American Society for Pharmacy Law

2012 Developments in Pharmacy Law Seminar XXIII

In Conjunction with the National Alliance of State Pharmacy Associations

November 15-18, 2012

Ventana Canyon Resort - Tucson, Arizona



This year ASPL will again hold its meeting in conjunction with the National Alliance of State Pharmacy Associations. ASPL has a long tradition of presenting authoritative and engaging speakers who discuss timely legal and policy issues that affect pharmacies and pharmacists. See the Agenda on page 2 for descriptions of the educational topics that are being offered this year. We invite you to join us and take advantage of this opportunity to not only learn but to network with other professionals who have an interest in pharmacy law.

Your choice!

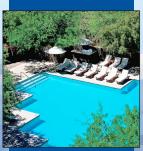
This year when you register for the Developments in Pharmacy Law Seminar you will have a choice between receiving your conference materials electronically on a thumb drive or in a conference binder.

If you choose to receive your conference materials electronically, you will receive a pre-loaded thumb drive when you check in onsite at the registration desk. Although we will still have to give you paper CE forms and evaluations, you will be emailed approximately one week prior to the conference with links to download and print the agenda and handouts.

PLEASE NOTE: we will not have a complimentary print desk at the event, so you must come prepared. You will be able to print in the hotel's business office at cost.

If you choose to receive your conference materials via conference binder there will be no change in the process. A binder will be prepared with all conference materials exactly as has been done in the past and you will pick it up when you check in onsite at the registration desk.





Register Today at www.aspl.org

Thursday, November 15, 2012

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

Friday, November 16, 2012

7:00 am – 5:00 pm ASPL Registration Open
7:00 am – 8:00 am Breakfast ASPL/NASPA

8:00 am - 8:15 am Welcome

8:15 am - 9:15 am **2012 Regulatory Enforcement Update**

This past year has seen new and bold actions by law enforcement and regulators to challenge the practices of pharmacies. The prescription drug abuse problem continues to cast a pall on the legitimate practice of pharmacy, and the federal government, through the DEA and FDA, have stepped up regulatory enforcement actions at pharmacies. It will be the aim of this presentation to review these legal developments and to provide guidance regarding measures that can be undertaken by pharmacies and their counsel to protect the pharmacy and offset the actions of the regulators.

William E. Fassett, PhD, RPh, Washington State University College of Pharmacy; Ronald Friedman, JD, Lane Powell (1 credit hour)

9:15am – 10:15 am **Developments in Controlled Substances Regulation and a Foggy Crystal Ball**

This presentation will provide additional details about the history of DEA regulatory interpretation and reaction to judicial decisions, the rationale for DEA enforcement actions, and some predictions about the future directions for DEA rule-making and enforcement.

D. Linden Barber, JD; Larry P. Cote, JD, Quarles & Brady LLP (1 credit hour)

10:15 am - 10.30 am Break

10:30 am – 12:00 pm Social Media Land Mines for Pharmacists

The growth of social media has challenged attorneys to apply traditional legal principals to new technology. This program will briefly describe the various forms of social media and explain application of legal principals related to defamation, privacy, trade secret, employment, the litigation process, and attorney ethics to the still evolving world of social media.

Randy Dryer, JD, Parsons, Behle & Latimer (1.5 credit hours)

12:00 pm - 1:00 pm Lunch - ASPL

1:00 pm - 3:00 pm **Case Law Update**

Again this past twelve months, courts, including the U.S. Supreme Court, have made far reaching decisions that will impact pharmacies, pharmacists, and the pharmaceutical industry. This annual presentation will discuss the Supreme Court's decisions to uphold PPACA, as well as court decisions that address the scope of pharmacists' duty to warn, the reach of the DEA authority, employee and employer rights, privacy and patient communications, conscientious objection sanctions, and other topics.

Roger Morris, RPh, JD, Quarles & Brady LLP; William J. Stilling, RPh, JD, Parsons Behle & Latimer (2 credit hours)

3:00 pm - 3:15 pm Break

3:15 pm – 4:45 pm HIPAA and HITECH: More Privacy and Security Regulations and Their Impact on Pharmacy Compliance, Patient Counseling, and Law Firms

The passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009 heralded new privacy and security requirements and more onerous penalties and enforcement of HIPAA. HHS has issued several versions of rules to implement the security breach, business associate, and penalty provisions. This presentation will explain how these provisions affect how pharmacies must comply, the impact of HIPAA and HITECH on patient counseling, and how lawyers must comply with privacy and security requirements as business associates.

Kevin N. Nicholson, RPh, JD, NACDS; Susan A. Buckna, JD, Shopko Stores Operating Company (1.5 credit hours)

6:30 pm – 9:30 pm Reception/Dinner - ASPL/NASPA

Saturday, November 17, 2012

7:00 am – 8:00 am Breakfast - ASPL/NASPA

8:00 am – 9:30am Legislative & Regulatory Update

This annual session will provide an overview of recently enacted and proposed laws and regulations that affect pharmacy.

Brian Gallagher, BS Pharm, JD, American Pharmacists Association (1.5 credit hours)

9:30 am – 10:30 am Ethical Decision Making for Attorneys and Pharmacists

As professional both pharmacists and lawyers face times in their day when ethical decisions need to be made. In this program we will explore selected parts of the legal Code of Professional Responsibility and the Pharmacist Code of Ethics as principles that can be applied to ethical decision making for both professions. We will explore teaching from Aristotle to General Patton and others to construct an ethical decision making algorism.

Kenneth R. Baker, RPh, JD, Ken Baker Consulting (1 credit hour)

10:30 am – 10:45 am Break

10:45 am – 12:15 pm **Veterinary and Human Compounding** Since the Food and Drug Administration Modernization Act (FDAMA)

of 1997 was passed, confusion has reigned over the legal parameters for pharmacy compounding. Contradictory court decisions, FDA's interpretation and enforcement of laws, and dissonance between FDAMA and FDA guidelines, have all contributed to the confusion. Similar factors have confounded compounders of veterinary products. This presentation will explain the laws, regulations, and court decisions affecting human and veterinary compounding so attendees can better understand the law and enforcement in these areas. Held in cooperation with the Food and Drug Law Institute.

Mark S. Brown, JD, King and Spalding LLP (1.5 credit hours)

1:30 pm – 4:00 pm Pharmacy Law Educators

This years pharmacy law education session will include a presentation and workshop component. The presentation will discuss active learning in and outside of the classroom while the workshops will include groups developing potential exercises and assignments that can be used for pharmacy law professors.

Sunday, November 18, 2012

7:00 am - 8:00 am Breakfast ASPL

8:00 am – 9:00 am **Trends in the Regulation of Automation**

This session will examine the types of automation available and application in patient care settings. The speakers will review select states' regulation of automation, including an examination of the five W's – Who can utilize automation, What medications may be stored, Why automation is used, Where automation is permitted, and When automation can be used; as well as potential federal Anti-Kickback Statute, Stark Law, and DEA issues.

Anne M. O'Brien, JD; Edward D. Rickert, BPharm, RPh, JD, Krieg DeVault (1 credit hour)

9:00 am – 10:00 am **Drug Manufacturer Coupon Co-Pay Programs: Legal, Policy and Business Considerations**

As drug manufacturers face rigorous formulary reviews for their products, stern generic and brand competition, and loss of exclusivity, the advancement of coupon co-pay programs have given them a new and forceful tool in their armamentarium to increase market share and drive profit. The presentation will review the legal, policy, and business aspects of Drug Manufacturer Coupon Co-Pay Programs and assess the value for the relevant stakeholders.

Matthew Seamon, PharmD, JD, Association Professor Nova Southeastern University College of Pharmacy, Of Counsel Fuerst Ittlmen (1 credit hour)

10:00 am - 10:15 am Break

10:15 am – 11:15 am Medication Therapy Management: Nuts, Bolts, and Legal Considerations

Medicare Part D requires prescription drug programs to provide Medication Therapy Management (MTM) for Medicare beneficiaries. This presentation will discuss the requirements for MTM, how pharmacists carry out MTM programs, recent changes in the Part D regulations governing MTM, the legal requirements and risks of MTM as this type of monitoring and intervention spreads to the private sector.

Doug Burgoyne, PharmD, RPh, VRx Pharmacy Services and William J. Stilling, RPh, JD, Parsons Behle & Latimer (1 credit hour)

11:15 am – 12:15 pm Challenges to Compliance in Current Regulatory Framework

As the regulatory environment becomes more complex, pharmacies are more frequently being investigated by administrative agencies. This program will discuss the ten most common compliance issues that are being faced by pharmacies before state boards of pharmacy, state controlled substance authorities, the Food and Drug Administration, and the Drug Enforcement Administration. It will also provide a framework for conducting self-audits of pharmacy operations practices and strategies for responding to agency investigations.

Laura Carpenter, RPh, JD, LLM, Carpenter Law Firm PC; Michael Simko, JD, Walgreens (1 credit hour)

Accommodations:

A block of rooms has been reserved for the ASPL Seminar at the Ventana Canyon Resort. The resort is located at 7000 North Resort Drive, Tucson, AZ 85750. Room rate is \$150 per night plus 13% tax. The special group rate will apply three days prior and three days after the conference dates, based upon availability of group rooms and group rates at the time of the request.

To make your reservation, call 1-800-234-5117. Be sure to identify that you are with the ASPL/NASPA meeting. The hotel reservation cut-off date is October 23, 2012. Reservations made after that date cannot be guaranteed the discounted rate or room availability. The room cancellation policy is 3 days in advance of arrival. Within the 72 hours, the deposit will be non-refundable.

Travel:

Air Transportation: The Loews Ventana Canyon Resort is conveniently located 19 miles (30 minutes) from Tucson International Airport (TUS). **Ground Transportation:**

Rental Car: Eight (8) National chains service the Tucson airport: Alamo, Avis, Budget, Dollar Car Rental, Enterprise, Hertz, National Car Rental, and Thrifty Car Rental. Self-parking is complimentary for those who have a room in the ASPL room block. Valet parking is available for \$9 per 24-hour period.

Taxi: Three (3) Taxi companies service the Tampa airport: AAA Airport Cabs, LLC (520-299-8294); Discount Cabs (520-388-9000); Flash Cab (520-798-1111). Taxi service is approximately \$50-\$60 (plus gratuity) each way.

Sedan Service: AAA Sedan (520-594-9444) offers car service to/from the Loews Ventana Canyon Resort. Sedan service is \$60 (plus gratuity) each way.

Shared Van Service: Arizona Stagecoach (520-889-1000) offers share-rides from the Tucson airport to the Loews Ventana Canyon Resort for approximately \$50 one-way. Roundtrip service is available for approximately \$92.00.

ACPE Continuing Education Credits Washington State

A total of up to 15 hours of continuing education credit will be available for attendees and these continuing education credits will be acceptable in all states that recognize ACPE providers. To receive credit for successful completion of this 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 continuing pharmacy education (CPE) tracking service, CPE Monitor, within 4 weeks after the program, and will then be accessible to participants at MyCPEMonitor.net.

CPE credits will be directly reported to the National Association of Boards of Pharmacy (NABP) through CPE Monitor. Please bring your NABP number to note on your CE form.

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

Need an NABP number? Please visit http://www.nabp.net/programs/cpe-monitor/cpe-monitor-service or www.cpemonitor.net.

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.



Name on Card:

Signature: _____

2012 Developments in Pharmacy Law Seminar XXIII

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Sponsored by American Society for Pharmacy Law

LAST DAY TO PRE-REGISTER FOR SEMINAR - OCTOBER 31, 2012

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. Credentials: (i.e. RPh, JD, PharmD, etc.) Please indicate: For CLE Credit, please provide: ■ Pharmacist Licensure State(s): _____ License #(s) _____ Company: City: _____ State: ____ Zip: _____ Phone: _____ Fax: _____ E-mail: _____ ☐ I want my materials electronically on a Thumb Drive Please in to attend ☐ I want my materials in print via a Conference Binder Thursday Medically necessary dietary needs: **Friday** ☐ Lunch - ASPL In case of Emergency Contact: ☐ Reception/Dinner - ASPL/NASPA Saturday ☐ Breakfast - ASPL/NASPA Phone: ■ Breakfast ASPL Sunday Registered Guest(s): **REGISTER BY OCTOBER 31 FOR EARLY BIRD DISCOUNT FULL CONFERENCE:** By 10/31 After 10/31 ■ ASPL Member \$570.00 \$645.00 receptions, Friday lunch and all seminar materials. ■ Nonmember \$700.00 \$800.00 ■ Spouse/Guest \$225.00 \$225.00 ☐ Student ☐ Tech. ☐ Paralegal \$375.00 \$300.00 ONE DAY REGISTRATION: ☐ ASPL Member ☐ Fri \$300.00 \$350.00 ☐ Sat ☐ Sun \$175.00 \$225.00 ■ Nonmember ☐ Fri \$370.00 \$420.00 ☐ Sat ☐ Sun \$200.00 \$250.00 ☐ Student ☐ Tech. ☐ Paralegal ☐ Fri \$175.00 \$205.00 ☐ Sat ☐ Sun \$100.00 \$130.00 Total Fees: ___ **Payment Method:** ☐ Check enclosed for full payment. Please charge my: ☐ MasterCard ☐ Visa Card Number: Exp. Date: _____ CVV#____



To Register Online Now!

	□ Attorney
	☐ Pharmacist/Attorney
	■ Student
	☐ Technician
	☐ Paralegal
	☐ Other
dicate which meals you/guests plan	
d:	
Reception - ASPL/NASPA	
☐ Breakfast ASPL/NASPA	

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

Cancellation policy: Cancellations must be received in writing. You can email to dscott@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, 2012. Refund of registration (less a \$150 administrative fee) will be granted for cancellations received in writing after October 1, 2012 but on or before October 31, 2012. Refunds will not be granted for no-shows or cancellations received after October, 31, 2012 regardless of cause. In the event of a no-show or cancellation after October 31, 2012, meeting materials will be forwarded to the address provided on your registration form.

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

Dustin Scott at dscott@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.