

# Innovations in Pharmacy Law Education in US PharmD Programs

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American  
Society for  
Pharmacy  
Law

**DEVELOPMENTS  
IN PHARMACY LAW  
SEMINAR DPL XXXV**



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# Conflict of Interest Disclosure

- I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.



# Learning Objective

- At the completion of this activity, the participant will be able to:
  - discuss innovative approaches to teaching pharmacy law to pharmacy students in US PharmD programs



# Assessment Questions

1. Pharmacy law and regulatory affairs is a required element of ACPE accredited PharmD programs.
  - a) True
  - b) False
2. Select the number of studies that have described a novel approach to teaching pharmacy law.
  - a) 4
  - b) 8
  - c) 12
  - d) 16



# Wide variation exists in delivering pharmacy law education in PharmD programs.<sup>1,2</sup>

- Pharmacy practice remains highly regulated in the US.
- ACPE Standards 2025 continue to include “pharmacy law and regulatory affairs” as a required element of accredited PharmD curriculums.<sup>3</sup>
- MPJE pass rates have declined in recent years.<sup>4</sup>
- Even with the removal of a law exam in some states, teaching pharmacy will remain vital to the PharmD curriculum and practice.<sup>5</sup>

<sup>1</sup>Rosenberg E, Albert EL, Mospan GA, Panther S, Ruble J, Stein RL. A Pilot Study Regarding Pharmacy Law Education Across Doctor of Pharmacy Programs. Am J Pharm Educ. 2020 Feb;84(2):7172. doi: 10.5688/ajpe7172. PMID: 32226064; PMCID: PMC7092790.

<sup>2</sup>Rosenberg E, Hsu SY, Mospan GA, Stein RL. A Follow-Up Study on Delivery of Pharmacy Law Education Across Doctor of Pharmacy Programs. Am J Pharm Educ. 2023 Jun;87(6):100055. doi: 10.1016/j.ajpe.2023.100055. Epub 2023 Mar 15. PMID: 37316118.

<sup>3</sup><https://www.acpe-accredit.org/pdf/Standard2025DRAFTForComment.pdf>

<sup>4</sup><https://nabp.pharmacy/wp-content/uploads/MPJE-Pass-Rates-2023.pdf>

<sup>5</sup><https://nabp.pharmacy/help/which-states-require-the-mpje/>



**Project Purpose: Evaluate the body of literature describing innovative approaches to teaching pharmacy law in US PharmD programs.**



# A scoping review was selected to identify the body of literature that exists on the topic.<sup>1</sup>

	Traditional Literature Reviews	Scoping reviews	Systematic reviews
A priori review protocol	No	Yes (some)	Yes
PROSPERO registration of the review protocol	No	No <sup>a</sup>	Yes
Explicit, transparent, peer reviewed search strategy	No	Yes	Yes
Standardized data extraction forms	No	Yes	Yes
Mandatory Critical Appraisal (Risk of Bias Assessment)	No	No <sup>b</sup>	Yes
Synthesis of findings from individual studies and the generation of 'summary' findings <sup>c</sup>	No	No	Yes

<sup>1</sup><https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-018-0611-x/tables/1>



# The scoping review was conducted in March 2024.

- Conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR)
- Databases searched: PubMed/MEDLINE, Embase, Scopus, and the Cumulative Index for Nursing and Allied Health Literature (CINAHL)
- Platform used: Covidence



# There were few inclusion criteria utilized in the scoping review.

1. Delivered in Doctor of Pharmacy program
2. Educational innovation included the topic of pharmacy law (not required to be in the pharmacy law course)
3. Doctor of Pharmacy program located in the US



**A total of 2,400  
unique abstracts  
were reviewed,  
but only 12  
studies met the  
inclusion criteria.**



# General Overview of 12 Studies Included

Study ID	Title	Population description	Method of recruitment of participants	Total number of participants
Deneff 2021	A Novel Approach to Pharmacy Practice Law Instruction	Third year pharmacy students enrolled in the Correlated Pharmacy Problem Solving Course at the University of Connecticut School of Pharmacy.	Required course activity	66
Mospan 2020	Using MyDispense to simulate validation of controlled substance prescriptions in a pharmacy law course	Second year pharmacy students enrolled in the pharmacy law course at Wingate University School of Pharmacy.	Voluntary	94
Parker 2018	Using a mock board of pharmacy disciplinary hearing to teach concepts related to administrative law, addiction, empathy, and professionalism	Fifth year pharmacy students enrolled in the Pharmacy Administration Module in a 0-6 Doctor of Pharmacy program at the Ohio Northern University Raabe College of Pharmacy.	Required course activity	141
Mospan 2018	Assessing the impact of a didactic lecture for student pharmacists on legislative advocacy	Second year pharmacy students enrolled in the Pharmacy Law and Ethics course at Wingate University School of Pharmacy	Voluntary	62
Steinhardt 2017	Active-learning Strategies for Legal Topics and Substance Abuse in a Pharmacy Curriculum	Students enrolled in one of three courses (Healthcare and Medication Safety, a two-credit-hour core course; Translational Pharmacogenomics, a three-credit-hour core course; and Drugs of Abuse, Addiction, and Law Enforcement, a two-credit-hour elective course) at the University of South Florida College of Pharmacy	Required course activity	Not disclosed



Study ID	Title	Population description	Method of recruitment of participants	Total number of participants
Karwaki 2017	A qualitative analysis of student-written law and ethics cases: A snapshot of PY2 student experience	Second year pharmacy students in the Pharmacy Law and Ethics Course at the University of Washington	Required course activity	66
Bess 2016	An Innovative Approach to Pharmacy Law Education Utilizing a Mock Board of Pharmacy Meeting	Third year pharmacy students enrolled in pharmacy law course at UTHSC College of Pharmacy.	Required course activity	Not disclosed
Stewart 2013	Student self-assessment of knowledge and application of legal concepts in a community pharmacy simulation	Second year pharmacy students enrolled in a one-credit-hour course in which the material from didactic course is reinforced through lab exercises at the University of Louisiana at Monroe College of Pharmacy.	Voluntary	42
Medina 2010	Relationship Between Case Question Prompt Format and the Quality of Responses	All P1 through P4 students and full-time and adjunct PharmD faculty members who worked with patients were invited to participate in the study at the University of Oklahoma College of Pharmacy. PhD faculty members who did not hold a PharmD were excluded from the study due to the clinical nature of the study cases.	Voluntary	197 students; 54 pharmacy faculty members
Spies 2008	Plaintiff or Defendant: Using Legal Cases to Teach Students Law	Second year pharmacy students enrolled in the Legal Principles of Pharmacy Practice course at the McWhorter School of Pharmacy	Required course activity	120 enrolled in the course, 119 completed the pharmacy law course, 103 completed the breakout session survey
Spies 2004	Effect of Pre-class Preparation of Legal Cases on In-class Performance	Second year pharmacy students enrolled in the pharmacy law course at college of pharmacy	Required course activity	63
Smith 2004	"Fix the Law" Project: An Innovation in Students' Learning to Affect Change	Second year pharmacy students enrolled in the Pharmacy Laws and Ethics course at the University of Washington School of Pharmacy	Required course activity	Not disclosed for 2003, 77 in 2002



# Description of Intervention and Outcomes

Study ID	Title	Intervention	Outcome(s) Measured
Deneff 2021	A Novel Approach to Pharmacy Practice Law Instruction	This Institutional Review Board–approved, two-year, qualitative, prospective, survey study was conducted in a case study class where students completed MyDispense exercises focused on common legal issues that arise in practice, both individually before and within groups during class. Participating students completed a qualitative survey directed at use of MyDispense for pharmacy law review, which included a series of close-ended questions graded on a Likert scale and open-ended questions thematically grouped.	Self-reported improvement in learning pharmacy law; acceptability of activity
Mospan 2020	Using MyDispense to simulate validation of controlled substance prescriptions in a pharmacy law course	Fourteen MyDispense practice exercises were created and implemented into a required second-year pharmacy law course. Completion of the MyDispense exercises and performance on the pharmacy law midterm exam were recorded. A questionnaire was administered to students to receive feedback on the exercises.	Midterm exam scores
Parker 2018	Using a mock board of pharmacy disciplinary hearing to teach concepts related to administrative law, addiction, empathy, and professionalism	The mock board hearing was conducted as part of the required curriculum. Faculty obtained materials from a prior board hearing. The actual respondent, lawyer, former executive director, and a board agent participated. Students served as board members and president, asked questions of the witnesses, and deliberated per board procedure. After the event, student learning and perceptions were assessed through knowledge-based, opinion-based questions, and open-ended questions.	Knowledge-based assessment questions
Mospan 2018	Assessing the impact of a didactic lecture for student pharmacists on legislative advocacy	An electronic pre- and post-survey was administered to second-year student pharmacists who attended a didactic lecture on advocacy within a pharmacy law course.	Pre-post survey about willingness to engage in advocacy



Study ID	Title	Intervention	Outcome(s) Measured
Steinhardt 2017	Active-learning Strategies for Legal Topics and Substance Abuse in a Pharmacy Curriculum	Medication Safety course student groups created films on a National Patient Safety Goal (NPSG) using a movie genre and presented them in film festival format. Pharmacogenomics course student groups taught ethical, legal, and social implications (ELSI) topics through presentation of short stories about comic book characters with genetic mutations. Students in the Drugs of Abuse course composed and performed dances depicting the mechanism of action of a drug in an in-class rave dance format.	Knowledge-based assessment questions
Karwaki 2017	A qualitative analysis of student-written law and ethics cases: A snapshot of PY2 student experience	A qualitative analysis of 132 student-written cases representing the team efforts of 1053 students over a 12-year time period was conducted. Student-written cases were coded and analyzed thematically.	Themes
Bess 2016	An Innovative Approach to Pharmacy Law Education Utilizing a Mock Board of Pharmacy Meeting	A mock Board of Pharmacy meeting was designed and incorporated into the Pharmacy Law course at the University of Tennessee College of Pharmacy. Students acted as Board of Pharmacy members and utilized technology to decide outcomes of cases and requests addressed in a typical 2 day Tennessee Board of Pharmacy meeting.	Not disclosed
Stewart 2013	Student self-assessment of knowledge and application of legal concepts in a community pharmacy simulation	Students role-played as pharmacists, technicians, and interns in a series of ten-minute community pharmacy simulations. Pharmacists oversaw typical operations and were presented with situations that challenged their knowledge of pharmacy law while background activities competed for their attention. Students completed pre- and post-assessments on their confidence in knowledge of legal requirements and their ability to recognize violations. Students in the pharmacist role completed an additional questionnaire concerning simulation events. All students completed a reflective writing assignment. Faculty observers evaluated student performance.	Self-reported confidence in learning pharmacy law



Study ID	Title	Intervention	Outcome(s) Measures
Medina 2010	Relationship Between Case Question Prompt Format and the Quality of Responses	Doctor of pharmacy (PharmD) faculty members and students responded to 2 pharmacy law/ethics cases, one followed by a case question prompt in multiple-choice format and the other by a question in open-ended format. The number of conclusions and the quality of the arguments generated were assessed using general linear modeling.	Evaluated activity responses
Spies 2008	Plaintiff or Defendant: Using Legal Cases to Teach Students Pharmacy Law	Students were broken into smaller groups and randomly assigned a legal case to arbitrate or defend. One week prior to the groups' presentation, all students were given the facts of a case that was reflective of issues covered during the lecture component of the course. Formative assessments were utilized in addition to an overall breakout satisfaction survey administered at the end of the course.	Self-reported improvement in learning pharmacy law; acceptability of activity
Spies 2004	Effect of Pre-class Preparation of Legal Cases on In-class Performance	Students in the course were randomly assigned to 1 of 4 firms. Prior to each class, the members of one firm were responsible for reading a case and being prepared to present information on it. Only that firm's members were given the case before the class period in which it was to be covered. During class, students in the firm were called upon to present the facts of the case and the principles of law that were applicable to pharmacists. Essay questions on the examinations were used to determine if those who were expected to prepare for the class outperformed those who were not expected to prepare.	Evaluated activity responses; exam scores
Smith 2004	"Fix the Law" Project: An Innovation in Students' Learning to Affect Change	In groups, students identified a law impacting the practice of pharmacy in need of "fixing," then they proceeded through a formal policy analysis process to "fix it." As the course progressed, students turned in consecutive pieces of their projects that corresponded with the steps in the policy analysis process, and were provided with constructive, developmental feedback from the course master.	Evaluated activity responses



# There are several takeaways to consider from this scoping review.

- Body of evidence evaluating the innovative approaches to teaching pharmacy law in the PharmD curriculum is limited (systematic review not recommended)
- Most required participation in intervention as part of the course
- Sample sizes were small
- Most included 1 year's worth of data
- Outcomes measured and reported vary widely



**An opportunity may exist to more robustly and consistently assess innovative educational approaches to teaching pharmacy law.**



# Assessment Questions -- Answers

1. Pharmacy law and regulatory affairs is a required element of ACPE accredited PharmD programs.
  - a) **True**
  - b) False
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  - a) 4
  - b) 8
  - c) **12**
  - d) 16



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