

Pharmacy Student Preparation for Compliance with Pharmacy Laws and Regulations

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Developments in Pharmacy Law Seminar XXIV

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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.



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Learning Objectives

- At the completion of this activity, the participant will be able to:
 - Identify methods of preparing students for the California Pharmacy Jurisprudence Exam (CPJE)
 - Understand the CPJE pass and fail rates of newly graduated pharmacist applicants
 - Recognize areas of weakness in regulatory compliance among new practitioners that are likely to result in exam questions



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Assessment Questions

- The CPJE includes True/False questions as part of the exam.
 - True or False?
- This CPJE questions often involve complex clinical situations where which one of the following is true:
 - The correct answers clearly state a conclusion of pharmacy law
 - The correct answers are the solutions that best address the clinical fact situation
 - The correct answers directly address the validity of the prescription



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Observations by California Board of Pharmacy

- Many new pharmacists have difficulty understanding pharmacy regulatory compliance requirements
- Jurisprudence exam changes are in response to lack of preparation in many areas
- Most recent pass rates measured April 2018 through September 2018:
 - CPJE pass rate is 78.2%



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Overall Pass Rates

CPJE: Overall Pass Rates		
	Frequency	Percent
Fail	465	21.8
Pass	1,664	78.2
Total	2,129	100

NAPLEX: Overall Pass Rates		
	Frequency	Percent
Fail	95	6.1
Pass	1,461	93.9
Total	1,556	100



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CPJE and NAPLEX Results

5 – Year Comparison of CPJE and NAPLEX Pass Rates (Percentage)				
	CPJE		NAPLEX	
	Fail	Pass	Fail	Pass
April 2013 – Mar. 2014	19.9	80.1	4.5	95.5
April 2014 – Mar. 2015	21.3	78.7	4.3	95.7
April 2015 – Mar. 2016	21.6	78.4	5.8	94.2
*April 2016 – Mar. 2017	34.6	65.4	10.1	89.9
April 2017 – Mar. 2018	29.7	70.3	7.9	92.1

*New content outline in effect

Pharmacy School Location

- In-state schools of pharmacy pass rates higher than that of out of state or foreign schools

Location of School		CPJE P/F		
		F	P	Total
California	Count	111	965	1076
	% within school	10.3%	89.7%	100.0%
Other US	Count	310	628	938
	% within school	33.0%	67.0%	100.0%
Foreign	Count	44	71	115
	% within school	38.3%	61.7%	100.0%
Total	Count	465	1664	2129
	% within school	21.8%	78.2%	100.0%

Licensing Exam and New Licensee Regulatory Compliance Readiness

- **Instruction to pharmacy law prior to or at the beginning of pharmacist internship**
 - Best to have a basic understanding of pharmacy law to begin internship
- **Drug Recognition**
 - Top 200 drugs by both brand and generic names
 - Specialty drugs (biologics) by both brand and generic names
 - Vaccines



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Sample CPJE Question

- Which of the following auxiliary labels belongs on a bottle of Vivotif Berna®?
 - "Refrigerate"
 - "For external use only"
 - "Avoid sunlight"
 - "Shake well"



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Sample CPJE Question

- A pharmacist is dispensing new prescriptions for fosamprenavir, ritonavir, and Truvada®. In reviewing the patient's profile information, the pharmacist notes allergies to furosemide, glipizide, and Bactrim®. The pharmacist should call the physician to change
 - Truvada® to Combivir®
 - fosamprenavir to saquinavir
 - Truvada® to Atripla®
 - fosamprenavir to tipranavir



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Licensing Exam and New Licensee Regulatory Compliance Readiness

- **Review of compliance requirements at each internship practice site**
 - Review of Pharmacist in Charge Self Assessment form at each practice site
 - Community, Compounding, Hospital Outpatient and Inpatient Pharmacies and Wholesaler self assessments
 - https://www.pharmacy.ca.gov/forms/17m_13.pdf
 - Invite interactive discussion with internship preceptors on Self Assessment issues where the student has questions



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Licensing Exam and New Licensee Regulatory Compliance Readiness



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Licensing Exam and New Licensee Regulatory Compliance Readiness

• Content Outline

- The exam is based upon an outline of topics that are posted on the Board of Pharmacy Website
- https://www.pharmacy.ca.gov/forms/exam_outline_after0416.pdf



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Licensing Exam and New Licensee Regulatory Compliance Readiness

• CPJE questions involve clinical situations seeking the best answer given complex facts

- No "True/False" questions
- No "Is this legal?" questions
- Answers do not directly address validity of the prescription but instead invite best solution to the question



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Sample CPJE Question

- A 37-year-old patient with schizophrenia has been treated with clozapine 500 mg daily for the past 4 months. The patient has the following past CBC results:

	WBC	Neutrophils
June 30	10.1	7.3
June 22	10.7	7.4
June 16	6.5	3.5
June 9	6.3	3.4
June 2	6.7	3.8

- On July 7, the patient's WBC is 7.2 and neutrophils are 4.3. The MOST appropriate recommendation for the pharmacist to make is to:
 - continue current therapy;
 - discontinue therapy;
 - hold therapy for 1 week and resume at 400 mg daily
 - repeat CBC and fill if WBC is greater than 8



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The CPJE Tests the Application of Law to General Pharmacy Practice

- Students who focus on a specific area of pharmacy practice in their internship sites may be at a disadvantage since the law questions tend to be varied as to areas of practice



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CPJE Composition

- The exam writers are not Identified but Represent Academia and Advanced Areas of Practice
- The questions tend to change reflecting the types of cases coming before the Board of Pharmacy
- Common question themes are evolving to include:
 - Corresponding responsibility and Controlled Substance Dispensing
 - Opioid Therapy in general
 - Compounding of drugs and requisite record keeping



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Next Exam Revisions

- Currently going through changes to assess exam effectiveness and testing of themes important to readiness for the challenges of current practice
 - May impact the 2019 or 2020 exams



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Discussion



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Assessment Questions – Answers

1. The CPJE includes True/False questions as part of the exam.
 - True or **False**?
2. This CPJE questions often involve complex clinical situations where which one of the following is true:
 - a. The correct answers clearly state a conclusion of pharmacy law
 - b. The correct answers are the solutions that best address the clinical fact situation**
 - c. The correct answers directly address the validity of the prescription



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