AGENDA

All times are Eastern Time Zone

Thursday, November 3, 2022

1:00 – 4:00 PM	**Board Meeting**
3:00 – 5:00 PM	**Registration Open**
5:30 – 7:30 PM	**Welcome Reception**

Friday, November 4, 2022

7:00 – 8:00 AM	**Breakfast**
7:00 AM – 5:00 PM	**Registration Open**
8:00 – 8:30 AM	**Welcome Remarks, Introduction of 2022 Board of Directors**
8:30 – 9:30 AM	**Opening Keynote: Disrupting the US Pharmaceutical Space, One Drug at a Time: A Discussion with CEO of Mark Cuban Cost Plus Drug Company** *Alexander Oshmyansky, MD, PhD - Mark Cuban Cost Plus Drug Company*
9:35 – 10:35 AM	**Federal Legislative and Regulatory Update** *Ilisa Bernstein, PharmD, JD, FAPhA - American Pharmacists Association* The U.S Congress and federal regulatory agencies have been busy this past year and there have been some significant changes impacting pharmacists and pharmacies. This session will provide an overview of new developments on the federal legislative and regulatory front, including an update on Medicare provider status, drug pricing and pharmacist payment reform, telehealth, drug supply chain security, drug importation, compounding, maintaining COVID-19 pharmacist patient care flexibilities, and more. The session will also look at what to expect on the national legislative and regulatory scene in 2023.
10:30 – 11:05 AM	**Break**
11:05 AM – 12:05 PM	**Ethics Session Professional Responsibility in the Practice of Pharmacy Law** *Robert R. Harrison, MHA, JD, LLM, FACHE - Stilling & Harrison, PLLC* This session will focus on four of the ABA Model Rules of Professional Conduct with specific application in the practice of pharmacy law: Rules 1.1 (Competence), 1.6 (Confidentiality of Information), 1.13 (Organization as a Client), and 4.3 (Dealing with Unrepresented Persons). While selected state examples will be included, the ABA Model Rules and associated annotations will serve as the standard for discussion. Seasoned practitioners will challenge and expand their understanding of the Rules, and earlier-career practitioners will develop a better appreciation for the special ethical implications of pharmacy law practice.
12:15 – 1:15 PM	**Lunch and Annual Business Meeting**
CONCURRENT SESSIONS:	

1:30 – 2:30 PM	**Drug Supply Chain Security Act (DSCSA)** *Josh Bolin - National Association of Boards of Pharmacy* *Scott Mooney, BS, MBA - McKesson Corporation* Although November 2023 appears to be off in the distant future, there is much for the supply chain (including dispensers) to do in preparation for the implementation of the Drug Supply Chain Security Act (DSCSA). Especially for the requirements for product tracing for regulators and national licensing standards. Attendees will be updated on the NABP DSCSA pilot project, general DSCSA changes, and the national licensing standards.
	Long-Term-Care Pharmacy. The Legal Gray Area Between Community and Institutional Pharmacy Practice. *Joseph Lavino, PharmD, JD - CVS Health* Long-Term-Care pharmacy is a unique pharmacy model that blends both community and institutional pharmacy practice. As such, many legal and regulatory issues may present themselves, which could impact pharmacy care for long-term-care patients. These regulatory challenges may lie in the delivery of medications to patients through automated dispensing systems or emergency kits. As many Boards of Pharmacy regulate and require the use of a prescription to dispense, many long-term-care settings utilize chart orders, which may cause concerns with the Federal False Claims Act or Board of Pharmacy regulations. DEA regulations address exceptions and requirements specific to long-term-care settings, which require unique policies and procedures to be adopted by long-term-care pharmacies to comply. Due to the institutional nature of the patient population, the utilization of collaborative practice agreements and formularies are used to control cost and are met with variable state regulations. The use of consultant pharmacists adds an additional layer of regulations that would place mandates on how a pharmacy performs medication reviews, destroys drugs or inventories controlled substances on the premises. Lastly, when Covid-19 first struck, it hit the long-term-care patients the hardest based on the fragility of this patient population. As such, many facilities shut their doors to any external persons wishing to enter the facility. This includes pharmacists who were legally mandated to perform activities in the facility. This presentation will shed light on the uniqueness of the long-term-care pharmacy model, the conflicts between state pharmacy and facility regulations that arise, and the opportunities presented to Boards of Pharmacy to amend regulations to allow pharmacies to optimize patient care.
CONCURRENT SESSIONS:	
2:40 – 3:40 pm	**Test & Treat** *Jeff Mesaros, PharmD, JD - Ro* *Scott Pace, PharmD, JD - Impact Management Group / Kavanaugh Pharmacy* Pharmacy-based Test and Treat programs increase access to health care by allowing pharmacists to perform appropriate assessments and diagnostic tests and to treat patients based on the results of those tests. Throughout COVID-19, pharmacies have stepped up to close a gap in care and improve health equity throughout the United States. Many states lack the regulatory framework to continue this valuable patient care service in the absence of the PreP Act allowances. This program will serve to review the regulatory framework of Arkansas and Florida and provide lessons learned for other states to work with regulatory agencies to maintain this standard of care.
	Trends in Drug Spending, Pricing, and Pharmacy Reimbursement

	Alan J. Arville, JD - Epstein Becker Green *Spreeha Choudhury, J.D., PharmD - Epstein Becker & Green* *Christopher R. Smith, J.D., LL.M. - Epstein Becker & Green* Federal and state lawmakers have renewed efforts to implement policies that address drug spending and pricing following a temporary toll on such efforts through the height of the pandemic. These renewed efforts are vast and impact all levels of the payer and supply chain. This presentation will provide a background overview on recent trends in prescription drug spending and pricing and then focus on the impact these trends may have on pharmacy reimbursement, separate and apart from any impact on patients or payers. Specific emphasis will be placed on the Centers for Medicare and Medicare's (CMS') 2021 Medicare Advantage and Part D Final Rule, which seeks to reform pharmacy direct and indirect remuneration (DIR) in Medicare Part D. The presenters will discuss how this Final Rule is likely to impact pharmacy reimbursement. Other topics will include: • State efforts to carve pharmacy benefits back into Medicaid fee-for-service; • Medicaid managed care reimbursement trends, including reimbursement floor mandates for Medicaid MCOs, trends in reimbursement models for drugs, and various state legislative and regulatory measures imposing limitations on pharmacy benefit managers (PBMs); • Policies contained within recent federal legislative packages, including possible changes to the National Average Drug Acquisition Cost (NADAC) survey process.
3:40 – 4:10 PM	**Break**
CONCURRENT SESSIONS:	
4:10 – 5:10 PM	**Developments in Laws and Regulations Impacting PBMs and Prescription Drug Access** *Jane Blaney, JD - Faegre Drinker Biddle & Reath LLP* *Jay Warmuth, JD - Faegre Drinker Biddle & Reath LLP* There has been a proliferation of laws, regulations and lawsuits impacting PBMs in recent years on both the state and federal levels, and these actions can have a broad impact on access to, and the distribution of, prescription drugs generally. At the state level, recent legislative and regulatory developments impacting PBMs range from more straight-forward licensing or registration requirements to regulations impacting a PBM's core operations, including pharmacy network contracting and reimbursement, its arrangements with manufacturers and drug wholesalers, and a PBM's dealings with health plan clients. At the federal level, regulatory proposals addressing Part D benefit design and implementation have created both flexibility and limitations on certain PBM activities. Further, both federal and state policymakers have considered and passed legislation aimed at increasing the transparency of prescription drug costs. This presentation will provide an overview of recent developments in PBM regulation and explore questions such as: Who are these laws and regulations designed to protect? What are the goals or objectives of the regulations? And are those objectives being achieved? We also will address a number of challenging legal issues that oftentimes arise in the context of these laws and regulations, including issues of federal statutory preemption and the cross-border application of certain state laws to multi-state or national health plan clients.
	Pharmacist Prescriptive Authority: Give Me That Pen! *Marty Allain, JD - REAL Solutions Group LLC* *Jennifer Baumgartner, PharmD, BCPP - REAL Solutions Group LLC* The slow, methodical grind of expanding pharmacist prescribing authority sounds eerily like a train gaining scant momentum on a rusty

	iron track. But progress is upon us as COVID has proven pharmacy to be an effective and easily accessible wellness destination while select states continue to expand prescribing authority. The fight is ongoing throughout Statehouses around the country. Medical associations battle, scheme, and harass non-physician professions into submission legislative session after session, but history will prove that doctors were on the wrong side of progress. The presentation will provide a brief overview of the history of pharmacist scope of practice along with insights on pharmacist prescribing regulation and engagement around the continuum of pharmacist prescriptive authority. Pull out our Rx pads and pens, pharmacists, it's time to write!
5:30 – 6:30 PM	**Reception**

Saturday, November 5, 2022

7:00 – 8:00 AM	**Breakfast**
7:00 AM – 5:00 PM	**Registration Open**
8:00 – 9:00 AM	**Pharmacists Ask: "What is my 'corresponding responsibility' in 2022, and what do I do about it?"** *Ron J. Friedman, JD - Karr, Tuttle, Campbell* *Karla L. Palmer, JD - Hyman, Phelps &McNamara PC* Pharmacists have been and remain on the front line of the nation's opioid crisis. One aspect that pharmacists have had to deal with in the past several years is how to "comply" with the Drug Enforcement Administration's somewhat vague regulation concerning exercising the pharmacist's "corresponding responsibly" when dispensing controlled substance prescriptions. The presentation will review the DEA's definition of corresponding responsibility, and the history of the same. We will review recent DEA administrative cases that address a pharmacist's corresponding responsibility requirements. We will also consider the Department of Justice's Prescription Interdiction and Litigation Task Force (PIL), the goals of the PIL, and recent federal enforcement actions brought by the Department of Justice seeking to enjoin pharmacists from dispensing prescriptions that have allegedly not been issued for a legitimate medical purpose. We will review what DEA considers are "red flags" of diversion, and what a pharmacist should consider when confronted with a prescription with alleged "red flags." We will conclude with a discussion of the Supreme Court's June 2022 decision in Ruan v. United States, which changed significantly the standard by which practitioners can be prosecuted for inappropriate prescribing of controlled substances, and its potential effect on pharmacist liability.
9:05 – 10:05 AM	**Ethics General Session - Ethical Obligations and Challenges Faced During Internal Investigations** *Nicholas Gonzales, JD, M.B.A., CHC, CHPC - The Kroger Co.* *Drew Howk, JD - Hall Render* *Scott Taebel, JD - Hall Render* This presentation will provide internal an external counsel an overview of ethical obligations and challenges faced during internal investigations and empower them to implement stronger, more defensible ethical practices whether they're managing the investigation as in-house counsel or supporting their clients as external counsel. This session will include a hypothetical case study applying the core ethical principles to a hypothetical retail-pharmacy investigation and share insights from in-house counsel and external counsel on the same.
10:05 – 10:30 AM	**Break**

10:30 AM – 12:35 PM	**Case Law Update** *Roger N. Morris, JD, RPh - Quarles & Brady LLP* *Jim Ruble, PharmD, JD - University of Utah College of Pharmacy* 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 civil and criminal cases at the state and federal level involving pharmacy employment issues, fraud claims by employees and the government (e.g., False Claims Act cases), negligence (malpractice), managed care, disciplinary actions by regulatory boards, controlled substances, and more. Whether you are an attorney, pharmacist, compliance officer, or work in any area related to pharmacy law, this fast-paced overview will inform you of the most important legal decisions affecting your practice.
CONCURRENT SESSIONS:	
2:00 – 3:00 PM	**ACPE Standards and the Effect of Pharmacy Law Educators** *J. Gregoyr Boyer, Dr. - Accreditation Council for Pharmacy Education (ACPE)* *Mary Kiersma, PharmD, PhD - Accreditation Council for Pharmacy Education (ACPE)* Attendees will be provided an overview of the standards revision process, a summary of program performance on the MPJE, and the variety of curricular models used by programs to teach pharmacy law. The annual monitoring process will be explained including the steps programs are required to complete if requirements are not met. The session will also describe challenges of law instruction based on curricular format and program location.
2:00 – 4:00 PM	**Diplomat, American Society for Pharmacy Law (DASPL) Candidate Capsule Summary Presentations** *Moderator: Erin L. Albert, MBA, PharmD, JD - Mark Cuban Cost Plus Drug Company, PBC* *Brett Barker, PharmD - NuCara Management Group* *Patrick Carpenter, MS, PharmD, RPh - Option Care Health* *Emily Do, PharmD, JD, MBA, CHC, BCPS, CSSBB - San Diego County* *Michael DeBisschop, PharmD - Medical College of Wisconsin School of Pharmacy* *Eman Kirolos, PharmD, RPh, MS - Walgreens* *Frank North, Pharm.D., M.P.A., R.Ph. - Texas A&M University* *Danielle Swenson, JD - IngenioRx, Inc.* In this session, the inaugural class of leaders through the ASPL Diplomat, American Society for Pharmacy Law program will each provide a capsule presentation of their year-long project for the ASPL inaugural leadership program. Candidates were required to study an area in pharmacy and/or pharmacy law that was of interest to the profession of pharmacy and their own professional backgrounds.

Sunday, November 6, 2022

7:00 – 8:00 AM	**Breakfast**
7:00 AM – 12:00 PM	**Registration Open**
8:00 – 9:30 AM	**A Culture of Safety- Has It Been Paralyzed?** *Donna Horn, RPh, DPh, MS, CHC - Fresenius Medical Care* *Karen Ryle, MS, RPh, DPh - Massachusetts General Hospital* *Symin JW Charpentier, PharmD JD - Brown Rudnick LLP* In March 2022, former nurse RaDonda Vaught was found criminally

	guilty of neglect and negligent homicide. A patient she had been caring for at Vanderbilt University Medical Center died after Vaught injected her with vecuronium instead of Versed (midazolam). Historically, workplace errors have been traced to individuals, and those individuals have been held responsible and accountable. It is a scapegoating and punitive system which assumes that human fallibility is the cause of errors and punishing individuals will help to decrease future errors. Punishing an individual for systemic issues may appear to provide closure but in fact does little to prevent future harm and may chill the act of bringing mistakes to light while the window for fixing those mistakes is still open. In a Just Culture, managers and organizations strive to implement system design features that give the workforce the best opportunity to perform patient care efficiently and safely. A Just Culture approach recognizes that systems can be the cause or source of an error. Individuals should not be punished for the failure of systems to anticipate human error. In a Just Culture, all workers know that safety is valued in the organization, and they continually look for risks that pose a threat. They are thoughtful about their behavioral choices and always thinking about the most reliable ways to get the job done correctly and safely. Using this recent case as a touchstone, the presentation will examine this State v. Vaught in depth through the lens of Just Culture, the history of criminal charges brought in medication error cases, and what pharmacists, nurses, and hospitals can do to protect patients and reduce risk of liability.
9:35 – 10:35 AM	**Double, Double Toil and Trouble: Avoiding Regulatory Pitfalls Related to Thy Hubs Interactions** *Simone Colgan Dunlap, JD - Quarles & Brady LLP* *Shannon Wiley, JD - Bass, Berry & Sims* This presentation will address key regulatory considerations implicated by pharmacy interactions with hubs--with a playful Shakespearian twist. If you have ever thought that hubs are greek to you, this presentation will give you the wings wherewith to fly confidently into the evolving world of hubs. Hubs play a unique role in the ecosystem of drug delivery and patient care and take on varied forms. For example, hubs may be HIPAA covered entities, may hold pharmacy licenses, or may not. Accordingly, there is no standard approach to interactions with hubs. Further, pharmacies may not have direct contracting relationships with hubs, which can complicate risk analysis. It is critical for pharmacies to understand the multiple regulatory constructs that should be analyzed when dealing with hubs to avoid regulatory pitfalls. The presenters will provide an overview of established and emerging hub models in the market, including discussion of data flows, enrollment, test claims, and recent trends. The presentation will then focus on the laws implicated by pharmacy/hub interactions including discussion of federal and state privacy laws, pharmacy laws, and fraud waste and abuse laws as well as impact on payor relationships and operational processes. Presenters will also provide practical risk mitigation strategies to manage and structure hub interactions. As patient access strategies continue to evolve, all pharmacies should be prepared to navigate hub interactions. As th**e** Bard said, “better three hours too soon, than a minute too late”!
10:35 – 10:45 AM	**Break**
10:45 – 11:45 AM	**Navigating Manufacturer Actions to Restrict 340B Drug Access at Contract Pharmacies: Critical Policies, Arguments, and Expectations** *Mark Ogunsusi, PharmD, Esq. - Powers Pyles Sutter and Verville PC* *William H. von Oehsen, Esq. - Powers Pyles Sutter and Verville PC*

	Enacted in 1992, Section 340B of the Public Health Service Act entitles certain safety-net providers to purchase from manufacturers outpatient drugs at a deeply discounted ceiling price defined by the 340B statute. Drug manufacturers agree to provide the 340B discount in exchange for their drugs being reimbursed under the Medicaid and Medicare Part B programs – two important markets for most manufacturers. For nearly three decades, the safety net hospitals and clinics participating in the 340B program – referred to as “covered entities” in the statute -- have dispensed their 340B drugs through independent pharmacies operating under contract with covered entities. These contract pharmacy arrangements allow covered entities to extend the reach of their 340B pharmacy programs to more patients and are especially important for hospitals and clinics that lack their own in-house pharmacies. Finally, the presentation will discuss federal and state bills aimed at curbing the manufacturers’ restrictive policies, and key predictions for the future of 340B contract pharmacy arrangements.