL, it moved for judgment as a matter of law under Fed. Rule of Civil Procedure 50(b) or a new trial under Fed. Rule of Civil Procedure 59.
**REASONING:** The court first addressed whether the pharmacist had a *physiological or psychological disability*. The EEOC defines physical or mental impairment to mean: “Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more body systems, such as neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, Immune, circulatory, hemic, lymphatic, skin, and endocrine . . . .” A physician testified the pharmacist exhibited an “unprepared, spontaneous reaction . . . that could not be rehearsed” that included turning white, looking annoyed, and almost fainting when the physician pierced his own skin with an insulin syringe and drew blood.

Next, the court concluded there was sufficient evidence that the *impairment was a “substantial limitation,”* which means the impairment substantially limits the ability of an individual to perform a major life activity as compare to most people.” However, an impairment “need not prevent, or significantly or severely restrict, the individual from performing a major life activity in order to be considered substantially limiting.” A physician’s testimony that the trypanophobia significantly restricted the pharmacist from performing any job involving administration of injections.

The court also found sufficient evidence that *trypanophobia is a neurological impairment* based on expert testimony that the impairment impacted the pharmacist’s neurological function through the “sympathetic branch of the nervous system,” which caused the anxiety which in turn caused those symptoms sufferers try to avoid.

The court then evaluated whether giving immunizations is an *essential job function*. If an employee cannot perform an essential job function with or without reasonable accommodation, the employer is not required to eliminate the function. Rite-Aid’s District Manager did not include giving immunizations in his description of plaintiff’s duties. None of the 16 “essential duties and responsibilities” in the job description included immunization. Thus, there was sufficient evidence that immunization was not an essential job function.

The court found that the pharmacist did not present sufficient evidence that Rite-Aid did not reasonably accommodate his disability by providing desensitization therapy, hiring a nurse, giving him technician position, or assigning him to a dual-pharmacist store.

The court turned to damages and sustained all damages except for the $900,000 of compensatory damages based largely on emotional distress because such damages would shock the judicial conscience. The damages are listed below.
<table>
<thead>
<tr>
<th>Type of Damages</th>
<th>Jury</th>
<th>Court’s Post-Trial Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back Pay</td>
<td>$485,633</td>
<td>Same</td>
</tr>
<tr>
<td>Front Pay</td>
<td>$1,227,188</td>
<td>Same</td>
</tr>
<tr>
<td>Non-pecuniary (emotional distress, etc.)</td>
<td>$900,000</td>
<td>$125,000</td>
</tr>
<tr>
<td>Total</td>
<td>$2,612,821</td>
<td>$837,821 (or new trial)</td>
</tr>
</tbody>
</table>

**HOLDING:**

1. The court held there was sufficient evidence to support each of the jury’s findings except for the finding that Rite Aid failed to provide reasonable accommodation by not allowing time off for “desensitization.”

2. The jury’s damages award was proper except for the non-pecuniary award for $900,000, which the court reduced to $125,000 or plaintiff could try the case again.

**G. Privacy—Disclosure of Patient Information**


**FACTS AND PROCEDURAL HISTORY:** Hinchy had “on-and-off sexual relationship with Davion Peterson.” Hinchey filled prescriptions, including birth control pills, at Walgreens. Peterson begins dating Audra Withers, a Walgreens pharmacist. Hinchy became pregnant by Peterson. Peterson learns he has herpes and tells Withers. Withers “became terrified” about potentially contracting an STD. So, Withers looked up Hinchy’s prescription files to look for information about STD. Eventually, Peterson wrote nasty emails to Withers saying: “I’m not trying to start any crap but I have a print out showing that you didn’t even refill ur [sic] birth control prescription for july or august [sic]” goes on to excoriate her.

Walgreens’ investigation concluded: (i) HIPAA/privacy violation occurred; (ii) Withers viewed Hinchy’s information for personal reasons; and (iii) there was no confirmation Hinchy revealed the information to third parties. Walgreens issued a written warning to Hinchy and required her to retake HIPAA training.

**VERDICT:** Jury found Hinchy suffered $1.8 million in damages and allocated 20% to Peterson (non-party and non-employee) and 80% to Walgreen and Withers.
REASONING AND HOLDING:

- Court did not opine on recognizing tort of public disclosure of private facts in Indiana.
- Pharmacy has a duty based on relationship between pharmacist and patient.
- Indiana law provides “[a] pharmacist shall hold in strictest confidence all prescriptions, drug orders, records, and patient information.”
- Therefore, there was a basis for negligence verdict against the pharmacist Withers.
- *Respondeat superior* liability: Even though Withers was not authorized to sneak a peek at patient records for personal reasons, her conduct was of the same general nature authorized by her employer.
- *Damages:* Based in part on: (i) Hinchy’s father learning of birth control use, herpes, etc.; (ii) mental distress, humiliation, feeling “completely freaked out,” violated, shocked, and confused; (iii) uncontrollably crying and general distrust of all health care providers; (iv) need for counselor; and (v) antidepressant at $75 per month.

H. Utah Cases Impacting Pharmacists Liability

1. *Learned Intermediary Doctrine:* A drug manufacturer is not liable for failure to warn patients of the dangers of prescription drugs if it adequately warns prescribers. This doctrine has been applied in most states to protect pharmacists from liability because it is the learned intermediary’s duty to decide whether a patient receives a prescription drug.

2. *Schaerrer v. Stewart’s Plaza Pharmacy, Inc., 79 P.3d 922 (Utah 2003):* Pharmacist who compounded once-a-day fen-phen was not liable. Learned intermediary doctrine protected pharmacists from product liability claims. “Although pharmacists can be held liable for negligence if there is a breach of duty, pharmacists are protected from claims if they fill a prescription precisely as directed by the manufacturer or physician.”


**RELIEF SOUGHT:** Plaintiff appealed trial court’s dismissal of case against pharmacy when plaintiff alleged the pharmacy dispensed Pondamin (fenfluramine) to patient after it had been withdrawn from the market.
ISSUE: Does the learned intermediary doctrine shield a pharmacy from a negligence claim when the pharmacy dispenses a drug withdrawn from the market without telling the patient or contacting the physician?

FACTS AND PROCEDURAL HISTORY: In early 1996, Dr. Poulson began prescribing fen-phen for Steven Downing. From February 1996 until September 2000, Hyland filled Downing’s prescriptions for fen-phen. On August 16, 2004, Downing brought negligence claims against Hyland for continuing to fill prescriptions for fenfluramine after it was withdrawn from the market by the FDA and the manufacturer. Downing alleged the pharmacy negligently filled his fen-phen prescriptions and failed to remove Pondimin from its shelves and inventory after the withdrawal.

REASONING: The Utah Supreme Court noted that Utah had adopted the learned intermediary doctrine to bar failure-to-warn claims under a strict liability theory in Schaeerrer v. Stewart’s Plaza Pharmacy, 79 P.3d 922 (Utah 2003). In Schaeerrer (a fen-phen one-a-day compounding case), the court also noted (probably as dicta because the parties agreed there was no causation for the negligence claim) that “[a]lthough pharmacists can be held liable for negligence if there is a breach of duty, pharmacists are protected from claims if they fill a prescription precisely as directed by the manufacturer or physician.”

The Downing court distinguished the Schaeerrer language and explained

The majority of recent decisions discussing the [learned intermediary] rule . . . have recognized limits or exceptions to its scope in the negligence context, concluding that its protections extend only to warnings about general side effects of the drugs in question, but not to specific problems known to the pharmacist such as prescriptions for excessively dangerous amounts of the drug or for drugs contraindicated by information about a patient. These holdings attempt to account for the nature of modern pharmacy practice and to apply traditional common law negligence rules to that practice.

The Court then explained it would limit the application of the doctrine’s application to negligence claims when the facts and public policy require such limitation. “The facts alleged here state a cause of action for negligence as a matter of law. A pharmacist owes the consumer a duty of reasonable care with respect to the sale of drugs not authorized for sale by the FDA or the manufacturer.”

HOLDING: The court reversed summary judgment because the learned intermediary doctrine does not shield a pharmacy in a case where a pharmacist dispenses a drug withdrawn from the market.

**RELIEF SOUGHT:** Pharmacy sought partial summary judgment to dismiss plaintiff’s claim that it breached its duty to properly counsel for OTC drugs.

**ISSUES:**

1. Does a pharmacist’s professional duties include properly counseling patients for OTC drugs?

2. Does the learned intermediary doctrine protect pharmacists from liability if the pharmacy provides incorrect advice for OTCs?

**FACTS AND PROCEDURAL HISTORY:** Deceased patient’s widow sued pharmacy alleging that employee pharmacist negligently informed her during a phone call that her husband could safely take Sudafed. Pharmacist denied this claim. Widow claimed that taking one Sudafed worsened her husband’s prostate problem and caused serious medical consequences. Widow sued for malpractice and lack of informed consent. Pharmacy moved for partial summary judgment because, even assuming the alleged conversation occurred: (i) a pharmacist’s duty of care does not encompass advising about OTC drugs; and (ii) the learned intermediary doctrine bars a claim for failure to warn.

**REASONING:** A pharmacist is not a true seller of prescription drugs because the prescriber chooses the product to sell. In the Utah Pharmacy Practice Act, “patient counseling” includes communicating information “in order to ensure proper use of drugs.” “[P]ractice of pharmacy” includes “providing information about the potential hazards of drugs.” The definition of drug includes OTC drugs. If a pharmacist answers a customer’s question and offers advice about OTC drugs, the pharmacist must advise and act in a non-negligent manner consistent with a reasonably prudent pharmacist’s response. The learned intermediary doctrine protects pharmacists from strict liability for failure to warn in the prescription drug setting because the pharmacist is acting only as a service provider, not an independent seller.

A pharmacist has discretion to recommend and sell OTCs. If pharmacists offer advice and recommendations to customers about OTC drugs, pharmacists are less like service providers and more like sellers of any other product. For OTCs, there is no prescriber, hence no learned intermediary and pharmacist must meet reasonably prudent pharmacist standard. In a modern day pharmacy, pharmacists serve as both sellers and service providers. If a pharmacy offers advice and recommendations about OTCs that turns out to be contrary to what a reasonably prudent pharmacist would give in a similar situation, the pharmacy cannot reap the benefits of offering advice but hide behind the learned intermediary doctrine to avoid the consequences.
**HOLDING:** The court denied pharmacy’s motion for partial summary judgment because:

1. A pharmacist has a duty to provide advice that meets the standard of care for a reasonably prudent pharmacist

2. The learned intermediary doctrine does not protect a pharmacist who negligently advises about OTC drugs.

**III. MOST COMMON VIOLATIONS FOUND DURING INSPECTIONS**

A. Expired drugs

B. Incomplete controlled substances inventories and documentation

C. Failure to produce controlled substances records *during* inspection

D. Failure to properly report theft or loss of controlled substances

E. Compounding issues

F. Improper transfer of controlled substances between pharmacies or between pharmacies and prescribers

G. Violations of operating standards for pharmacies

H. Pharmacies destroying controlled substances

I. Board of Pharmacy is concerned in many cases about the support management provided to pharmacists for compliance
IV. HOW TO KEEP UP WITH PHARMACY LAWS AND REGULATIONS

Many problems pharmacists face when inspected by state board of pharmacy personnel result from not keeping up with legislation and regulation. Each year the Utah Legislature meets for 45 days starting the fourth Monday each January. Almost every year, the legislature passes laws affecting pharmacy. One can find those laws at http://le.utah.gov/ and searching for "pharmacy" in the toolbar. Once the legislation becomes law it is codified in the Utah Code, most frequently as part of the Pharmacy Practice Act, Title 58, Chapter 17b.

Once the session is over, the Utah Division of Occupational and Professional Licensing (“DOPL”) often promulgates rules to implement many of the laws passed. Proposed rules are generally discussed by the Board of Pharmacy at its regular meetings on the fourth Tuesday of each month. To find out which proposed regulations will be discussed or proposed, check the Board's agenda at the DOPL website, which links here to Utah’s Public Notice Website. Once a Board meeting is over, materials from the meeting and an audio recording of the Board’s meeting can be found at Public Notice Website.

Once a rule is proposed, it must be published in the Utah Bulletin, which is published twice a month. The Utah Bulletin will include a description of the proposed rule, the text of the proposed rule, and the potential effective date of the rule. One set of changes to the Pharmacy Practice Act Rules were filed June 10, 2013; published in the Utah Bulletin on July 1, 2013; and had an August 8, 2014 effective date.

Finally, anyone licensed by DOPL should check the DOPL website. For pharmacists, applicable state laws and regulations can be found at the pharmacy page.

As of the date of this handout, the most recent updates of the most applicable laws are dated:

Pharmacy Practice Act--2015
Pharmacy Practice Act Rules--February 24, 2015
Controlled Substances Act--2015
Controlled Substances Act Rules--January 8, 2013
Controlled Substances Database Act--2015
DOPL Act Rules--August 21, 2014
DOPL Act--2015

Keep an eye out for new dates for laws and rules.
V. Legal Rights and Obligations When Facing an Investigation from DOPL

A. Organization of DOPL

1. DOPL Director—Currently Mark Steinagel
   a. Bureau Managers (oversee several professions)—Current Bureau Manager for Pharmacy is Dane Ishihara (email dishihara@utah.gov)
      (i) Licensing Board (e.g., Board of Pharmacy)
      (ii) DOPL Investigations
          (a) Separate from boards
          (b) Current supervising investigator is Lynn Hooper (email lhooper@utah.gov)
          (c) Boards usually do not know about specific investigations

2. Boards are not the same as DOPL.
   a. Boards and DOPL have much different authority and roles.
b. Utah licensing boards have little actual authority. *See* generally Utah Code Ann. § 58-1-201, et. seq.

(i) Boards make recommendations

(ii) Boards approve passing exam scores

(iii) Boards assist in establishing standards

(iv) DOPL act in “collaboration with” Boards

(d) License qualifications, unprofessional conduct definitions, etc.

c. Actual legal authority for most licensing issues rests with DOPL.

d. BUT, boards have enormous authority as expert advisers to DOPL.

e. Pharmacy Board has seven members and responsibilities are described at Utah Code Ann. § 58-17b-201.

3. **Generally, investigations are started by a complaint.**

a. Instructions for filing complaint are on DOPL’s website at Complaint Process.

b. DOPL has some 30 investigators and inspectors.

c. Investigators are specialized for professions.

d. Several (about four) investigators and inspectors focus on pharmacy issues.

e. Generally, investigator is POST trained; inspectors are not.

4. **A complaint about a pharmacy is investigated by one of the assigned investigators.**

a. DOPL has a policy manual that governs investigators’ behavior and how investigations should be handled.

b. DOPL refuses to disclose the policy manual based on GRAMA protection.

c. DOPL enters complaint information into a database.

d. Complaints are protected records under GRAMA. *See* Utah Code Ann. § 63G-2-305.

e. Investigative file is protected.
5. **DOPL is represented by the Utah Attorney General’s office.**

   a. Several attorneys are assigned to DOPL.

   b. These assigned attorneys generally handle only administrative actions, not criminal actions by the state.

   c. The investigation may end with no recommendation for discipline.

   d. Investigations often result in referral to an Assistant Attorney General (“AAG”).

   e. The AAG may draft a Stipulation and Order

   f. Stipulation and Order contains:

   g. Admission of unlawful and unprofessional conduct

   h. Sanctions against license

6. **Presentation of Proposed Stipulations**

   a. Sometimes investigators have presented a proposed stipulation to the pharmacist and asked for a signature.

   b. Sometimes an investigator has asserted that the Board of Pharmacy will revoke a license if the pharmacist does not sign the stipulation.

   c. **THIS IS NOT TRUE**

      (i) The BOP does not know about ongoing investigations.

      (ii) The BOP will act as the “jury” at the hearing and cannot know about the case beforehand.

      (iii) If presented with a proposed stipulation, DO NOT SIGN IT.

         (e) Take time to read it.

         (f) Take a few days to think about it.

         (g) Seek legal counsel

         (h) Often the facts are incorrect.
7. **Formal Action**

a. If the stipulation is not executed, case is referred to another Asst. AG for formal action.

b. Formal action begins when DOPL files a Petition and Notice of Agency Action

c. Pharmacist must file a response

d. The case proceeds under the:

e. Utah Administrative Procedures Act ("UAPA")

f. DOPL procedural rules

g. The Pharmacy Practice Act

h. After pharmacy files response, the parties engage in discovery and prepare for a formal hearing.

i. Formal hearing (in general):

j. Like a trial

k. Administrative Law Judge ("ALJ") presides

l. BOP is the jury

m. Both sides present evidence

n. Decision:

   (i) BOP meets after the hearing and makes a decision.

   (ii) The ALJ drafts the decision.

   (iii) DOPL Director reviews decision and can accept, modify, or reject.

   (iv) Appeal:

   (v) File appeal with Department of Commerce

   (vi) Appeal to Utah Court of Appeals or Utah Supreme Court

8. **Consequences of License Sanction**

a. Report to the National Practitioners Database
b. Potential exclusion government health care programs (Medicaid, Medicare, etc.)

c. Must report sanction to other states and on future applications for licensure

9. Examples of obligations under a stipulation or order:

   a. Cannot work alone
   
   b. Drug testing
   
   c. Report to BOP regularly
   
   d. Loss of license or loss of job
   
   e. Cannot serve as a PIC with probation

C. DOPL’s Authority to Inspect

1. Before conducting an inspection

   a. Inspector shall, after identifying the person in charge:
   
   b. Give proper identification;
   
   c. Request to see the applicable license or licenses;
   
   d. Describe the nature and purpose of the inspection; and
   
   e. Provide upon request, the authority of the Division to conduct the inspection and the penalty for refusing to permit the inspection
   
   f. After the inspector meets the requirements for inspection, the inspector can:

      (i) Examine any record, prescription, order, drug, device, equipment, machine, electronic device or media, or area related to activities for which a license has been issued or is for the purpose of ascertaining compliance with the applicable provisions of this chapter

      (ii) Take a drug or device for further analysis if considered necessary

2. Inspector can:

   a. Temporarily seize a drug or device which is suspected to be adulterated, misbranded, outdated, or otherwise in violation of this chapter, pending an adjudicative proceeding on the matter
b. Box and seal drugs suspected to be adulterated, outdated, misbranded, or otherwise in violation of this chapter

c. Dispose of or return any such drug or device

3. **Inspection shall be during regular business hours.**

D. **Consequences of Inspection**

1. If DOPL concludes a person violated the Pharmacy Practice Act or Controlled Substances Act, the Division may:

2. Issue a fine or citation (Utah Code Ann. § 58-17b-504)

3. DOPL also has authority to:

4. Revoke, suspend, restrict, or place a license on probation

5. Issue a public or private reprimand

6. Issue cease and desist order

E. **Responsibilities of Licensee**

a. Cooperate with an inspector by:

b. Providing access to regulated areas (pharmacy, storage of prescriptions, storage of drugs)

c. Providing access to records, drugs, devices

d. Answering questions about where records and other items are stored

e. *Failure to permit an inspection is unlawful conduct (Utah Code Ann. § 58-17b-501(1))*

F. **Things that Are Not Required**

1. Licensee does not have to:

a. Engage in an interview (inspector cannot compel answers to questions)

b. Go offsite to speak with an inspector

c. Take a drug test

d. Provide business records other than records related to drugs (e.g., invoices)
e. Admit to incriminating acts

G. How to Act during Inspection

1. Follow company procedures
2. Contact supervisor or pharmacist-in-charge
3. Allow access only if inspector meets the statutory requirements.
4. Be cordial and cooperative regarding access to records, drugs, and devices.
5. Get a receipt for items taken.
6. Contact attorney?
   a. Most often, no. But, in some circumstances, it’s warranted.
7. DO NOT sign a stipulation and order
8. DO NOT sign anything except:
   a. Receipt for items taken by inspector
   b. Acknowledgment of inspection form
9. Other than the receipt or acknowledgment, anything you sign:
   a. May waive important legal rights permanently
   b. May result in loss or restriction of license
   c. May be an admission of incorrect facts
   d. May be an admission to violation of laws that are not applicable

H. How to Act after Inspection

1. Consult with supervisor or PIC
2. DO NOT sign anything from DOPL (except receipt for items taken by inspector and acknowledgment of inspection form) without seeking counsel or advice
3. DO NOT go to DOPL for an interview without seeking counsel or advice
4. DO NOT discuss any potential violations with anyone other than counsel
   a. Such persons could be subpoenaed as witnesses
   b. Discussions with counsel will be protected by attorney-client privilege
I. DEA Inspections

1. DEA may inspect any place where controlled substances records are kept or where persons registered under the CSA practice. See U.S.C. § 880; 21 C.F.R. § 1316.01-13

2. Administrative inspections

3. Must be made in reasonable manner and during regular business hours

4. DEA may inspect any place where controlled substances records are kept or where persons registered under the CSA practice. See U.S.C. § 880; 21 C.F.R. § 1316.01-13

5. Inspection by consent
   a. Warrant not necessary
   b. Consent to inspection must be informed
   c. Consent can be withdrawn at any time during inspection
   d. Notice of Inspection of Controlled Substances form must be provided to pharmacy which must contain specific information

6. Inspection by administrative warrant

7. Administrative warrant substitutes for a regular search warrant
   a. The required showing of probable cause is lower to obtain an administrative warrant
   b. Standard for probable cause is valid public interest
   c. Inspector applies to a judge for the warrant
   d. No need to attempt consensual inspection first
   e. Owner can be arrested for refusal to allow inspection

J. FDA Inspections

1. Compounding is the most common reason for the FDA to inspect.

2. Rules for 503 and 503B compounders are different

3. FDA can inspect pharmacies, but inspections are more limited than for manufacturers.

4. BUT, if a pharmacy is in violation of state compounding laws, FDA can investigate more broadly.

5. FDA can only inspect at reasonable times, “all pertinent equipment, finished and unfinished materials, containers, and labeling therein.”
6. Unlike with a drug manufacturer, it does not have the right to inspect “records, files, papers, processes, controls” or other related documents of a pharmacy that meets certain criteria.

7. This later exception only applies if no compounding occurs or if compounding complies with all state compounding laws.

8. The FDA would say it needs to inspect to see if state laws are followed.

9. Normally, to overcome any problems with scope of inspection, the FDA brings a DOPL inspector.

10. DOPL has more certain, broader authority than the FDA.

11. FDA inspector asks DOPL inspector to ask for documents and other items.

K. General Guidelines for Inspections

1. DOPL, DEA, and FDA have a right to inspect pharmacies.

2. When inspector enters, obtain credentials from inspector.

3. If they present proper credentials, provide access to records, drugs, and devices.

4. DO NOT sign any documents other than receipts or acknowledgment of the visit.

5. Follow company protocols.

6. Contact supervisor or PIC.

7. Do not leave the inspector alone; have someone with inspector at all times.

8. Make copies of documents; don’t let inspector do so.

9. Have all questions directed to one person.

10. Inspectors cannot compel anyone to answer questions.

11. If you answer, be truthful.

12. If you don’t know an answer, don’t answer or say you will check.

13. Take notes of questions, inspector’s activities, and what is reviewed and taken from pharmacy.

14. Contact counsel if necessary