

American Society for Pharmacy Law

26th Annual Developments in Pharmacy Law Seminar

November 12-15, 2015

Trump National Doral - Miami, Florida

Register Today at www.aspl.org



Developments in Pharmacy Law Seminar XXVI

We invite you to join us to attend 13 informative educational sessions and earn 15 hours of legal and pharmacy continuing education credits while networking with your colleagues and friends.

ACPE Continuing Education Credits

WASHINGTON STATE
UNIVERSITY



Participants may earn up to 15 contact hours (1.5 continuing education units) of Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) credit. Sessions approved for CPE credit are listed with an ACPE universal activity number and number of continuing education units. To receive credit for successful completion for any activity, the participant must complete an attendance form and an activity evaluation form at the conclusion of the program. Verification of participation will be reported to the CPE tracking service, CPE Monitor, within 4 weeks after the program, and will then be accessible to participants at MyCPEMonitor.net.

You will need your NABP e-profile ID to note on your CE form so that it may be reported to CPE Monitor. If you have not yet obtained your NABP e-Profile ID, you may do so by visiting MyCPEMonitor.net, creating an e-Profile, and registering for CPE Monitor. Be sure to register for CPE Monitor to ensure that your e-Profile ID is fully activated.

The Washington State University College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

CPE now requires that all pharmacy continuing education (CE) credits must be processed and claimed no later than 60 days from the date of the live activity.

Continuing Legal Education Credits

If you intend to apply for continuing legal education credits, please be sure to indicate the state (or states) in which you are licensed and the corresponding license number(s) on the conference registration form. Quarles & Brady, LLP will process the CLE credits for the Developments in Pharmacy Law Seminar.



Continuing Legal Education credit will be applied for based on attendee return of the "Continuing Legal Education Credit Certificate of Attendance Form" at the conclusion of the seminar.





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Accommodations:

A block of rooms at a discounted rate has been reserved for the ASPL Seminar at the Trump National Doral. The resort is located at 4400 NW 87th Avenue, Miami, Florida. The discounted room rate is \$190 per night plus tax (currently 13%) as long as you make your reservation by October 15, 2015.

Make your reservation by calling the hotel at 1-855-878-6700 or [online](#). If calling, be sure to identify that you are with the ASPL meeting so that you get the group rate.

Travel:

Air Transportation:

The Trump National Doral is conveniently located within 10 miles of the Miami International Airport (MIA).

Ground Transportation:

Rental car: 10+ national chains service the Miami International Airport. For a listing and contact information, [click here](#).

Taxi: Taxis are available curbside, outside baggage claim. Approximate cost is \$30 (plus gratuity) each way.

Shuttle: Super Shuttle Vans, 305-871-2000 are available to reserve in advance. Shared ride van service from Miami International Airport is approximately \$26 (plus gratuity) each way.

Afternoon of Golf

Are you interested in playing a round of golf on Saturday? For the second year, we are hosting an ASPL golf-outing. This year, we are playing the famous Blue Monster Golf Course, which is home to the World Golf Championships – Cadillac Championship. Play will begin on Saturday starting around Noon. The type of format (e.g., scramble) will be dependent upon the number of players. The cost will also depend on the number of players, but a fair estimate is \$400. Please respond to Aaron Moore by September 5, 2015 if you intend to play and/or have any questions. Aaron's contact information is amoore@gdlldlaw.com or 410-783-4994.

Thursday, November 12, 2015

- 9:00 am – 5:00 pm **ASPL Board Meeting**
- 3:00 pm – 5:00 pm **Registration Open**
- 5:30 pm – 7:00 pm **ASPL Opening Reception**

Friday, November 13, 2015

- 7:00 am – 5:00 pm **Registration Open**
- 7:00 am – 8:00 am **Breakfast**
- 8:00 am – 8:15 am **Welcome**
- 8:15 am - 9:15 am **Legislative and Regulatory Update**
The Legislative and Regulatory Update provides conference attendees with a general overview of current laws and regulations impacting pharmacists and pharmacies. The speakers for this session have extensive experience in pharmacy legislation and regulations and currently work for organizations that represent community/retail pharmacists and managed care pharmacists. This will give attendees a broad-based perspective.
Mary Jo Carden, RPh, JD, Academy of Managed Care Pharmacy; Kevin N. Nicholson, RPh, JD, NACDS
(1.0 credit hour)
- 9:15 am – 10:15 am **HIPAA for Pharmacies:
A Government Perspective**
The Office for Civil Rights (OCR) is intensifying its enforcement of the HIPAA Privacy, Security and Breach Notification Rules. Through the review of breach notifications and annual reports and through discussions with representatives of various chain pharmacies, OCR realizes that there may be some confusion in the pharmaceutical industry as to what does and does not constitute a reportable breach in the pharmacy context. This session will discuss the 2013 Omnibus Regulations as they apply specifically to pharmacies. In addition, the obligations of pharmacies to comply with federal civil rights statutes in their provision of services, particularly with respect to their disabled customers and to customers with limited English proficiency, will be examined.
Celeste Davis, Esq.; Andrew Kruley, Esq. U.S. Department of Health and Human Services – Office for Civil Rights
(1.0 credit hour)
- 10:15 am – 10:30 am **Break**

Register Today at www.aspl.org

10:30 am – 12:00 pm **Expanding Patient Access to Care by Maximizing the Value of Pharmacists on the Health Care Team**

As the health care environment continues to evolve, pharmacists are emerging as a viable solution to improving access to care. While pharmacists have been providing services beyond dispensing of medications for decades, in recent years, there have been notable successes in advancing practice, addressing significant public health issues and for those advocating for the pharmacy profession and the pharmacists role in patient care. This session will be about the recent legislative changes at the state level, opportunities at the federal level, and how these changes are impacting pharmacists, the services they offer, the patients they serve and the system in which they work.
Stacie Maass, BSPHarm, JD, American Pharmacy Association
(1.5 credit hours)

12:00 pm – 1:00 pm **Lunch & Annual Business Meeting**

1:00 pm – 3:00 pm **Case Law Update**

This annual summary provide pharmacists, compliance personnel, and attorneys an overview of some of the most important court decisions since November 2014. The summary will address issues ranging from pay-for-delay arrangements; employment discrimination and retaliation; pharmacy-PBM contracts; whistleblower and False Claims Act claims; state regulatory boards' authority; tort claims involving product liability, learned intermediary doctrine, and negligence; privacy; and more.
Roger Morris, RPh, JD, Quarles & Brady; William Stilling, RPh, MS, JD, Parsons Behle & Latimer
(2 credit hours)

3:00 pm – 3:15 pm **Break**

3:15 pm – 4:15 pm **The Extinction of Legal Luddites: Technological Competence As An Ethical Obligation**

This session will address the ethical obligations of attorneys and their pharmacy clients to maintain technological competence. Attorneys and pharmacists must ensure the confidentiality, integrity, and accessibility of records. For attorneys such obligations arise from the revised Model Code of Professional Conduct. For pharmacists, such obligations arise from the APhA Code of ethics and federal and state laws such as HIPAA. Technology has changed every aspect of the legal and pharmacy professions. The interests of attorney and clients are aligned to manage ephemeral messaging and other platforms that didn't exist five years ago and to prevent villains from accessing pharmacies' health care and financial information through cyber-attacks against attorneys, who have been viewed plum targets.
Randy L. Dryer, JD, Honors College, University of Utah
(1 credit hour)

4:15 pm – 5:15 pm **The Learned Intermediary Doctrine and Pharmacists' Duty to Warn**

Most lawsuits involving prescription drugs center on a claim that the drug manufacturer failed to warn the patient of the drug's possible risks. As a defense to these claims, most states recognize some form of the learned intermediary doctrine, under which the pharmaceutical manufacturer is charged with providing adequate warnings of a drug's risks to the physician, rather than the patient. The learned intermediary doctrine has traditionally been a defense to failure to

warn claims against pharmacists as well. This session will provide an overview of court decisions rejecting the doctrine's application to pharmacists and analyze evolving legal theories and potential liabilities.

Mihai Vrasmasu, JD and Rebecca Ocariz, JD, Shook, Hardy & Bacon LLP
(1 credit hour)

6:30 pm – 8:30 pm **Reception**

Saturday, November 14, 2015

7:00 am – 12:00 pm **Registration Open**

7:00 am – 8:00 am **Breakfast**

8:00 am – 9:00 am **Current Controlled Substance Climate and Working Together to Mitigate Prescription Drug Abuse**

Recent regulatory changes regarding the use of controlled substances in the treatment of chronic pain were made as an effort to prevent the growing abuse of prescription pain medications. While Boards of Pharmacy encourage pharmacists to use professional judgment, and fill what they consider a valid prescription for a legitimate medical purpose, enforcement actions against drug wholesalers and pharmacies coupled with news reports of pharmacy robberies and increased liability have made it difficult for pharmacists to practice their profession with confidence and compassion and for some patients to obtain their necessary medications. The panel will discuss collaborative ways to mitigate the problem.

Jeffrey Mesaros, PharmD, JD, Florida Board of Pharmacy, CVS Health; Albert, MBA, PharmD, JD
(1 credit hour)

9:00 am – 10:00 am **The Death With Dignity Laws: What Do They Ask of Pharmacists?**

The developed world is in the throes of reexamining how we die, where populations have long life expectancies, access to highly developed health care systems, and die of diseases that typically end in extended downhill courses. Among the many responses are so-called right-to-die measures. Three US states--Oregon, Washington, and Vermont--now have "Death With Dignity" laws; two more permit physician-assisted dying--Montana and one county in New Mexico--and various measures for legalization have been introduced in some 24 states. Various forms of medically assisted dying are legal in four European countries, and court and legislative action has been taking place in many more. This talk will explore why right-to-die issues have become so pressing in recent years, what ethical issues particularly relevant to pharmacy they raise, and what the Death With Dignity laws require of pharmacists.

Margaret Batten, PhD, School of Medicine, University of Utah
(1 credit hour)

10:00 am – 10:15 am **Break**

10:15 am – 11:15 pm **Biosimilar Substitution - Is Purple the New Orange?**

The Biologics Price Competition and Innovation Act (BPCI) pathway for interchangeable biosimilars is proving controversial. Biosimilar substitution laws are creating a legal patchwork with provisions ranging from prescriber veto/prior notification to automatic substitution. Pharmacists are key to the future of biosimilars. The session will address the critical issues of pharmacovigilance, naming using different nonproprietary names, interchangeability via the “Purple Book” or therapeutic interchange in institutional settings, and potential liability for biosimilars approved for select indications. The BPCI patent litigation process will be compared/contrasted to Hatch-Waxman paragraph IV litigation.

Martha M. Rumore, PharmD, JD, MS, LLM, FAPhA, Touro College of Pharmacy, Sorrell, Lenna & Schmidt, LLP

(1 credit hour)

11:15 am – 12:45 pm **Legal Issues Surrounding Refill Reminders and Other Adherence and Loyalty Programs**

Medication adherence programs help promote patient health, and pharmacy loyalty programs offer discounts, coupons and rewards to help reduce healthcare costs. However, a complex assortment of federal and state legal standards restrict – and can sometimes even prohibit – these programs. This session will explain how these programs can run afoul of the anti-kickback statute, the “patient remuneration” prohibition in the civil monetary penalty law, HIPAA privacy rules, “Usual and Customary” reimbursement standards, restrictions in the Telephone Consumer Protection Act (TCPA), and other legal standards. New proposals, such as proposed rules issued by OIG and pending action by the FCC, could broaden the ability of pharmacies to offer adherence and loyalty programs to patients will be discussed.

Don L. Bell, JD, National Association of Chain Drug Stores

(1.5 credit hours)

2:00 pm – 4:30 pm **Pharmacy Law Educators**

■ **Reinforcing Law and Ethics with Active Board of Pharmacy Cases**

Many pharmacy students find pharmacy law courses to be difficult and not immediately relevant. This session describes a method to help bring “the law to life” using pending cases (“Accusations”) before the California Board of Pharmacy, with alleged violations ranging from billing fraud to controlled substance issues. Students present statutes and regulations as they apply to the alleged facts, apply the law to the facts and predict the most likely outcome. Students identify ethical principles implicated in the cases. Finally, students argue mitigating and aggravating factors and how this might affect the disciplinary outcome.

Robert L. Stein, PharmD, JD, School of Pharmacy, Keck Graduate Institute

■ **Applying the Law Review Model to Pharmacy & Healthcare Education: Development of an Open-Access, Student-Driven Multimedia Journal Review at a College of Pharmacy and Health Sciences**

Although schools of law frequently offer law review as a prestigious, invitation only, co-curricular activity, we know of no other programs in healthcare and pharmacy offering a similar

journal review driven by students across a college or university campus. Due to an emphasis in ACPE 2016 of leadership, self awareness, and entrepreneurship in Standard 4, we decided to start, fund and run an open-access healthcare multimedia journal called BU Well. We will discuss how it was started, and how it could be applied at other colleges of pharmacy through pharmacy law educators.

Erin Albert, MBA, PharmD, JD, Butler University

Sunday, November 15, 2015

7:00 am – 12:00 pm **Registration Open**

7:00 am – 8:00 am **Breakfast**

8:00 am – 9:00 am **The Buck Stops Here: The Regulatory Landscape Affecting Pharmacy Marketing and Reimbursement**

Government payers and private plaintiffs have become increasingly aggressive in challenging pharmacy practices, claiming not only that certain practices violate the False Claims Act and/or Anti-Kickback Statute, but also that voluntary disclosures are insufficient. This program will review lessons learned from qui tam litigation and government settlements involving pharmacies will; highlight open legal questions of liability involving Medicaid and Medicare Part D claims; offer guidance on internal review of overpayments and voluntary disclosures; and provide tips on how to investigate and respond to a false claims case.

Catherine M. O’Neil, JD and Stephen Cummings, JD, King & Spalding

(1 credit hour)

9:00 am – 10:00 am **Major Issues Confronting Pharmacy Technicians as their Roles Evolve**

A panel presentation about the evolving role of pharmacy technicians and some of the major challenges that poses will be discussed. Some of the issues that will be examined include: uniformity among states regarding technician registration, licensure, and/or certification; the impact of standardized education and training; the value of creating a pharmacy technician scope of practice; disciplinary action among technicians; the pros and cons of expanded technician roles; and what does provider status for pharmacists mean for pharmacy technicians.

Adam Chesler, PharmD and Everett McAllister, MPA, RPh, PTCB; Kim Sveska, RPh, JD, Foley, Baron, Metzger, Juip; Janet Liles, MSHS, CPhT, PTEC

(1 credit hour)

10:00 am – 10:15 am **Break**

10:15 am – 11:15 am **Pharmacy Employment Law – Do’s and Don’ts of Policy and Litigation**

This presentation will review preventive policies and legal strategies for dealing with the recent prominence of employment law as a matter of concern for pharmacy employers. Assertions of age or gender discrimination, failure to accommodate a disability, and termination in violation of public policy will be discussed, including a \$2.6 million verdict for a pharmacist terminated after claiming needle phobia as a disability, a pharmacy faculty member case finding that the university had failed to prevent discrimination by other faculty members, and cases alleging that pharmacists were terminated for insisting on adhering to the law.

William E. Fassett, RPh, PhD, FAPhA, Washington State University

(1 credit hour)



2015 Developments in Pharmacy Law Seminar XXV

November 12 - 15, 2015

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To Register Online Now!

LAST DAY TO PRE-REGISTER FOR SEMINAR - OCTOBER 20, 2015

Please print or type participant information exactly as you would like it to appear on your badge. **Please use a separate form for each registrant.**

Name: _____

Credentials: (i.e. RPh, JD, PharmD, etc.) _____

For CLE Credit, please provide:

Licensure State(s): _____ License #(s) _____

Company: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ E-mail: _____

Medically necessary dietary needs: _____

In case of emergency contact: _____

Phone: _____

Registered guest(s): _____

- I am a first time ASPL Conference attendee
- I plan to attend the Saturday afternoon Pharmacy Law Educators Session

Please indicate:

- Pharmacist
- Attorney
- Pharmacist/Attorney
- Student
- Technician
- Paralegal
- Other _____

Please indicate which meals you/guests plan to attend:

- Thursday** Reception
- Friday** Breakfast
- Lunch
- Reception
- Saturday** Breakfast
- Sunday** Breakfast

You have a choice between receiving your conference materials electronically on a thumb drive or in a conference binder. Please select one option.

- I want my materials electronically on a Thumb Drive
- I want my materials in print via a Conference Binder

REGISTER BY OCTOBER 1 FOR EARLY BIRD DISCOUNT

FULL CONFERENCE:	By 10/1	After 10/1
<input type="checkbox"/> ASPL Member	\$570.00	\$645.00
<input type="checkbox"/> Nonmember	\$700.00	\$800.00
<input type="checkbox"/> Spouse/Guest	\$225.00	\$225.00
<input type="checkbox"/> Student <input type="checkbox"/> Tech. <input type="checkbox"/> Paralegal	\$300.00	\$375.00
ONE DAY REGISTRATION:		
<input type="checkbox"/> ASPL Member <input type="checkbox"/> Fri	\$300.00	\$350.00
<input type="checkbox"/> Sat <input type="checkbox"/> Sun	\$175.00	\$225.00
<input type="checkbox"/> Nonmember <input type="checkbox"/> Fri	\$370.00	\$420.00
<input type="checkbox"/> Sat <input type="checkbox"/> Sun	\$200.00	\$250.00
<input type="checkbox"/> Student <input type="checkbox"/> Tech. <input type="checkbox"/> Paralegal		
<input type="checkbox"/> Fri	\$175.00	\$205.00
<input type="checkbox"/> Sat <input type="checkbox"/> Sun	\$100.00	\$130.00
Total Fees: _____		

Registration fee for Seminar includes attendance at all seminar sessions, breakfast, refreshment breaks, Thursday and Friday receptions, Friday lunch and all seminar materials.

Cancellation policy: Cancellations must be received in writing. You can email to jbascom@associationcentral.org or fax to 217-529-9120. Your cancellation is null and void unless you receive confirmation of cancellation from the ASPL office. Refund of registration (less a \$50 administrative fee) will be granted for cancellations received in writing on or before October 1, 2015. Refund of registration (less a \$150 administrative fee) will be granted for cancellations received in writing after October 1, 2015 but on or before October 31, 2015. Refunds will not be granted for no-shows or cancellations received after October 31, 2015 regardless of cause. In the event of a no-show or cancellation after October 31, 2015, meeting materials will be forwarded to the address provided on your registration form.

Payment Method:

Check enclosed for full payment.

Please charge my: MasterCard Visa

Card Number: _____

Exp. Date: _____ CVV# _____

Name on Card: _____

Signature: _____

Register on-line at www.aspl.org

ASPL is accepting on-line registrations at www.aspl.org

or, you can mail registration form to:

American Society for Pharmacy Law

3085 Stevenson Drive - Suite 200 - Springfield, IL 62703

or fax to: 217-529-9120.

Payment must accompany registration.

Direct registration questions to

Janet Bascom at jbascom@associationcentral.org or 217-529-6948

ASPL is a 501(c)(3) non-profit, voluntary professional association and all contributions are fully tax deductible. The ASPL Federal Tax ID Number is: 52-1250852.