

The Legal Blueprint




Dylan DeCandia, PharmD

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Dylan DeCandia PharmD has no relationships with ineligible companies.

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Learning Objectives

- 1 → **RECALL** the key governing bodies and their roles
- 2 → **RECOGNIZE** important details, dates, and timelines for a pharmacy manager
- 3 → **DESCRIBE** the duties of pharmacy technicians and interns
- 4 → **DETERMINE** the roles and responsibilities of a pharmacy manager
- 5 → **IDENTIFY** key pharmacy laws that pharmacy managers should implement in practice

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Are you ready?

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Pharmacy Manager

Pharmacist-in-charge (PIC)

Manager of Record

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Increased Need for Skilled Pharmacy Managers

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Scope of Practice

- Pharmacy prescribing
- Administrative Burden
- Public health initiatives

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Workload

- Complex responsibility
- Increased workload
- Staff strain

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Staff Burnout

- Staff turnover
- Medication errors

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Inspections

- State
- Insurance
- Federal or Medicare

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Pharmacy Regulatory Bodies

- 01The Food & Drug Administration (FDA)
- 02Drug Enforcement Agency (DEA)
- 03The Joint Commission (TJC)
- 04State Board of Pharmacies (BOP)

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01	02
U.S. FOOD & DRUG ADMINISTRATION	DEA United States Drug Enforcement Administration
<ul style="list-style-type: none"> ● Creating and enforcing regulations for all consumer products ● Pharmacy supply chain management ● FDA reporting 	<ul style="list-style-type: none"> ● Federal enforcement for controlled substance laws ● DEA reporting

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03The Joint Commission (TJC)	04State Boards of Pharmacy (BOP)
<ul style="list-style-type: none"> ● Independent, non-profit entity ● Enforcement and creation of pharmacy practice standards ● Accredits healthcare facilities and services 	<ul style="list-style-type: none"> ● Creates pharmacy laws and regulations specific to each state ● Licenses, registrations, penalties ● State inspections!

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Pause & Ponder

Congrats! Your management promoted you to pharmacy manager. Take a moment and consider your new responsibilities. What have you seen pharmacy managers oversee in the past? Who or what do you supervise?

(please type a response in the chat!)

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Pharmacy Manager Responsibilities

The retail pharmacist scope of practice is evolving and pharmacies are getting busier, causing responsibilities to increase in complexity.

To understand these complexities, pharmacy managers require a deep understanding of state and federal laws across the following departments

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The Personnel **New Pharmacy Managers**

Who needs to know?
 Why do they need to know?
 What do they need to know?
 When do they need to know?

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The Personnel **New Pharmacy Managers**

Who needs to know?
 Why do they need to know?
 What do they need to know?
 When do they need to know?

THE STATE BOARD OF PHARMACY!!!

- Some states require more than reporting

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The Personnel **New Pharmacy Managers**

Who needs to know?
Why do they need to know?
What do they need to know?
 When do they need to know?

- Inspections surprise you! Don't surprise the inspector
- A new person is responsible for the future of the pharmacy
- **PRO TIP:** Previous pharmacy manager reports they are stepping down

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The Personnel **New Pharmacy Managers**

Who needs to know?
 Why do they need to know?
 What do they need to know?
When do they need to know?

- Controlled substance inventory
 - Alabama
 - Nevada
 - New Jersey
 - Texas
- **PRO TIP:** Reconcile and record a full controlled substance inventory regardless of law

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Staff Compliance

The Personnel

- 1. License Renewal**
 - 45 days before license expiration
 - Fast track renewal PINs
 - Renewal deadlines
 - Annual?
 - Biennial?
- 2. Continuing Education (CE)**
 - National Association of Pharmacy (NABP) and CPE Monitor
 - Specifications for renewal:
 - Law requirement (congrats!)
 - Live requirement (congrats!)
 - CE Audits

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Staff Compliance

The Personnel

- 3. Federal Training Requirements**
 - Upon hire and annual trainings!
 - HIPAA
 - Fraud, Waste, and Abuse
 - Pseudoephedrine
- 4. Compliance Softwares**
 - Chain vs Independent
 - In-house proprietary softwares
 - Outsourced softwares
 - Integrate with current pharmacy systems to proper tracking
 - Some offer addition training courses for **staff or managers!**

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Pause & Ponder

You've completed hundreds of prescriptions, but the list keeps growing! Meanwhile, your pharmacy technicians, Ethan and Matthew, are bickering about renewing their pharmacy technician license. They seem unsure about their requirements after hearing other pharmacists talk about CE credits.

Do pharmacy technicians complete CE credits for license registration renewal? What resources can you show them? Why is it necessary to keep staff educated?

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- Technician**
- Registered with each state's Board of Pharmacy
 - Pay to play!
 - No testing
 - Minimal qualifications
 - Limited scope of practice

- Intern**
- *Pharmacist in training*
 - 1500 hours, 40 hours/week
 - Requires pharmacy intern preceptor at practice site
 - Broader scope of practice

- BOTH:**
- Register with each state's Board of Pharmacy
 - Assist the pharmacist in daily prescription duties

- DIRECT SUPERVISION**
- In-process and final checks during prescription filling
 - Intern ratio, technician ratio

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 Certified Pharmacy Technicians



- National licensure from The Pharmacy Technician Certification Board
- Required in certain states
 - Texas
 - North Dakota
 - Virginia
- Pharmacist:Technician ratio
- Continuing Education
 - Improved staff knowledge
 - Avoid complacency

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Pharmacy Personnel in Various States

Connecticut	Massachusetts	New Jersey	New York
Pharmacy Manager	PIC (resident pharmacy) or Manager of Record (non-resident pharmacy)	PIC	Supervising Pharmacist or PIC
Pharmacy Technician (2:1 or 3:1 ratio)	Pharmacy Technician (3:1 or 4:1 ratio)	Pharmacy Technician (2:1 ratio)	Pharmacy Technician (2:1 ratio)
Pharmacy Intern	Pharmacy Intern	Pharmacy Extern (student) Pharmacy Intern (post-graduation)	Pharmacy Intern

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Name Tag Laws

01

New York and Massachusetts

- Requires only pharmacist

02

New Jersey

- All pharmacy personnel

03

Iowa

- New pharmacy practice act
- Original name tag laws repealed

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What does the pharmacy manager oversee?

↓

Business Devoted to Pharmacy Pharmacy within independent business


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What does the pharmacy manager oversee?

↓

Business Devoted to Pharmacy





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What does the pharmacy manager oversee?

↓

Walmart 

 CVS pharmacy

Pharmacy within independent business

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Pause & Ponder

The prescriptions keep piling up, patients are upset, there is simply not enough room or staff to manage the workload. Thankfully, you have notified your pharmacy owner, Frank, and he (finally) determined that the pharmacy needs a new, larger location.

As pharmacy manager, what tasks do you perform during the move? Does Frank need your help or can he manage the BOP by himself?

(please type a response in the chat!)

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Pharmacy Licensure

New Pharmacy Application

The Pharmacy

- New vs relocating pharmacy
- Pharmacy manager interviewing with the board
 - Connecticut
 - Massachusetts
 - New Jersey

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CT License Renewal Information

License	Date Required (Annually)	New License Cost (\$)	Renewal License Cost (\$)
Pharmacist	January 31st	200	100
Pharmacy Technician	March 31st	50	50
Pharmacy	August 31st	750	190

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Pharmacy Logistics

The Pharmacy

Hours of Operation

- Open long enough to provide care to all patients:
 - 40 hours/week
- Pharmacy closures
- Controversial in rural states
 - Maine
 - Montana

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Pharmacy Logistics

Key Signage Checklist	
Sign	Specifications
Pharmacy License	Conspicuously posted
Pharmacy manager name	Clearly and readily identifiable to patients and customers
Generic Drug Substitution	"THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE"
Reporting of prescription errors	Block letters not less than one inch in height Lettering in a size and style that allows for consumers to read without difficulty at the prescription department distribution counter "If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling 1-800-842-2649"


Signage

- Outdoor vs indoor signage
 - Business devoted to pharmacy practice?
- Post hours of operation
- Unscheduled closures
 - Other available pharmacies
 - Reopening times

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Equipment



Temperature tracking!

Refrigerator

- 2 to 8 degrees C
- OR
- 36 to 46 degrees F

Freezer

- Minus 25 to minus 10 degrees C
- OR
- Minus 13 to 14 degrees F

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Equipment

The Pharmacy

Subject to Inspection

- Refrigerator, freeze, scales, balances, pill counters
- Clean, working order
- New Jersey:
 - Spatulas, volumetric devices, pharmaceutical references



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DOCUMENT!

E-Prescribing

Controlled Substances

The Prescription

Legend Drug Inventory

Record Keeping

Quality Assurance

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Document Document Document

DOCUMENT

Document Document Document

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Pause & Ponder

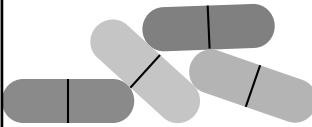
What are your state's electronic prescribing laws? How does your staff handle/check written controlled substance prescriptions? Do you accept verbal prescriptions for controlled substances?

(please type a response in the chat!)

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Controlled Substances






Prescribing Trends

- Opioid epidemic forced law changes
 - Opioids prescribing trends downward
- Stimulants
 - Upward trend between 2012-2022

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E-Prescribing Controlled Substances

 <p>Benefits</p> <ul style="list-style-type: none"> ● Goodbye bad handwriting! <ul style="list-style-type: none"> ○ Less phone calls to doctors office ● Medication error prevention ● Safety, quality, efficacy of dispensing and prescribing 	 <p>New Jersey & Vermont</p> <ul style="list-style-type: none"> ● Vermont: <ul style="list-style-type: none"> ○ 50th state to <i>allow</i> e-prescribing (controls) ● New Jersey <ul style="list-style-type: none"> ○ Legislators preventing e-prescribing mandates ○ Recent bill ended 01/12/26 	 <p>New York</p> <ul style="list-style-type: none"> ● First state to <i>mandate</i> e-prescribing for ALL prescription medication
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Controlled Substances



Prescription Drug Monitoring Program


- Goal
 - Report & track patient controlled substance habits
 - Identify Diversion
- Control substance scheduling → states report different medication
 - Gabapentin (V vs none)



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Controlled Substances



Prescription Drug Monitoring Program


- State limitations per controlled substance fill!
 - Reaffirm current practices
- Check before filling any controlled substance prescription
 - Complacency!



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Controlled Substances



Legend Drug Inventory

- Federal Law: Significant Loss
 - Quantity lost in relation to the business,
 - Medication lost: diversion candidate?
- DEA Form 106: Electronic




How to monitor Stock?

- Perpetual Inventory → use any system that helps backcount
 - Automated dispensing cabinets (ADCs)
 - Logbooks

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Controlled Substances



Legend Drug Inventory

- Ordering Controlled Substances
 - DEA Form 222 (electronic or print versions)
 - Schedule II invoices




Federal Law: Biennial Inventory

- Check state requirements
- Record time the staff counted the inventory
- Record staff member responsible

● Perpetual inventory will improve efficiency of biennial inventory

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Legend Drug Inventory



Return to Stock Medications

- Credit the insurance (reverse any claim)
- Prevent misbranded medications
 - Drugs name, strength, lot number, manufacturer, expiration date, NDC
- Neat shelves and readable labels!

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The Prescription

Record Keeping Requirements	Prescription Records	Medication Error Documentation
Controlled Substance Inventories	Pharmacist Prescribing Screening	<p>Connecticut:</p> <ul style="list-style-type: none"> ● Three years ● 48-hours to retrieve <p>Federal</p> <ul style="list-style-type: none"> ● CMS - 10 years

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Inspection Checklist

Hours of Operation		Yes	No	Advised
1	Is the pharmacy open to provide pharmaceutical services for at least thirty-five hours per week? [Section 20-376-13]			
Pharmacy Signage				
1	Is the pharmacy's pharmacy license conspicuously posted within the pharmacy? [Section 20-669(a)]			
2	Is the name of the pharmacist manager conspicuously posted within the prescription department of the pharmacy or in immediate proximity to it? [Section 20-376-21]			
3	Is the pharmacist manager's name displayed in a location and in a manner so as to be clearly and readily identifiable to patients and customers? [Section 20-376-21]			
	Is there a sign posted in a location easily seen by patrons at the counter where prescriptions are dispensed stating that "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE?" [Section 20-619(g)]			

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Pause & Ponder

A patient calls you over for consultation. She received someone else's prescription! As a newly promoted pharmacy manager, what steps do you need to take? Who is responsible?


(please type a response in the chat!)

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Quality Assurance & Reporting

What went wrong?

Error Occurs

Alert 

Policy Review

Policy Improvement

Documentation:

- Prescription error reporting forms
- Document information related to the incident

Reach out to involved parties:

- Patient
- Doctor
- 'Offending' staff

Manager dissects policy:


- Was the error a result of poor policies?
- Where is the pharmacy vulnerable to liability?

Prevent future errors!!!

- Make the change
- Educate the staff

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Quality Assurance & Reporting



Managing an Error

- Staff education
- Error prevention
 - Medication error criminalization
 - MISTAKES HAPPEN → Communicate!
- Staff meetings
 - Review new policies, educate
 - Eyes everywhere


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FDA Medwatch

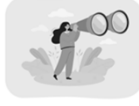
- Post-marketing surveillance system
- Reports Issues:
 - Med quality
 - Adverse events
 - Therapeutic failure
- Promote public health initiatives!

National Coordinating Council for Medication Error Reporting and Prevention

- Resource for improving quality assurance programs
- Provides strategies for understanding and preventing errors




The Prescription



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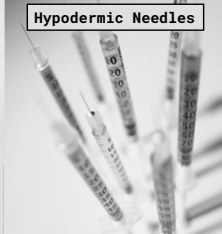
Additional Laws Impacting Pharmacy Practice




Poison Prevention Act of 1970

Federal law mandating child resistant packaging for all medications

State-level public health initiative to increase access to safe needles




Hypodermic Needles



Omnibus Budget Reconciliation Act 1990

Federal law designed to improve dispensing laws for Medicaid patients

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Poison Prevention Act

Child Resistance

- Manufacturers and pharmacies → child resistant packaging for all medication
- Prescriptions default to resistant caps
- Patients may request non-resistant caps
 - Document, document, document!
- Proper medication storage at home: educate

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Hypodermic Needles

Over-the-Counter Needles

- NJ Harm Reduction & CT Syringe Services
 - 10 needles or fewer per purchase
 - No specified weekly/monthly limit
- New York Expanded Syringe Program
 - 10 needles or fewer per purchase
 - Daily purchase permitted
- California: no purchase limits

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Omnibus Budget Reconciliation Act 1990 (OBRA)

Improved Dispensing Laws

- Originally Medicaid beneficiaries
 - Policies adopted by states overtime
- Pharmacies responsible for obtaining, recording, and maintaining patient info
- Drug Utilization Review
 - Staple to current practice
 - Review previous medications
- Broadened patient rights
 - Must offer counseling!

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Pharmacist Prescribing

Blessing or Curse?

- Document, document, document!!
 - Intake documentation: Eligibility criteria
 - Screen medical history
- Contraceptive Prescribing
 - 30 states + D.C.
 - Training → retain training records and certification for all staff
- U.S. Medical Eligibility Criteria for Contraceptive Use

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Pause & Ponder

The stack of prescriptions is falling over. Matt and Ethan have not stopped arguing about nonsense in three hours. The line of patients stretches out the door and they are tired of waiting. But wait... What is that? Through the glass doors a figure appears with sunlight glimmering around her. The light is bright, but you recognize her. Is it your savior? A floater pharmacist? A technician returning from vacation?

Nope. The state inspector. She expects you to move fast despite the 30 barking patients.

(please type a response in the chat!)

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Constant State of Readiness

Are you ready?

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