Developments in Pharmacy Law Seminar XXXII

NOVEMBER 04-07 2021

All times are Pacific Time Zone. All sessions marked with * are part of the 10 hours of virtual CE.

Thursday, November 4, 2021

1:00 - 4:00 PM — **Board of Directors Meeting**

3:00 - 5:00 PM — **Registration Open**

5:30 - 7:30 PM — **Welcome Reception**

Friday, November 5, 2021

7:00 - 8:00 AM — **Breakfast**

7:00 AM - 5:00 PM — **Registration Open**

8:00 - 8:30 AM — **Welcome Remarks, Introduction of 2021 Board of Directors**

8:30 - 9:30 AM — ***COVID Response from a Federal Perspective**

Brandon Hardin, PharmD, US **Navy Personnel Command**

CAPT Hardin will present on the topic of the Federal COVID-19 Vaccine Response. He will describe his role and activities while assigned to the Vaccine Planning Unit and Vaccine Implementation Unit within the Centers of Disease Control and Prevention's COVID-19 Vaccine Task Force, in support of Operation Warp Speed. These planning and implementation units were focused on supporting the 64 jurisdictions in developing plans for and implementing the allocation, distribution, administration and tracking of safe and effective vaccines to the US population.

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 2022.

10:35 - 11:05 AM — **Break**

11:05 AM - 12:05 PM — ***Kumbaya Has No Place in Mentorship: How to Build Successful Mentorship Programs In-House to Foster Diversity and Inclusivity (*Ethics Session*)**

K. Brooke Salazar, JD PHR, **Apex Benefits**

Studies have shown that successful mentorship programs have increased retention of diverse talent from 9% to 24%, as opposed to formal policies, complex complaint reporting mechanisms, and other formalized programs. This session is designed to teach mentors how to build a successful mentorship relationship. Successful mentorships are built on a foundation of vulnerability, empathy, and honesty. Mentors must do the foundational work of building trust through sharing stories of failure and showing empathy, in order to be able to give the mentee honest, frank feedback. Growth occurs through discomfort for both parties, as it may

uncomfortable for either party to give or receive honest feedback. However, through building the foundational relationship, the mentor will be able to give honest feedback that while uncomfortable will ultimately lead to growth and success. This session will give the mentor the tools and skills to build fruitful mentorship relationships.

12:15 - 1:15 PM **Lunch**

12:45 - 1:15 PM **Annual Business Meeting**

1:30 - 2:30 PM **Concurrent Session: Managing the Maze of Medical J/C/Q Code Drugs**

Erin Albert, PharmD, JD, MBA, CPBS, CHVP, **Apex Benefits**

Often in healthcare insurance and benefits, self-funded and fully insured commercial employers have little notice or understanding that they cover drugs in both the pharmacy benefit as well as the medical benefit. Most new drugs and biologicals with higher-cost therapies are infused outpatient maintenance drugs, and often not billed under the pharmacy benefit, but under the medical benefit. However, medical benefit drugs are rarely provided under contracted, established rates with third-party administrators (TPAs) or Administrative Services Only medical benefits providers (ASOs). In this session, we will explore understanding how the J/C/Q code medical drugs are billed, and provide strategies for managing these high dollar therapies in the medical benefit, pharmacy benefit, and share the trickle-down effects of better management of these potentially high-dollar therapies.

1:30 - 2:30 PM **Concurrent Session: PBM Legislation and Regulation in Michigan: An update with a focus on 340B for Self-Funded Employers.**

James Horton IIBS, JD, **Rx-Legal, P.C.**

With the anticipated regulation of Pharmacy Benefit Managers (PBM's) in Michigan, the presentation will examine the issues addressed within the law and its benefits/risks and impact to Pharmacies, Pharmacists, Consumers and Businesses in the State. A general overview of the Law and its multi-faceted approach to addressing the impact of PBM's in the Pharmacy field will be discussed.

A focus will be concentrated on the 340B pricing regulation involving the issue of not having a different cost of goods reimbursement contract term. What impact, if any, will this have on self-funded employer groups and prescription drug pricing/prescription drug plans? Are there alternatives to structure a PBM contract to allow a self-funded employer to share/recoup in the actual drug cost savings of the 340B program? Contract Pharmacy direct Agreements? Actual acquisition cost used for cost of medication reimbursement?

The audience should take away from the presentation the status of legislation in the States concerning PBM's and what if anything can be done to decrease the cost of prescription drug plans to self-funded employer groups and their employees.

2:40 - 3:40 PM **Concurrent Session: Offering "Value-Added" Services to Customers While Avoiding Prohibited Inducements**

Jeffrey Baird, BBA., JD, **Brown & Fortunato and** ***Bradley Howard, BA, JD,*** **Brown & Fortunato**

An important way for a pharmacy to set itself apart from its competitors is to offer services to existing and prospective patients…services that other pharmacies cannot offer. As the nation's health care delivery system moves away from the fee-for-service model to a value-based care model, government enforcement agencies are encouraging health care providers to provide "value-added" services to patients…with the goal of narrowing the socio-economic gap and making preventive health care available to everyone. For example, the Centers for Medicare and Medicaid Services ("CMS") recently relaxed the restrictions of the federal physician self-referral statute ("Stark") and the federal beneficiary inducement statute and the Office of Inspector General ("OIG") recently relaxed the restrictions of the federal anti-kickback statute ("AKS"). At the same time, it is important that the pharmacy not go so far that it inadvertently violates these statutes. This program will discuss (i) the federal laws governing value-added services to patients; (ii) those value-added services that are legally acceptable; (iii) those value-added services that may trigger a government enforcement action.

2:40 - 3:40 PM

Concurrent Session: Retail Chain Pharmacy Stock Management and Optimization: Distribution and Delivery Trends

Todd Nova, JD, **Hall Render and** ***Joe Cesarz, PharmD*****, Visante**

This presentation will focus on federal and state regulatory issues facing multi-state retail chain pharmacies seeking to optimize drug inventories in warehouses, distribution centers, central-fill pharmacies, licensed pharmacies and other remote locations. Among other issues, the presenters will address the application of disparate federal and state standards that govern the operational and licensure requirements associated with full package and amber vial transfers in both the intrastate and interstate setting. The presenters will also discuss the role that state boards of pharmacy play in interpreting these standards while addressing the practical considerations of positions taken by regulatory bodies that can be inconsistent with both the law and with their own subregulatory guidance.

3:40 - 4:10 PM

Break

4:10 - 5:10 PM

Concurrent Session: Biosimilars: The Promise and the Reality

Francis Palumbo, RPh, PhD, JD, **University of Maryland and** ***Lee Rosebush, RPh, PharmD, MBA, MS*****, Baker & Hostetler**

When Congress passed the Drug Price Competition and Patent Term Restoration Act (aka Hatch-Waxman) in 1984, it did not include biologics which are large molecules. Thus the provisions for bioequivalence, for example, were applicable only to small molecule drugs. Biologics remained in a brand name world where the only reasonable path to approval was through a BLA. It was not until 2009 when Congress passed the Biologics Price Competition and Innovation Act that there was now a pathway for less expensive "generic" biologics to enter the marketplace. Unlike with generic drugs, FDA established a two-tiered approach to biosimilar approval. The first is approval of the biosimilar itself. The second is approval of the biosimilar as a substitute for a brand name prescription. Initial uptake was slow as the industry attempted to find its way through the new FDA requirements for biosimilar approval. Biosimilars are now being approved at an increasing pace and have now reached some level of critical mass where they can begin to exert some influence in the biologics marketplace. So far 29 biosimilars have been approved. 2020 was a somewhat slow year but that can be attributed to Covid-19 as FDA and others have struggled with pressing issues surrounding the pandemic. However, to date none have gone through the process for approval as a substitute for the brand name biologic. Instead, the biosimilars are basically competing head-to-head with the branded products for placement on formularies. Biosimilar prices tend to be about 20 percent less than the brand name products and this was somewhat disappointing in the marketplace. The lack of approved substitutes likely contributes greatly to this narrow difference. All the while vaccines and insulin products remain very expensive.

4:10 - 5:10 PM

Concurrent Session: DEA Updates

Larry Cote, JD, **Cote Law PLLC and** ***James Carroll, JD,*** **DC Consulting LLC and** ***Uttam Dhillon, JD,*** **DC Consulting LLC**

Given the significant changes and pending changes to DEA reporting and compliance obligations in recent years, this session would address practical operational considerations associated with implementation of these standards. Topics to discuss might include suspicious order identification and reporting processes, Power of Attorney delegation processes/models, CSOS enrollment for retail pharmacies, and exclusion checking. The session will also address general policy matters related to the opioid crisis and the broader prescription drug epidemic, including prevention and treatment initiatives and national and global enforcement priorities.

5:30 - 6:30 PM

Reception

Saturday, November 6, 2021

7:00 - 8:00 AM

Breakfast

7:00 AM - 5:00 PM

Registration Open

8:00 - 9:00 AM

*Not Throwing Away Our Shot: How the Response to COVID-19 is Shaping Retail Pharmacies' Role in Public Health Crises

***Kala Shankle, JD,* NACDS and *Lindsay Holmes, JD,* Amazon.com, Inc.**

The early days of the COVID-19 pandemic were filled with a litany of complex legal, political, and public policy matters that shaped retail pharmacies' role in the public health emergency response. Despite these challenges, by the time the Nation was ready to be vaccinated in early 2021, America's retail pharmacies had become a cornerstone of the COVID-19 response and played an integral role in getting COVID-19 shots into arms. This presentation will discuss the temporary band-aids implemented during the pandemic that allowed pharmacies in engage in the COVID-19 response, including those around the delivery of care and the dispensing of medication. Then, this presentation will examine current efforts to empower pharmacies to engage in the response to current and future public health crises.

9:05 - 10:05 AM

*Health Disparities and Vaccine Distribution: What Have We Learned and Where do We Go from Here? (*Ethics Session*)

***Lee Rosebush, RPh, PharmD, MBA, MS,* Baker & Hostetler and *Marc Wagner, PharmD, JD, MBA,* Baker & Hostetler**

The speakers will provide an overview of the PREP Act as it relates to the COVID-19 response. Attendees will compare and contrast the Federal and State responses to the evolving distribution of COVID-19 vaccines. Policies will be critically analyzed to offer suggestions for the next pandemic response.

10:05 - 10:30 AM

Break

10:35 AM - 12:35 PM

*Case Law Update

***Roger Morris, RPh, JD,* Quarles & Brady LLP and *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.

2:00 - 3:00 PM

State Statutory and Regulatory Update – Emerging Trends and Hot Topics

***Laura Carpenter, BS, Pharm, JD, LLM,* Bula Intelligence**

As the scope of pharmacy practice is continuously expanding, patients' access to healthcare is improving. The expansion also presents new and exciting opportunities for pharmacies and pharmacists. However, the risk is that most pharmacists are already stretched. If not managed well, the expanding pharmacy practice can quickly turn into additional responsibilities, which negatively impacts the wellbeing of pharmacy staff, pharmacy practice, and patients.
In this talk, we will survey recently passed legislation expanding opportunities for pharmacists. We will also explore some of the key legislative changes and trends affecting pharmacy technicians' scope of practice which can free pharmacists to embrace their expanding role fully.

3:05 - 4:05 PM

State Policy Options for Prescription Drug Affordability

***Andrew York, Pharm, JD,* Maryland Prescription Drug Affordability Board**

This presentation will provide an overview state policy options to promote drug affordability. The overview will include a summary of each policy, the mechanism for enacting the policy (legislation, regulation, etc.), potential

benefits and consequences of each policy, and potential legal considerations for each policy. The policies will include upper payments limits, reverse auctions, bulk purchasing, and other available policies. This presentation will align with a report that the Maryland Prescription Drug Affordability Board will publish by the end of the year.

Sunday, November 7, 2021

7:00 AM - 12:00 PM **Registration Open**

8:00 - 9:00 AM ***FDA's Final Memorandum of Understanding with States: "What a Long Strange Trip Its Been": 2021 Update**

***Karla Palmer, J.D.,* Hyman, Phelps & McNamara, PC**

Since 1999, compounding pharmacies have been grappling with when, if ever, FDA would promulgate the "final" Memorandum of Understanding between FDA and States addressing shipment of compounded formulations interstate. its been "a long time coming," but after 20-plus years, tens of thousands of comments from industry, and three different drafts, FDA published its "Final" MOU in October 2020, to be effective a year later. FDA was sued the next day by a a group of compounding pharmacies, which lawsuit was supported by two amicus curiae groups that submitted briefs in support. As counsel to one of the amicus groups that filed a brief in support of Plaintiffs' challenge to the MOU, Ms. Palmer will address arguments made by the parties, and those considered by the court. In November 2021, at the time of the ASPL conference, we likely will be able to address not only where compounding industry was... from 1999 to the present, but we will also discuss the roll out and signing of the MOU by various states, and those states that have refused to sign. We will consider the NABP's current and future role in information collection related to the MOU's reporting requirements per the grant it received from FDA. Lastly, we will consider the future of interstate shipment of compounded preparations from a national perspective, upon the finalization of the MOU process, which will have occurred by October 2021. We we hope to engage in an interactive discussion concerning compounding and interstate shipment, including reporting and potential prohibitions, after finalization of the MOU.

9:05 - 10:05 AM ***Recent Regulation and Law Affecting Pharmacy Benefit Managers**

***Bradley Wasser, Esquire,* Duane Morris LLP and *Jonathan Swichar, Esq.,* Duane Morris LLP**

Over the past few years numerous states have imposed new laws and regulations affecting the business and operations of PBMs. Such laws have permitted the expansion of pharmacy network access rights, the ability to distribute prescription drugs on a wider scale and impact on pharmacy reimbursement. Additionally, there have been significant legal decisions which will help clarify, facilitate and dictate changes to existing legislation and impact new legislation impacting PBMs. Specifically, the United State Supreme Court's decision in Rutledge v. PCMA will change how states may enact law involving the rights of pharmacies and the impact of such rights on PBMs.

This presentation will provide an overview of the recent developments across states in legislation and regulation of pharmacies and PBMs. It will discuss the impact of these laws on the business of PBMs operating in those states and the impact of those laws on the pharmacies in those states. The presentation will additional explore the recent legal rulings of such laws and the types of legal challenges and issues that arise out of such legislation and regulation. Finally, it will explore the potential future impact of such regulations given the newly created legal precedent.

10:05 - 10:20 AM **Break**

10:20 - 11:20 AM ***Telehealth: How Far We've Come; How Much Further There Is To Go**

***Patrick Carroll, MD,* Hims & Hers and *Elizabeth Baney, JD,* Faegre Drinker LLP, and *Reema Taneja, Esq.,* Nixon Gwilt Law**

We will discuss where telehealth is and where it is going from the provider and legal practitioner perspectives. In our talk we will share data on how patient-initiated care has changed during the pandemic, offer insight gleaned from new research on consumer behavior, and forecast where the practice and policy are headed.