AUBURN UNIVERSITY
Harrison College of Pharmacy

HARRISON COLLEGE OF PHARMACY
CONTINUING EDUCATION

IQVIA - 27th Controlled Substances and State Regulatory Conference

Mr. Brinks, Ms. Fullwood, Dr. Gordon, Dr. Macy, Ms. McDermott, Ms. Palmer, Ms. Quasba, Mr. Roberts, Mr. Thacker, Dr. Ward

September 3- 5, 2025 in Savannah, GA

PROGRAM OVERVIEW

In a market of ever-changing state and federal regulations, it is critical to hear details of the latest regulatory compliance challenges and learn valuable strategies for navigating the changing industry landscape. As the industry's premier annual conference on Controlled Substances and State regulatory compliance for more than 25 years, this year's conference will again provide attendees with unmatched legal, regulatory, and industry updates from government officials, law firms, and leading industry stakeholders and provide impactful networking opportunities throughout the conference. Registration for this conference is through IQVIA. There is no additional registration fee for CE credit.

Following registration, participants will have access to course instructions, updates, presentations, live program information, program evaluation, CE certificates and credits, etc. **This program is approved for 6.75 ACPE Contact Hours, .675 CEUs.** Once credit is awarded, transcripts will be available online within 24 hours on the learner's CPE Monitor profile at http://nabp.pharmacy/.

The Office of Alumni and Professional Affairs strongly encourages each participant to check their profile online within 60 days of attendance to ensure credit has been awarded properly. ACPE will not accept CE submissions after 60 days from the live seminar date.

This program is offered through a partnership with IQVIA.

TARGET AUDIENCE

This knowledge-based program is intended for Pharmacists (ACPE).

LEARNING OBJECTIVES

- Explain the risks of counterfeit drugs for customers and patients, including “double danger.”
- List key tactics used by bad actors to create counterfeits and how knowledge of these may impact pharmaceutical practice.
- Summarize some examples of major policy and enforcement changes made to the medicine supply chain to enhance patient safety.
- Review the current status of federal telehealth legislation/regulations and how the pharmaceutical industry has changed since implementation.
- Discuss how North Carolina's currently implemented telehealth regulation/policies affects pharmacists and pharmacies, and changes would occur if there was a federal change in policy.
- Identify key pieces of both the existing and proposed federal telehealth regulation and potential impact to pharmacists and pharmacy.
- Review the history of DEA's evolving review and enforcement of a pharmacist's "corresponding responsibility" through DEA regulations.
- Explain the DEA's schedules of controlled substances and ongoing concerns with Schedule 2 controls; however, address the corresponding responsibility obligation concerning Schedules 3-5 drugs as well.
- Identify the so-called "red flags" of diversion and abuse announced by DEA through DEA administrative and Federal Court actions decisions involving pharmacists.
- Define a pharmacist's considerations concerning what exactly are red flags of diversion and abuse when filling controlled substance prescriptions, including how to dispel reg flags in order to properly dispense.
- Explain the critical need for advanced counterfeit identification technologies within the controlled substance supply chain, specifically addressing the risks posed to manufacturers, distributors, and pharmacies.
- Describe the development and deployment of NABP's "Pulse" platform, including its foundational principles and how it facilitates secure communication and verification among trusted trading partners.
- Identify real-world applications and benefits of product verification technology, referencing examples such as actions taken by state Boards of Pharmacy to quickly identify and address illegitimate products.
- Discuss how new technologies like Pulse contribute to enhanced compliance with federal and state regulations (e.g., DSCSA) and a more secure, transparent drug supply chain.
- Discuss the importance of being prepared for various types of natural disasters by creating and utilizing response plans.
- Identify ways to adhere to regulatory requirements and compliance standards before, during, and after natural disasters
- Explain how to conduct post-disaster assessments, including debriefing sessions, preparing after-action reports, and updating the response plan based on findings to ensure continuous improvement in emergency preparedness.
- Identify Key Regulatory Bodies and Their Audit Focus Areas
- Describe Best Practices for Maintaining Continuous Audit Readiness
- Outline an Effective Inspection Response Plan
- Discuss Internal Compliance Monitoring and Self-Audit Capabilities
- Define drug diversion
- Perform significant loss analysis by applying DEA factors to determine whether a controlled substance loss is ”significant” and requires reporting
- Discuss the impact of drug diversion on patient safety, public health, and pharmacy integrity

ACTIVITY COMPLETION REQUIREMENTS

To complete the steps for CE credit, each attendee will be required to access and review program materials located within the online course, attend the live program, enter the attendance code within the course that was provided at the conclusion of the program, complete the program evaluation within the online course, and claim credit within the course. Please contact hcopce@auburn.edu if you have any questions or needs related to this online CE program.

FACULTY DISCLOSURES

Programming in with AUHCOP is in any way involved, whether as sole provider or joint-providership, shall exhibit fair content balance, providing the audience with information of multiple perspectives from which to form a professional opinion. In addition, the fair balance will assure than information provided does not discuss since commercial product. Brand names of all products included in the content may be mentioned for identification purposes only.
Presenters in any continuing education offering will acknowledge and disclose any affiliation with the provider and such information will be made available to the audience.
Faculty disclosures will also be included on an introductory slide during the presentation.
Presenters and others in control of content have no actual or potential conflict of interest in relation to this program.

ACCREDITATION INFORMATION

The Auburn University Harrison College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider for continuing pharmacy education; credits are recognized nationwide. The Universal Activity Number for this knowledge-based program is **0001-9999-25-021-L04-P** and is intended for pharmacists.

Disclosure statement:
No individuals in a position to control content for this activity have any relevant financial relationships to declare.

PROGRAM AGENDA

September 4, 2025

8:30am – 9:30am **Who's Getting Hurt by Counterfeit Drugs?** - Rick Roberts
Rick Roberts, a professor at the University of San Francisco and a member of The Partnership for Safe Medicines' Advisory Board, began thinking about the problem of medicine safety after he received two different counterfeit versions of Serostim (human growth hormone). After giving himself an injection one day, Roberts noticed a stinging sensation that had never happened before. When he asked his pharmacist about it, he learned that authorities had found counterfeit versions of Serostim in the U.S. drug supply. His medicine was among the lots that were recalled. Since this frightening experience, Roberts been a staunch advocate for medicine safety and will discuss not only his personal story, but the current pharmaceutical counterfeit challenges.

9:45am – 10:45am **Telehealth – Time Will Tell**
Scott Brinks, Gray Fullwood, Nisha Quasba,
With the current challenges of the administration and the executive order halting federal rulemaking, the future of telehealth remains unclear after the first of the year. Understanding challenges by pharmacies in addressing the current requirements and preparing for possible changes will be discussed by the panel during this session.

11:00am – 12:00pm
Understanding Red Flags - Increasing Pharmacists Awareness of Drug Diversion - Karla Palmer
Pharmacists are expected to exercise "corresponding responsibility" in evaluating controlled substance prescriptions for signs of potential diversion and abuse. This session will explore the issue of "red flags," patient care, and whether to fill or not fill a prescription.

1:15pm – 2:15pm
Counterfeit Identification - New Technology Moving Detection Forward - Ilisa Bernstein
Counterfeits lurk in the shadows, but your detection tools don't have to. The National Association of Boards of Pharmacy invites you to explore Pulse, a powerful new platform to shine a spotlight on product authenticity and enhance supply chain safety. We'll delve into the vital reasons behind Pulse's development and its practical deployment, illustrating its capacity to facilitate secure communication and instant product verification with trusted partners. Learn from real-world successes, such as the decisive actions by the Arkansas Board of Pharmacy, as we showcase how Pulse is a game-changer for manufacturers, distributors, and pharmacies in the ongoing fight against illicit controlled substances.

2:30pm – 3:30pm
Emergency Preparedness/Disaster Recovery – Lessons Learned from Hurricane Helene
Gray Fullwood and Jonathan Thacker
The significant disaster last fall from Hurricane Helene impacted North Carolina pharmacies and the communities in ways that were not imaginable. While pharmacies and regulators plan for disasters, understanding the unexpected challenges and lessons learned will be explored during this session.

4:00pm – 5:00pm
Ready or not, here they come! Maintaining pharmacy inspection/audit readiness
Jamie McDermott, Director and Amanda Ward,
Pharmacies are subject to audits and inspections by many regulating bodies, such as DEA and state licensing boards. This session will cover topics to help you stay "audit ready" and be prepared for your inspection.

September 5, 2025

10:15am – 11:00am
Preventing Drug Diversion in Pharmacy Settings: Best Practices, DEA Regulations, and Comprehensive Security Strategies - Danielle Gordon
Discussion surrounding the critical issue of drug diversion in pharmacy settings

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Ilisa Bernstein, PharmD, JD, FAPhA, is President of Bernstein Rx Solutions, LLC, where she advises clients on navigating the complexities of drug and pharmacy regulatory policy and compliance issues, strategies, and advocacy. Dr. Bernstein served nearly five years at the American Pharmacists Association (APhA), including a 13-month tenure as APhA's 14th CEO and Executive Vice President -- the first woman to lead APhA in its 172-year history. She oversaw strategic operations for APhA, the Board of Pharmacy Specialties, and the APhA Foundation. She joined APhA in 2019 as Senior VP for Pharmacy Practice & Government Affairs and guided the association as the voice of pharmacists in all practice settings. Her public service spans over 30 years at the U.S. Food and Drug Administration (FDA), where she held multiple senior leadership roles. As deputy director of FDA's Office of Compliance in the Center for Drug Evaluation and Research, she shaped national policies and enforcement strategies for drug compliance. She also served for 19 years in senior policy advisor roles in the Office of the Commissioner, starting at FDA as a clinical pharmacology reviewer. Dr. Bernstein currently serves on the Board of Trustees of the United States Pharmacopeia (USP), and held other board positions, including the Alliance for Safe Online Pharmacies, Pharmacy Quality Alliance, and the APhA Board of Trustees. In 2023, she was honored with the Distinguished Alumni Lifetime Achievement Award from the University of Michigan College of Pharmacy and received the Top 50 Most Influential Pharmacy Leaders Award by the Pharmacy Podcast Network. Dr. Bernstein was also senior associate director of worldwide regulatory affairs at Pfizer and completed a post-doctoral clinical residency at the National Institutes of Health. She earned her PharmD from the University of Michigan College of Pharmacy and her JD from American University Washington College of Law.

Scott Brinks currently serves as the Administrator of Diversion Prevention & Engagement for a large hospital system, where he is responsible for overseeing all activities related to controlled substances. Mr. Brinks is a former Drug Enforcement Administration (DEA) Diversion Investigator with over 25 years of experience. He began his career with DEA in 2001, following prior service as a Military Police Officer in the U.S. Army and as a civilian police officer. During his time with the DEA, he served in the Detroit Field Division, Cleveland Resident Office, where he conducted major pharmaceutical investigations. He later held supervisory roles in Indiana and Illinois, managing complex national diversion cases. At DEA Headquarters, Mr. Brinks held several key leadership positions, including Staff Coordinator of the Policy Section, Unit Chief of the Liaison Section, and Section Chief of the Regulatory. Drafting and Policy Support Section. In that capacity, he directed agency-wide efforts on regulatory policy, regulatory drafting and legislative initiatives until his departure from the DEA in 2024. Mr. Brinks is widely recognized for his deep expertise in DEA regulations, policy development, and controlled substance compliance. Throughout his distinguished career, he has served as a trusted resource on matters related to pharmaceutical diversion, regulatory interpretation, and legislative initiatives. He has provided comprehensive training to hundreds of professionals, including federal, state, and local law enforcement officers, as well as members of the pharmaceutical and healthcare industries. Mr. Brinks earned a Master of Arts in Pastoral Counseling from Liberty Baptist Theological Seminary and a Bachelor of Arts in Sociology from St. Leo University. Throughout his career, he has been honored with numerous awards and commendations, including the United States Attorney's Award for Distinguished Service and the National Health Care Anti-Fraud Association (NHCAA) Investigation of the Year Award.

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Gray Fullwood, Director of Investigations with the NC Board of Pharmacy, leveraging extensive experience in regulatory compliance and enforcement. Over 19 years as a Special Agent with the North Carolina State Bureau of Investigation, specializing in pharmaceutical narcotics and environmental crimes.

Danielle Gordon is a dual-credentialed healthcare professional and attorney, currently serving as Assistant General Counsel and Senior Compliance Manager at Memorial Sloan Kettering Cancer Center (MSK). With a unique background in pharmacy and law, Danielle leads MSK's Controlled Substance Compliance and Drug Diversion Prevention Program, ensuring institutional adherence to the Controlled Substances Act and DEA regulations. Danielle began her career at MSK in 2009 as a Senior Pharmacist, delivering clinical pharmacy services across inpatient and outpatient settings. In 2017, she transitioned to the Compliance Department, becoming MSK's first Drug Diversion Manager—a role in which she pioneered the institution's approach to controlled substance oversight and internal investigations. She provides strategic guidance on regulatory matters, including DEA licensing, prescribing practices, and incident reporting, and collaborates closely with clinical and research teams to uphold compliance standards. Danielle holds a Doctor of Pharmacy (PharmD) from Rutgers University School of Pharmacy and a Juris Doctor (JD) from New York Law School. She is admitted to the New York State Bar.

Jaime McDermott is the Controlled Substance Compliance Director for Kroger Health, where she leads enterprise-wide efforts to ensure regulatory compliance and responsible pharmacy practices across one of the nation's largest retail healthcare organizations. With nearly 30 years of experience in pharmacy and over a decade dedicated to controlled substance compliance, she brings deep expertise in DEA regulations, risk mitigation, and operational execution. Throughout her career, Jaime has held a variety of leadership roles at both the Pharmacy and Corporate levels, giving her a broad perspective on patient care, pharmacy operations, and regulatory strategy. Her leadership reflects a balance of technical knowledge and a deep-rooted belief in the value of people and purpose in advancing the profession of pharmacy and helping people live healthier lives.

Karla Palmer serves as Director for Hyman, Phelps & McNamara. As a litigator with over 33 years' experience, Karla advises clients throughout the pharmaceutical supply chain – from manufacturers and distributors to outsourcing facilities, pharmacies and doctors – on a range of legal and regulatory issues. These matters include DEA and FDA regulations and guidance, government inspections and investigations, Form 483 observations, warning letters, consent decrees, and administrative and federal proceedings. She represents entities and individuals in matters involving their DEA registration, including investigations, orders to show cause, immediate suspension matters, hearings and federal appeals of the same. Karla is a nationally recognized leader in the compounding space, both for Section 503A and 503B facilities. She regularly counsels clients on all aspects of compliance with state and federal statutes, regulations and guidance. Karla has written about and addressed industry audiences across the country on DEA and FDA and compliance, including all aspects of the passage and implementation of the 2013 Drug Quality and Security Act including both compounding and supply chain issues, its guidance documents, and implementing regulations.

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Nisha Quasba is a seasoned government and regulatory affairs professional at Faegre Drinker Consulting with a proven track record of navigating the legislative landscape to drive meaningful policy reforms. Through her advocacy, she has successfully built bipartisan, bicameral support for critical legislation, shaping policies that resonate with diverse stakeholders. Her work has made a significant impact on the rare disease community, the telehealth sector, and the practice of pharmacy. A dedicated public health policy advocate, Nisha is committed to safeguarding public health and safety through informed policymaking. Before joining Faegre Drinker, she served as a public policy specialist with the Association of Public Health Laboratories, where she facilitated collaboration between government agencies, policymakers, and association members to advance key public health initiatives.

Professor Rick Roberts teaches at the University of San Francisco in both the Performing Arts Department and the Department of Rhetoric and Language. After being diagnosed with HIV/AIDS in 1988 he began taking AZT- the only drug available at the time. Since then, he has taken thousands of doses of medications, including counterfeit drugs. As a result of his experience, Roberts has appeared on national radio, television, and in print media discussing pharmaceutical counterfeiting and issues of medicine safety. He has testified before various governing bodies including the U.S. Senate and numerous state legislatures. He is an Advisory Board Member for The Partnership for Safe Medicines. Professor Roberts continues to advocate for the establishment of greater protections for consumers of pharmaceuticals in the U.S., along with working to effect policy related to the global drug counterfeiting crisis.

Jonathan Thacker is a pharmacy and compliance executive with experience leading enterprise-wide pharmacy operations and compliance programs across healthcare, retail pharmacy, and other highly regulated industries.

Amanda Ward, PharmD, MS, BCGP, DASPL, is passionate about pharmacy law and regulations and helping pharmacists find unique ways to impact patients, either directly or indirectly. Since graduation from West Virginia University School of Pharmacy in 2008, Dr. Ward has held several non-traditional pharmacist roles. She has worked as a long-term care pharmacist, community pharmacist, regulatory consultant pharmacist, managed care pharmacist, and an ambulatory care pharmacist. In 2021, Dr. Ward obtained her MS Pharmacy degree in Pharmaceutical Outcomes and Policy from the University of Florida, in the pharmaceutical regulation specialty track. In 2024, Dr. Ward completed the American Society for Pharmacy Law's Diplomat program.

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