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ERNEST MARIO SCHOOL OF PHARMACY PRECEPTOR NEWSLETTER

Newsletter Editors:

Geeny Lee, PharmD, BCOP
Ashmi Philips, PharmD, AAHIVP
Mariam Hanna, PharmD
Britney Mbeng, PharmD
Ruth Li, PharmD
Vismita Kandasamy, PharmD

Experiential Education Office (EEO)

Contact: 848-445-6849
rotation@pharmacy.rutgers.edu

Dean Donna Feudo, BSP Pharm, RPh
Associate Dean of Experiential Education
dmfeudo@pharmacy.rutgers.edu

Janice Allunario, BSP Pharm, RPh
Pharmacy Field Manager
janice.allunario@pharmacy.rutgers.edu

Nina Raps, BSP Pharm, RPh
Pharmacy Field Manager
ntsai@pharmacy.rutgers.edu

Joyce DaSilva
Senior Program Coordinator
jdasilva@pharmacy.rutgers.edu

Katelyn Jo
Program Coordinator
katelynj@pharmacy.rutgers.edu

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Greeting

Message and updates from Dean Donna M. Feudo:

Dear Preceptors,

As the spring semester ends and the new academic rotation year is under way, I want to share updates based on the new ACPE Standards of 2025. To comply with these standards, EMSOP and our Experiential Education Committee have been planning new processes, activities, and revisions for assessment and grading. Here are some highlights:

- Single Document: The 2025 standards combine the previous separate Guidance document into one comprehensive document standards if you wish to access the full document www.acpe-accredit.org/pdf/ACPEStandards2025.pdf.
- Focus on Outcomes: Emphasis on educational outcomes and the assessment of student achievement levels, including the use of Entrustable Professional Activities (EPAs).
- Curriculum Integration: EPAs are now integrated into Standard 2: Curriculum, allowing programs to develop program-specific EPAs.
- Expanded Scope: Topics in Appendix 1 now include diagnosing and prescribing, reflecting advancements in the scope of practice for pharmacists.

Greeting (continued)

IPPE Highlights:

- **Expectations:** Involvement in contemporary U.S. practice models, interprofessional practice, professional ethics, and patient care activities.
- **Duration:** EMSOP IPPE community and hospital/health system rotations are 160 hours with at least 80 hours (50%) involved in patient care in both settings.

APPE Highlights:

- **Expectations:** Emphasis on continuity of care, incorporating acute, chronic, and wellness-promoting patient-care services in various settings. In the aggregate, APPEs expose students to diverse populations that include age; gender; neurodivergent, race/ethnicity, and socioeconomic factors; and disease states.
- **Duration:** EMSOP APPE rotations are 200 hours each with 8 rotation cycles. Majority focused on patient care.
- **Required APPE:** Completed in the U.S. or its territories, involving interprofessional communication and collaboration in four practice settings: (1) community pharmacy; (2) ambulatory care; (3) hospital/health system pharmacy; and (4) inpatient adult patient care.
- **Elective APPE:** Opportunities for professional maturation, breadth and depth of experience, and exploration of various sectors of practice.

Starting in cycle 1 of the new rotation academic year 2025-2026, updated IPPE and APPE rotation grade/assessment forms and syllabi that have been distributed through CORE ELMS. To reinforce our commitment to ensuring students are "APPE Ready and Licensed Ready" according to new standards, midpoint evaluation will now be required with the final grade evaluation form. This will also help us evaluate the longitudinal learning growth of our students on a yearly basis along with preparation for our next ACPE self-study. Please note that the Longitudinal Assessment Form (LAF) will be retired.

Once again, we sincerely appreciate all the time, effort and dedication you offer our students and program and are grateful for your support as you share in our success

Take care.

Donna M. Feudo, BSPharm., RPh.

Ernest Mario School of Pharmacy

Associate Dean for Experiential Education and Clinical Affairs

Adjunct Clinical Professor





Community Outreach - Dismantling Barriers in Our Community, One Event at a Time

Prepared by Maram Ayadi and Valerie Fortouna
PharmD Candidates 2025

Throughout our rotations, we have had the invaluable opportunity to see pharmacists lead with knowledge and compassion—professionals who inspired us to pursue this path ourselves. Pharmacists are among the most accessible and trusted healthcare providers in the community and beyond dispensing medications, they educate patients, promote healthy lifestyles, and act as essential links between individuals and the broader healthcare system.

One of the most powerful aspects of pharmacy practice we have witnessed is the role pharmacists play in addressing social determinants of health (SDOH)—the non-medical factors such as income, education, health literacy, and transportation that significantly influence health outcomes. Unfortunately, these factors often create barriers to proper medication use and overall wellness. Pharmacists are uniquely positioned to help bridge these gaps, especially through community outreach.

Our experiences through the Community Service Outreach Requirement (CSOR) have given us first-hand insight into the impact pharmacists can have outside of traditional healthcare settings. We have had the opportunity to participate in blood pressure screenings, where we met patients at local community events or clinics—and provided tailored education on medications, disease states, and the importance of lifestyle management. We have also volunteered at various vaccine clinics, not only educating patients on the importance of immunizations but also helping remove transportation and accessibility barriers by bringing these services directly to their communities. These experiences have been both enlightening and deeply fulfilling. What started as a requirement quickly became a passion. We found ourselves eagerly seeking out more events, drawn by the chance to connect with patients, provide guidance, and be that helping hand for someone navigating health challenges in their everyday life. Community outreach has become an essential part of our growth and development as future pharmacists.

In pharmacy, community outreach is not just an extension of our profession—it is a necessity. It allows us to step beyond the counter and make a tangible difference by empowering patients, improving health outcomes, and fostering trust. Through compassionate care and personalized education, pharmacists help dismantle SDOH-related barriers and create healthier, more informed communities.

We have chosen to go above and beyond the required hours because, for us, this work is meaningful. It's not just about fulfilling a checkbox—it's about genuinely wanting to serve, to advocate, and to give back. Community outreach has shown us the power of presence, of meeting people where they are, and it has reaffirmed our commitment to becoming healthcare professionals who are as compassionate as they are knowledgeable.

Rotation Highlight: Prescription for Growth - A Summer APPE Teaching Experience and the Importance of Peer-led Education

Prepared by Umair Kadri, PharmD Candidate 2025



Every summer has a story for someone to tell, cherish, and hold onto. For 80 undergraduate students in 2024, their summer story involved an enriching experience where they learned about what their future careers in healthcare may look like. The Summer Health Professions Education Program (SHPEP) at Rutgers New Jersey Medical school is a six-week summer enrichment program that provides resources to undergraduate students from disadvantaged backgrounds.¹ This program equips students with the skills and knowledge necessary to navigate the application process and transition into professional programs in pharmacy, medicine, nursing, and dentistry.¹ Additionally, they are offered coursework in basic sciences, clinical experiences, financial literacy training, and professional development opportunities.

For four APPE pharmacy students on rotation with Dr. Marc Sturgill, their summer story turned out to be much more than a teaching rotation. These APPE pharmacy students served as Peer Student Leaders and mentors for the SHPEP scholars, guiding the course and mentoring all scholars, including six students that were interested in entering pharmacy school. But more than this, the connections that they built in terms of camaraderie, communication, presentations skills, and communication still resonate with them and have helped build skills important to navigate life after pharmacy school. Importantly, those APPE students also received Rutgers IRB approval to assess the effectiveness of an interprofessional pharmacy student peer-led curriculum for pre-health undergraduates. This research was presented at the 2024 ASHP Midyear Conference held in New Orleans, LA.

Literature shows that peer-led teaching, as implemented by the SHPEP program, creates a more comfortable and engaging learning environment compared to traditional lectures.^{2,3} This approach encourages active participation and expression of opinions that leads to academic, motivational, and social benefits for students.^{2,3} Peer leaders also gain from the experience, enhancing their confidence, communication, leadership, and organizational skills.⁴

Rotation Highlight: Prescription for Growth - A Summer APPE Teaching Experience and the Importance of Peer-led Education

Prepared by Umair Kadri, PharmD Candidate 2025 (continued)

Qualtrics surveys were presented to pre-health and pre-pharmacy students in addition to the four peer-leaders on the first and last days of the program. The study question being tested was whether student peer-led teaching would increase scholar confidence, comprehension, and participation. Results of the surveys showed that peer-led education and mentoring, guided by the APPE students, brought significant value to pre-health students, pre-pharmacy students, as well as the peer-led instructors. There were statistically significant improvements across the board for all questions on the Likert scale in pre and post-survey results in the pre-health scholars group.

Some key takeaways from the research are that pharmacy students, due to their closeness in age and experience, created a more relatable and engaging learning environment for the undergraduate students. Importantly, in the pre-pharmacy cohort, pre-pharmacy scholars were able to build confidence in preparing for pharmacy school applications and interviews. Peer-led instructors also saw personal and professional growth, including improvements in presentation skills, communication, time management, and confidence. Considering the success of peer-led teaching not only from the educational standpoint, but also through the positive feedback from the scholars, it would be beneficial to consider implementing this approach across all future SHPEP programs. This may also show benefit on clinical rotations by having a layered learning approach.



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“Knights of the Round Table”: Our Experience with the Knight ScholarRx Program

Prepared by Grace Jeong, Kurt Langomes, Jack Lyman, PharmD Candidates 2025

When we joined the Knight ScholarRx program, we knew it would be an amazing opportunity, but had no idea just how impactful it would be. Between learning new clinical skills, presenting research, and receiving invaluable mentorship, the program has helped shape us into the pharmacists we aspire to become. And yes, it also solidified our relationship with caffeine, but that’s a story for another day.

The Knight ScholarRx program is designed to develop scholarship, service, and leadership—and it absolutely delivered. Over four rotations, we tackled everything from optimizing patient care in the ICU and CCU, formulating medication regimens for AFib and Heart Failure in the cardiology clinic, and helping patients with HIV access life-changing therapies. A unique benefit of the program is its structure, which prioritizes completing the majority of clinical APPE rotations at the start of the P4 year. This approach not only provides a strong foundation of diverse patient care experiences that we can carry forward into subsequent rotations but also gives us multiple clinical experiences to highlight on our CVs and discuss during interviews.

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Above all, what made this program truly special were the connections we were able to build with our preceptors. Our Knight ScholarRx preceptors weren’t just mentors—they became advocates, letter writers, and sometimes even lunch buddies (thank you, Dr. Greer!). These are the people we still turn to for advice, and their support continues to drive us forward.

Being a Knight Scholar wasn’t easy. It pushed us out of our comfort zones and into situations where we were expected to adapt fast, develop independence, and think critically. But looking back, none of us would trade a single moment. This program gave us a network of mentors, the confidence to pursue our goals, and memories we’ll carry forever. So, here’s to scholarship, service, and leadership, and to the incredible people and experiences that made it all possible. And if you’re wondering—yes, we still drink a lot of coffee.

Updates in the Management of COPD: Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2025 Report

Prepared by Bavly Hani, Marian Awad, Nada Daoud, PharmD Candidates of 2025

Background

Chronic obstructive pulmonary disease (COPD) remains a leading cause of morbidity and mortality worldwide. According to the World Health Organization (WHO), COPD was the fourth leading cause of death globally in 2021, responsible for approximately 3.5 million deaths, accounting for 5% of all deaths.¹ In the United States, the Centers for Disease Control and Prevention (CDC) reports that more than 13 million Americans (4.3%) were diagnosed with COPD in 2023.² The economic burden of COPD is substantial. A 2017-2018 Medical Expenditure Panel Survey estimated that COPD-related healthcare costs in the United States totaled \$24 billion annually for adults aged 45 and older, including \$11.9 billion in prescription drug costs, \$6.3 billion in inpatient costs, and \$4.3 billion in outpatient and emergency room visits.³

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) was launched in 1997 to raise awareness and improve the prevention and treatment of COPD.⁴ The organization collaborates with the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), and the WHO to publish annual reports that provide updated clinical guidelines.⁴ The GOLD 2025 Report introduces new pharmacologic updates, including novel vaccination recommendations and two new treatments: ensifentrine and dupilumab.

Vaccination Recommendations

Vaccination remains an essential component of COPD management, helping reduce the incidence of lower respiratory tract infections and exacerbations.⁵ The GOLD 2025 Report highlights additional benefits of the influenza vaccine, particularly its role in reducing the risk of stroke, in addition to preventing COPD exacerbations requiring hospitalization.⁶ The pneumococcal vaccine recommendations have also been updated to include pneumococcal conjugate vaccine (PCV) PCV21 as an alternative option to PCV20.⁷ Furthermore, for respiratory syncytial virus (RSV) prevention, adults aged 75 and older, as well as those aged 60 and older with chronic lung disease, should receive a single dose of an RSV vaccine.⁸ Additionally, all patients with COPD should stay up to date with COVID-19 vaccinations as per CDC recommendations.⁹

Ensifentrine

The GOLD 2025 Report introduces ensifentrine (Ohtuvayre), an inhaled phosphodiesterase (PDE) 3 and 4 inhibitor that provides both bronchodilator and anti-inflammatory effects.¹⁰ Administered as an inhalation suspension via a standard jet nebulizer, ensifentrine is dosed at 3 mg twice daily.¹⁰ The ENHANCE trials, evaluating ensifentrine versus placebo, demonstrated significant improvements in lung function, dyspnea, exacerbation rates, and time to first exacerbation in patients with moderate-to-severe COPD.¹⁰

Dupilumab

Additionally, the GOLD 2025 Report introduces dupilumab (Dupixent) as a new add-on therapy for patients with COPD who have Type 2 inflammation. Dupilumab is a monoclonal antibody that blocks interleukin-4 and interleukin-13 receptors, thereby reducing airway inflammation. It is administered as a 300 mg subcutaneous injection every two weeks. The NOTUS trial, a phase III, double-blind, randomized study, found that in patients with COPD, chronic bronchitis, and blood eosinophil counts ≥ 300 cells/ μ L, dupilumab significantly reduced exacerbation rates and improved lung function compared to placebo.¹¹ Prior to this update, GOLD recommended roflumilast or azithromycin as add-on therapy for patients experiencing continued exacerbations on triple inhaler therapy: long-acting beta-agonist (LABA) + long-acting muscarinic-agonist (LAMA) + inhaled corticosteroid (ICS).⁴ The 2025 GOLD Report now suggests that patients with exacerbations on LABA+LAMA+ICS who have blood eosinophils ≥ 300 cells/ μ L should consider dupilumab as an add-on therapy, based on the NOTUS trial findings.¹¹

Updates in the Management of COPD: Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2025 Report

Prepared by Bavly Hani, Marian Awad, Nada Daoud (continued)

Management of ICS Withdrawal

Another key focus of COPD management in recent years has been the withdrawal of ICS in certain patients. Studies such as the COPE trial and other analyses have examined the consequences of ICS withdrawal, particularly regarding its effects on lung function and exacerbations.¹²⁻¹⁶ Research has shown that while some patients may safely discontinue ICS therapy, withdrawal can lead to disease deterioration and increased exacerbation risk in certain subgroups.¹²⁻¹⁶ The GOLD 2025 Report continues to refine its guidance on ICS withdrawal and patient selection for alternative therapies.

Conclusion

Staying up to date with the latest advancements in COPD management is essential for healthcare professionals, particularly pharmacists, who play a crucial role in optimizing patient care through pharmacologic therapy. The GOLD 2025 Report provides valuable insights into evolving treatment strategies, including new pharmacologic options and updated vaccination recommendations. As research continues to refine best practices, integrating these updates into clinical decision-making will be key to improving outcomes for individuals living with COPD.

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FDA lifts hold on Opell's trial to Support Switch of Tadalafil (Cialis) To OTC

Prepared by: Christian Edelstein, PharmD Candidate of 2025

Edited by: Jimmy Gonzalez, PharmD, MPH, BCPS

On January 21, 2025, the FDA lifted a clinical hold on a planned actual use trial (AUT) to support the partial switch of the erectile dysfunction drug, tadalafil (Cialis), from a prescription to an over-the-counter (OTC) medicine by Opella, Sanofi's Consumer Healthcare business. The FDA originally placed the trial on hold in 2022 due to concerns over its protocol design. This decision marks tadalafil as the first phosphodiesterase 5 (PDE-5) inhibitor to undergo an AUT.

There are two types of Rx-to-OTC switches, the full switch and the partial switch. In a full switch, a sponsor/manufacture requests conversion of the drug covered under the new drug application (NDA) entirely to a nonprescription marketing status; after the full switch, the drug is only available as a nonprescription drug. For example, levocetirizine was fully switched from prescription only to OTC in 2017. In a partial switch, a sponsor requests conversion of some conditions of use, like an indication, to nonprescription marketing status while retaining others within a prescription status. Thus, after a partial switch the drug is available as a prescription drug for certain uses and a nonprescription drug for other uses. For example, lidocaine 4% patches are available OTC while lidocaine 5% patches are prescription only.

Rx-to-OTC switch trials, like the AUT, help determine whether a drug can be safely used without direct healthcare provider oversight. AUTs are a key study in this process because they assess the safety of a prescription drug under conditions resembling non-prescription use. AUTs are designed to observe and evaluate how the consumer performs the functions that were formerly managed by a physician, like making a diagnosis, evaluating contraindicating conditions, how to use the drug, monitoring its effects, and modifying or discontinuing use.

The potential switch of tadalafil to OTC would have large effects for patients. Easier access to erectile dysfunction (ED) treatment would decrease the need or frequency of medical examinations for those hesitant to seek treatment due to stigma. Decreasing provider visits and prescription processing at the pharmacy may also decrease consumer healthcare costs in obtaining this medication. However, it is important to note that increased accessibility underscores the importance of patient education to ensure appropriate use as well as a demonstrated margin of safety from AUTs or similar studies.

The FDA's decision to lift the hold on Opella's trial is a step forward in making ED treatments more accessible to the public and reducing the stigma surrounding the medication. The Rx-to-OTC switch of tadalafil could set a precedent for other medications, allowing patients to become empowered to manage their own health.

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