

American Society for Pharmacy Law



Developments in Pharmacy Law Seminar XXX

2019 ASPL Fall Meeting

November 7-10, 2019

**Westin San Diego Gaslamp Quarter
San Diego, CA**

ASPL is a nonprofit professional association for individuals with an interest in legal issues as they pertain to pharmacy, pharmaceuticals and related products and services. The ASPL annual seminar brings together over 300 industry professionals to share the most up-to-date, relevant and practical information.

Seminar goals include:

- Educate attendees on current and relevant information on wide-ranging pharmacy law issues.
- Provide pharmacy law educators with learning opportunities on the latest teaching methodologies and course curriculums relevant to pharmacy law education.
- Assist attendees with continuing education requirements through a program comprised of speakers and topics that offer 15 hours of continuing legal and pharmacy education credits to pharmacists, attorneys, pharmacist-attorneys and pharmacy-law educators.



Register Today at www.aspl.org



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Accommodations:

A block of rooms at a discounted rate has been reserved for the ASPL Seminar at the Westin San Diego Gaslamp Quarter. The hotel is located at 910 Broadway Circle, San Diego, CA 92101. The discounted room rate is \$209 per night plus tax if you make your reservation by 5pm PST October 14, 2019. For reservations call 1-888-627-8563 and indicate you are with the ASPL 2019 conference. There are a limited number of government rate rooms available. The government block rate is only available by calling the Westin reservations department at 1-888-627-8563 and referencing "ASPL Government".



Air Transportation:

The **Westin San Diego Gaslamp Quarter** is conveniently located 2 miles from the San Diego International Airport (SAN).

Ground Transportation:

Attendees are responsible for providing their own transportation to/from the hotel. Taxis, shuttles, ride share and rental cars are available at the airport.

ACPE Continuing Education Credits

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 create an account on <https://cmetracker.net/CAMPBELL/Catalog> and complete 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 CMETracker.net account 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.

Campbell University College of Pharmacy & Health Sciences 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

Quarles & Brady LLP

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.

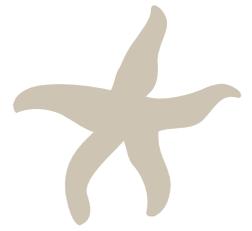
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Developments in Pharmacy Law Seminar XXX

Thursday, November 7, 2019

- 1:00 PM – 4:00 PM **Board of Directors Meeting**
3:00 PM – 5:00 PM **Registration Open**
5:30 PM – 7:30 PM **Opening Reception**

Friday, November 8, 2019

- 7:00 AM – 5:00 PM **Registration Open**
7:00 AM – 8:00 AM **Breakfast**
8:00 AM – 8:30 AM **Welcome and Introduction of
2020 Board of Directors**

8:30 AM – 9:30 AM **Keynote Speaker**
**Law or Lawless - the Future of Pharmacy
Regulation**

(1.0 credit hours, 0.10 CEU*)

*Carmen Catizone, MS, RPh, DPh, Executive Director
National Association of Boards of Pharmacy*

Pharmacy regulation is facing significant challenges to traditional strategies. One such challenge is the action of state legislatures to reduce or eliminate regulations and barriers to innovation and pharmacist mobility. This presentation will discuss the changing regulatory environment and its impact on pharmacy regulation and patient safety presently, and in the future. Contemporary matters such as pharmacist licensure transfer, prescription monitoring programs (PMPs), and suspicious order reporting will be used as illustrative examples of current and future trends.

9:35 AM – 10:35 AM

**Preparing for the Future by Understanding the
Changing Landscape of Litigation and Enforcement
Initiatives Against Pharmacies, Pharmacists and
Other Providers**

(1.0 credit hours, 0.10 CEU*)

Alissa Smith JD, MS, Dorsey & Whitney LLP; John Marti, Dorsey & Whitney LLP

The opioid-related litigation and enforcement initiatives unfolding across the country provide useful lessons for pharmacies, pharmacists and other providers. First wave litigation involved governments focusing primarily on pharmaceutical companies'

culpability in the epidemic. A second wave of litigation and legal initiatives focuses on providers and distributors, and may extend to employee benefit plans. This session will be presented by a former federal prosecutor with deep experience in healthcare fraud including matters targeting pharmacies and providers, and a health care regulatory and transactional attorney with deep experience representing pharmacies, pharmacists and providers. The presenters will provide an up-to-date review of the most recent opioid-related cases, settlements and enforcement actions taken against pharmacists, pharmacies and providers, analyzing what is alleged to have gone wrong in each matter. This presentation will provide practical advice that pharmacists, pharmacies and other providers can apply in their daily operations to prevent, prepare for, and defend against these initiatives. The session will be interactive with time for questions and audience discussion.

10:35 AM – 11:05 AM **Break**

11:05 AM – 12:05 PM

Attorney/Client Privilege

(1.0 credit hours, 0.10 CEU*)

Drew Hawk, JD, Hall Render

This session will provide a review of what privilege is and what it is not, and continue with detailed discussions on difficulties faced by in-house counsel and recent interpretations of the principles of privilege.

12:15 PM – 01:15 PM **Lunch**

12:30 PM – 12:45 PM **Annual Business Meeting**

01:30 PM – 02:30 PM

**Regulatory Compliance Involving the Use of Ekits,
and Navigating Theft/Loss Reporting Requirement
for Controlled Substances in the Long Term Care
Sector**

(1.0 credit hours, 0.10 CEU*)

Ronald Friedman, JD, Karr Tuttle Campbell; Blake Griese, PharmD, JD, Healix Infusion Therapy; Charles Hartig, PharmD, JD, Hartig Drug Company

The Drug Enforcement Administration permits the use of manual and electronic Emergency Kits (Ekits) at long-term care facilities by pharmacies in order to attend to the needs of patients, without having to register those devices as independent DEA registrants, so long as certain conditions are met. Identifying those

Register Today at www.aspl.org

Friday, November 8, 2019 - Continued

conditions as well as the grey areas that involve their use in the long-term care sector will be the focus of this presentation. In addition, we will explore questions involving the reporting obligations of pharmacies regarding thefts and losses in the long-term sector and challenges pharmacies face in interpretation of those obligations.

01:30 PM – 02:30 PM

Telepharmacy – The Good, The Bad, and The Ugly

(1.0 credit hours, 0.10 CEU*)

Lindsay Holmes, BakerHostetler; Benjamin Daniels, JD, MPP, Foley & Lardner LLP

This presentation will cover key considerations for telepharmacy businesses, including regulatory compliance risks associated with different business models and operations. The presentation will address telepharmacy business models, including pharmacy-telemedicine provider relationships, telepharmacy licensure, telepharmacy-specific state laws, and telepharmacy services arrangements. The presentation will inform the learner about best practices when operating and/or engaging with telepharmacies, as well key risk areas to manage. The presentation will also cover recent enforcement actions and outline strategies to mitigate risks.

02:40 PM – 03:40 PM

A Global View of Online Pharmacy Practice

(1.0 credit hours, 0.10 CEU*)

Melissa Madigan, PharmD, JD, NABP; Ulrich Grau, JD, D + B Lawyers; Libby Baney, JD, Faegre Baker Daniels LLP

Online health care practices are growing at a rapid pace, with online pharmacy practices leading the way. As technologies and new business models evolve, regulators are challenged to ensure patients are protected and illegal operations are halted. Risks for patients are great and include receipt of prescription drugs without a prescription, unapproved drugs, sub- or super-potent drugs, adulterated drugs, or counterfeits, including opioids. Also of great concern is the fact that the opioid crisis is expanding throughout the globe, fueled by online sales. Speakers will share up-to-date, real-life online pharmacy scams and reports of patient harm, and describe legal and other requirements for compliance for online pharmacy practice in the U.S., Canada, Europe, China, India, and other large economies.

02:40 PM – 03:40 PM

Dispensing Controlled Substances: Navigating a Minefield of Contradictions

(1.0 credit hours, 0.10 CEU*)

Larry Cote, JD, Cote Law PLLC; Kimberly Frazier, JD, Walmart Inc.

When it comes to prescription controlled substances, especially opioids, pharmacists are being forced to navigate a minefield of conflicting rules and guidance from various regulatory and industry authorities. In addition to providing an overview of the current enforcement and litigation landscape, this presentation will address the various minefields that pharmacists must traverse when dispensing controlled substances, such as: inconsistent DEA guidance

regarding professional judgement and corresponding responsibility; state specific prescribing requirements; CDC guidelines; partial fills of controlled substances; high-risk medication combinations; the use of PDMPs when making dispensing decisions; federal and third-party payor requirements; collaboration with prescribers; and MAT. In addition, the presenters will provide practical advice and industry best practices for navigating these contradictions while ensuring that patients are able to obtain drug therapies for legitimate medical purposes.

03:40 PM – 04:10 PM Break

04:10 PM – 05:10 PM

Employment Law for Pharmacies and Pharmacists

(1.0 credit hours, 0.10 CEU*)

Sweta Patel, JD, Klein, Hockel, Iezza & Patel P.C.; Jonathan Klein, JD, Klein, Hockel, Iezza & Patel P.C.

Operation of a successful pharmacy requires adept compliance and supervision of a multitude of laws and regulations applicable to pharmacy practice. But too often ignored is even a basic understanding of developing employment law practices that minimize liability while maximizing productive and even happy staff. This seminar will look at the overlap between employment law, disciplinary guidelines and pharmacy practice, with specific focus on issues confronting pharmacies and pharmacy managers in everyday practice. We'll address disability and religious accommodation in the workplace, give overviews on effective investigatory and consistent enforcement of disciplinary practices, and bring our unique perspective as both pharmacy lawyers and employment lawyers to this interactive discussion.

04:10 PM – 05:10 PM

PBM, Pharmacies and Politics: Drug Price Policy Changes Impacting Your Business

(1.0 credit hours, 0.10 CEU*)

Jay Warmuth, JD, Faegre Baker Daniels LLP; Kristina Cruz, JD, Prime Therapeutics; Tricia Beckman, JD, Faegre Baker Daniels LLP

In this session, a panel of pharmacy benefit manager (PBM) and drug price policy experts will highlight some of the more impactful federal and state drug policy actions (and proposed actions) and explore how these changes could reshape the prescription drug distribution industry. Key questions to be discussed include: Will drug costs really go down if rebates are eliminated entirely? What is the effect of applying price concessions/direct and indirect remuneration (DIR) at the point-of-sale? Who would benefit (or not) from government 'negotiation' for drug prices or price controls? Will transparency result in lower prices (and for whom)? Does Canada want to sell us its drugs (and is it worth it)?

05:30 PM – 07:00 PM Reception

Saturday, November 9, 2019

7:00 AM – 05:00 PM **Registration Open**

7:00 AM – 8:00 AM **Breakfast**

8:00 AM – 9:00 AM

Federal Legislative and Regulatory Update

(1.0 credit hours, 0.10 CEU*)

Jenna Ventresca, JD, APhA

9:05 AM – 10:05 AM

The Ethical Implications of Withholding or Withdrawing Medication Therapy from Patients with Dementia – The Story of Casey Kasem

(1.0 credit hours, 0.10 CEU*)

Cynthia Hall, PharmD, JD, MS, Florida A&M University College of Pharmacy and Pharmaceutical Sciences

With dementia prevalence on the rise, there is a growing need for guidance on health care decision-making for incapacitated patients. This session presents the ethical principles guiding health care decision-making, tools utilized to make such decisions, and an exploration of the moral dilemmas often experienced by loved ones designated to make decisions for end-stage dementia patients. Pharmacists may be called upon in the future to incorporate such discussions in their practices.

10:05 AM – 10:30 AM **Break**

10:35 AM – 12:35 PM

Case Law Update

2.0 credit hours, 0.20 CEU*)

William Stilling, RPh, MS, JD, Stilling & Harrison Health Care Law; Roger Morris, RPh, JD, Quarles & Brady LLP

ASPL's annual case law update will provide summaries of court decisions, lawsuits, and settlements from the last twelve months. The presentation will explore a variety of pharmacy related state and federal, civil and criminal cases involving employment issues, fraud claims by employees and the government (e.g., False Claims Act cases) negligence (malpractice) managed care, discipline actions by regulatory boards, controlled substances, and more. Whether you are an attorney, pharmacists, compliance officer, or work in any area related to pharmacy law, this fast-paced overview will inform you of some of the most important legal decisions that affect your practice.

02:00 PM – 03:00 PM

Blunt Talk About Cannabis: A Primer on Legalization and Use of CBD - A State and Federal Overview

(1.0 credit hours, 0.10 CEU*)

Karla Palmer, JD, Hyman, Phelps & McNamara, P.C.; Alice Mead, JD, LLM, Greenwich Biosciences

Cannabidiol (CBD) is one of the primary components of the cannabis plant. Interest and its use in both drug products and dietary supplements has rapidly increased in the past few years, and

is expected to continue to rise. For some time, particularly in the United States, there has been considerable confusion concerning the legal status of CBD, and the requirements that govern importation, distribution, and research. Alice Mead and Karla Palmer will address the status of CBD in the United States in both drug products and dietary supplements. They will also provide an overview of the use and regulation of CBD, as that term is used by DEA, FDA and as interpreted in the Federal Agricultural Improvement Act (AIA) of 2018 (i.e., the Farm Bill) which Congress passed in December 2018. Ms. Mead will address FDA's approval and DEA scheduling of Epidiolex® in September 2018 for treatment of epilepsy, which is the first ever FDA-approved drug that contains CBD. Specifically, FDA approved GW Pharmaceuticals' Epidiolex® in the United States for treatment of seizures associated with Lennox-Gastaut syndrome or Dravet Syndrome, two rare and severe early-onset, drug-resistant epilepsy syndromes. The panelists will also discuss generally U.S. laws and regulations relevant to CBD, hemp, and "CBD hemp extract," as well as the status of CBD under the laws of selected other countries.

02:00 PM – 03:30 PM

Pharmacy Law Educators - Pharmacy Students' Ethical Perceptions on Withholding or Withdrawing Medications in Late Stage Dementia Patients

(1.5 credit hours, 0.15 CEU*)

Cynthia Hall, PharmD, JD, MS, Florida A&M University College of Pharmacy and Pharmaceutical Sciences

This study demonstrated that there are knowledge gaps among pharmacy students concerning end-of-life care. With an increase in the prevalence of dementia, a lack of knowledge of advance directives, substitute decision making rules and laws, and the ethics involved in end-of-life care (particularly concerning withholding and withdrawing medication therapy) can compromise patient care. The ethics involved in end-of-life care is a topic requiring further inclusion within the pharmacy school curriculum.

03:05 PM – 04:05 PM

NCPDP's Impact – From Legislation to Patient Safety

(1.0 credit hours, 0.10 CEU*)

Lee Ann Stember, NCPDP; John Klimek, RPh, NCPDP

Get the latest on NCPDP, the ANSI-accredited SDO and the pharmacy industry's broadest and most impactful forum for collaboration that brings together government agencies and industry stakeholders to problem-solve the industry's most pressing challenges. Learn about NCPDP's top strategic initiatives " a model solution to help address the opioid epidemic, standardization to improve patient access to specialty medications, a real-time prescription benefit transaction that provides unprecedented transparency that can transform the patient/provider relationship and improve adherence; and a no-charge offer that enables the pharmacy industry to take advantage of advanced patient matching services and standards. In this session, attendees will also hear about NCPDP's EDvocacy impact on the Hill, its activities in Real-Time Prescription Benefit Verification (RTPBV), Electronic Prior Authorization (ePA), 340B and its new Specialty Pharmacy Work Group.

Saturday, November 9, 2019 - Continued

03:30 PM – 05:00 PM

Pharmacy Law Educators - Using a Flipped Classroom Model to Deliver Pharmacy Law Content: One PharmD Program's Experience

(1.5 credit hours, 0.15 CEU*)

Jennifer Adams, PharmD, EdD, FAPhA, Idaho State University

Pharmacy law is a topic that must be included in all PharmD programs, per the 2016 ACPE Standards and Guidelines. This can be accomplished myriad ways, some that engage learners better than others. Join us for a session discussing a different pedagogical approach - the flipped classroom model.

Sunday, November 10, 2019

7:00 AM – 12:00 PM Registration Open

7:00 AM – 8:00 AM Breakfast

8:00 AM – 9:00 AM

Drug Pricing Reform: The Impact On Pharmacies

(1.0 credit hours, 0.10 CEU*)

Don Bell, JD, National Association of Chain Drug Stores; Alan Arville, JD, Epstein Becker Green

The federal government is implementing major proposals that promise to dramatically reform drug pricing and reimbursement. States are also pursuing a wide array of proposals to increase drug price transparency and reduce drug costs. These drug pricing initiatives are expected to have a tremendous impact on pharmacies for many years to come. This session will provide an update on major proposals to eliminate pharmacy "DIR" fees, limit manufacturer rebates through the anti-kickback statute, set payments for Medicare Part B drugs based on international prices, negotiate Medicare Part D drug prices, and other important legislative and regulatory proposals that will have a monumental impact on the future of pharmacies.

9:05 AM – 10:05 AM

The Continuing Controversy Over Drug Importation

(1.0 credit hours, 0.10 CEU*)

Francis Palumbo, RPh, PhD, JD, University of Maryland School of Pharmacy; Lee Rosebush, PharmD, JD, MS, MBA, Baker & Hostetler,

Congress passed The Prescription Drug Marketing Act (PDMA) in 1987. There have been many attempts to amend the statute to allow for importation from, primarily, Canada, though none ever really gained traction. Despite this, many consumers did and still do go to Canadian websites to purchase their medications. Over the years, FDA softened its stance on personal importation when entering the U.S. from outside countries, and states have passed legislation asking the federal government for waivers from the PDMA, among other issues. Today, this issue of importation is still very much alive with proposed legislation continually emerging at the federal and state levels. There are currently three major pieces of federal legislation; the Affordable and Safe Prescription Drug

Importation Act; Safe and Affordable Drugs from Canada Act; and the Personal Drug Importation Fairness Act. In this presentation we will review these and other legislative initiatives and discuss the legal and regulatory issues surrounding them. We will also focus on recent trends in state legislation.

10:05 AM – 10:20 AM Break

10:20 AM – 11:20 AM

HIPAA Happy Update and a View of the Ever Expanding World of Privacy Regulation

(1.0 credit hours, 0.10 CEU*)

Denise Bloch, JD, Lathrop Gage LLP

This presentation will provide a refresher on the HIPAA basics including privacy practices and HIPAA's role in pharmacy, to ensure familiarity and compliance with the regulations impacting pharmacy patient privacy and medical records, as well as an overview of potential fines and penalties for breaches, along with examples of recent privacy breaches. In addition, there will be an overview of the California Consumer Privacy Act, including the information to which it applies, the regulatory fines and the private right of action it provides for consumers, and its potential impact on pharmacy including the changes needed to websites that collect personal information as well as other notices required by the CCPA. There will also be an overview of the FTC regulations barring unfair and deceptive acts and practices in or affecting commerce, including pharmacy. Finally, there will be an overview of the ever increasing range of state regulations impacting patient and consumer privacy that may involve pharmacy operations.

*Activity Type = Knowledge

ASPL EVENT APP!

ASPL will once again be providing all conference information through an event app. For those attendees wanting a hard copy of the conference materials, we are offering the purchase of the binder for \$20. **PLEASE NOTE:** due to the production & shipping time of the binders, final copies of presentations may not be included. Binders will only be available onsite for those who have pre-ordered them.

Register Today at www.aspl.org



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LAST DAY TO PRE-REGISTER FOR SEMINAR - OCTOBER 25, 2019

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

First Time Attendees & Conference Mentor

To ensure our 1st time attendees enjoy a smooth and meaningful conference, ASPL is introducing a Mentor Program which pairs 1st timers with past conference attendees. These "mentors" will serve as official greeters to the attendees, introduce them to others, and answer questions regarding ASPL and the conference.

Please select:

- I am willing to serve as a conference mentor.
- I would like to be paired with a mentor.

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

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

Payment Method:

Check enclosed for full payment. Charge my: MasterCard Visa

Card Number: _____

Exp. Date: _____ CVV# _____

Name on Card: _____

Signature: _____

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.

REGISTER BY OCTOBER 1 FOR EARLY BIRD DISCOUNT

FULL CONFERENCE:	Early	Late/Onsite
<input type="checkbox"/> ASPL Member	\$625.00	\$725.00
<input type="checkbox"/> Nonmember	\$755.00	\$855.00
<input type="checkbox"/> Government Rate*	\$450.00	\$450.00
<input type="checkbox"/> Spouse/Guest	\$280.00	\$280.00
<input type="checkbox"/> Student	\$355.00	\$455.00
ONE DAY REGISTRATION:		
<input type="checkbox"/> ASPL Member <input type="checkbox"/> Fri	\$355.00	\$455.00
<input type="checkbox"/> Sat or <input type="checkbox"/> Sun	\$230.00	\$330.00
<input type="checkbox"/> Nonmember <input type="checkbox"/> Fri	\$425.00	\$525.00
<input type="checkbox"/> Sat or <input type="checkbox"/> Sun	\$255.00	\$355.00
<input type="checkbox"/> Student <input type="checkbox"/> Fri	\$230.00	\$330.00
<input type="checkbox"/> Sat or <input type="checkbox"/> Sun	\$155.00	\$255.00
<input type="checkbox"/> Binder (Mobile App is FREE)	\$20.00	

Total Fees: _____

*Full time state or federal employee of government agency or education institution only.

Register on-line at www.aspl.org

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

you can mail registration form to:

ASPL - P.O. Box 7317 - Springfield, IL 62791

or fax to: 217-529-9120.

Payment must accompany registration.

Direct registration questions to Janet Bascom at

jbascom@associationcentral.org or 217-529-6948

Cancellation policy:

Cancellations must be received in writing. You can email to administration@aspl.org. 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, 2019. Refund of registration (less a \$150 administrative fee) will be granted for cancellations received in writing after October 1, 2019 but on or before October 25, 2019. Refunds will not be granted for no-shows or cancellations received after October 25, 2019 regardless of cause. In the event of a no-show or cancellation after October 25, 2019, meeting materials will be forwarded to the address provided on your registration form.