





Principles for Sound Pharmacy and Therapeutics (P&T) Practices: What's Next?





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Principles for Sound Pharmacy and Therapeutics (P&T) Practices: What's Next?

Welcome to AMCP's Partnership Forum on Principles for Sound Pharmacy and Therapeutics (P&T) Practices: What's Next? Your participation today not only will help us refine P&T practices to meet the needs of an evolving health care system, it also will help us shape the future of our profession.

It's not an overstatement to say that P&T committees represent the very foundation of managed care pharmacy. The informed decisions that stem from a P&T committee's scientific assessment of products allows us to carry out our mission of ensuring all patients have access to needed medications, while also remaining good stewards of limited health care dollars.

Over the years, P&T committees have become a common fixture across the health care spectrum, including in Medicare Part D programs, health insurance marketplace plans, commercial health plans, Medicaid programs, and other public payers. But that doesn't mean we shouldn't step back and take a fresh look at how the P&T process functions to today's world.

It has been nearly 20 years since AMCP and other stakeholders adopted the *Principles for a Sound Formulary System*, and the evolution in health care suggests the need for an update. That's the task before us today. In this Forum we will:

- Identify how P&T committees are evaluating different types of evidence, and what role exists for additional types of information, such as real-world evidence and patient-reported outcomes;
- Identify ways for the P&T committee composition and process to support value-based care;
- · Consider ways to resolve potential conflicts of interest in the P&T process; and
- Provide recommended updates to AMCP's original document, "Principles for a Sound Formulary System"

At the conclusion of this Forum, we will gather consensus recommendations and identify actionable steps that AMCP and other stakeholders may take to promote and advance P&T best practices. The recommendations will be published in a proceedings document later this year in the *Journal of Managed Care & Specialty Pharmacy*.

As with all of our Forums, this one benefits from the wide range of thought-leaders at the table. Once again we are fortunate to tap the expertise of stakeholders representing patients, payers, providers, government, and biopharmaceutical companies. Thank you again for taking time to join us today. I also would like to thank our sponsors who helped make this event possible: Amgen, Genentech, Merck, National Pharmaceutical Council (NPC), Novo Nordisk, Pharmaceutical Research and Manufacturers of America (PhRMA), Precision for Value and Takeda.

I look forward to a very productive event.

Sincerely,

Susan A. Cantrell, RPh, CAE

AMCP CEO





Jeff Lee, PharmD, FCCP
Associate Dean for Academic Affairs
Lipscomb University College of Pharmacy

Jeff Lee is Associate Dean for Academic Affairs at Lipscomb University College of Pharmacy in Nashville, Tennessee.

He is past-Chair of the *Format* Executive Committee for AMCP where he led the development of the AMCP *Format for Formulary Submissions*, v.4.0. Prior to this role, he held senior-level positions in health economics and outcomes research in the industry setting.



THUR, MAR 28

7:00 am - 8:00 am

8:00 am – 8:30 am	Welcome and Introductions
8:30 am – 9:15 am	Presentation An Overview of Trends in Use of Evidence for Payer Coverage Decisions
9:15 am – 10:00 am	Panel Guideline and Evidence Assessments for P&T Committees Objective: Panelists will discuss how P&T committees are evaluating external and new sources of information for coverage and formulary decisions.
10:00 am – 10:15 am	Break

10:15 am - 11:30 am Breakout Session #1

Breakfast

Best Practices and Recommendations for Including New Evidence and Patient Perspectives

Objective: Participants will review the document, *Principles for a Sound Formulary System* and provide recommended updates to P&T practices for:

- · Inclusion of new types of evidence
- Inclusion of patient/consumer perspectives

11:30 am – 12:45 pm Networking Lunch



THUR, MAR 28

Panel

Reflections on the 2013 HHS OIG Report, "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions"

Objective: Panelists will discuss the impact of the OIG Report on Conflict of Interest, what we've learned since 2013 and what additional needs there are to address potential conflicts of interest in the P&T process.

Breakout Session #2

Best Practices and Recommendations to Ensure Ethical P&T Practices

Objective: Participants will review the document, *Principles for a Sound Formulary System* and provide recommended updates to P&T practices for:

- · Managing conflicts of interest
- Supporting transparency in the P&T process

Break

Full Group Discussion

Next Steps for AMCP and Stakeholders

Participants identify actionable steps that AMCP and other stakeholders may take to promote and advance P&T best practices and specific Forum recommendations.

Forum Summary and Conclusions

12:45 pm - 1:30 pm

1:30 pm – 2:45 pm

2:45 pm - 3:00 pm

3:00 pm - 3:30 pm

3:30 pm - 3:45 pm



Danial Baker, PharmD, FASHP, FASCP

Director, Drug Information Center Washington State University College of Pharmacy and Pharmaceutical Sciences

Danial Baker is a professor of Pharmacotherapy at Washington State University's College of Pharmacy and Pharmaceutical Sciences and director of its Drug Information Center since 1983. Current consulting positions: Express Scripts Specialty Drug Advisory Board; The Formulary Monograph Service; and United States Pharmacopeia's Healthcare Quality and Safety Expert Committee, Medicare Model Guidelines Committee, and USP Drug Classification Expert Panel. Previous experience includes: Pharmacy & Therapeutics Committee for Medco Health Solutions, Washington State's Drug Utilization and Education Council, IHC Health Plans, and Whatcom Medical Bureau.



Vincent Baldwin

Senior Clinical Program Manager Cigna-Healthspring Corporation

Vincent Baldwin is a Senior Clinical Program Manager with Cigna-HealthSpring where he leads the team responsible for formulary strategy and development for all Medicare products. His career in managed care began at EmblemHeath, a regional plan based in New York. His past responsibilities have included clinical oversight of coverage determinations, MTM program development, drug monograph creation, Part B drug management, clinical program oversight and formulary management and operations. He received his Doctorate of Pharmacy from St. John's University and is a Board Certified Pharmacotherapy Specialist.



Eric Cannon, PharmD, FAMCP

Vice President of Pharmacy Benefit Services SelectHealth

Eric Cannon has a diverse range of pharmacy experience including hospital, retail, long term care and home health areas. He makes frequent presentations to employers, brokers and healthcare providers on pharmaceutical trends and pharmaceutical management techniques. He also served on the Institute of Medicine of the National Academies Committee, Preventing Medication Errors. Currently, he is the Vice President of Pharmacy Benefit Services for SelectHealth, a subsidiary of Intermountain Healthcare. SelectHealth is part of one of the nation's top 100 integrated health systems. Intermountain's not-for-profit system includes 22 hospitals, physicians, clinics and services and health insurance plans from SelectHealth.





James Chambers, MPharm, MSc, PhD

Associate Professor Tufts Medical Center

James Chambers is an investigator at the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center, and an Associate Professor of Medicine at Tufts University School of Medicine. His research is focused on examining the factors that influence payer coverage of medical technology and quantifying pharmaceutical innovation. He graduated from Queens University in Belfast with an MPharm degree and previously worked as a pharmacist in the UK and Ireland. James also obtained an MSc from the University of York and PhD from Brunel University, both in Health Economics.



Ryan Cox, BS Pharm, RPh, MBA Vice President, Access Experience Team Precision for Value

Ryan Cox has over 25 years of pharmacy experience, including nearly 20 years of experience in managed care. Prior to coming to Precision For Value, he was Director of Specialty Pharmacy at Highmark Blue Cross Blue Shield, where he was responsible for overall specialty drug strategy. Before that, he was Highmark's Director of Clinical Pharmacy Strategies, overseeing the development and execution of strategy for Highmark's formulary management and utilization management programs. He also worked closely with pharmaceutical manufacturers on establishing benchmarks for risk-based contracts. Previous to Highmark, he held senior positions at Humana, CareSource (Dayton, Ohio), and Anthem (WellPoint).



Lee Ding, PharmDAssociate Director, Managed Care Liaison
Genentech

Lee Ding is an Associate Director of Managed Care Liaison team at Genentech, US Medical Affairs. In this position, his team responsibilities include providing clinical information for the Genentech portfolio to commercial and public payers, PBMs, SPs and IDNs to optimize patient access. Prior to Genentech, he was the Director of Pharmacy at Wellmark Blue Cross Blue Shield and Health Alliance Medical Plan. At the health plans, he managed pharmacy and DME benefits, chaired the P&T committee, renegotiated PBM contract and pharmacy network reimbursement, pharmaceutical contracting, led physician's academic detailing team and provided employer's benefit consultation.



Julie DiTucci-Reiter, PharmD
Clinical Policy and Programs
Steward Health Choice

Julie DiTucci-Reiter joined Steward
Health Care in April of 2017. Her
responsibilities include drug policy
development, clinical management
strategies, PBM oversight, and other
clinical programs with emphasis on
high-cost specialty drugs. Julie has
more than 20 years of experience
in managed care clinical roles with
participation on several P&T committees
involving Medicaid, Medicare, and
Commercial lines of business. Prior to
joining Steward Health Care, she held
various positions at Molina Healthcare
Inc. and Presbyterian Health Plan.



Jennifer Graff, PharmD
Vice President, Comparative

Vice President, Comparative
Effectiveness Research
National Pharmaceutical Council

Jennifer Graff leads research and policy initiatives at NPC to advance the use of evidence to inform health care decision-making. Her areas of focus include research and education to support increased access to and use of high-quality data, development and adoption of good research methods, and policies to enable the exchange of truthful and non-misleading information to support stakeholder decision-making. Prior to joining NPC in 2009, she led strategic health economic and outcomes research activities at MedImmune and Pfizer Pharmaceuticals. She has authored over 20 peer-reviewed articles and presents frequently on policy issues affecting the biopharmaceutical industry.



Estay Greene, PharmD, MBAVice President, Pharmacy Services
Blue Cross Blue Shield of North Carolina

Estay Greene is the Vice President of Pharmacy Services for Blue Cross NC. He is responsible for the management of the prescription drug program and benefits. This includes planning, coordinating and directing the development and implementation of new and existing prescription drug benefits and pharmacy management programs, initiatives and functions for all lines of business. He provides leadership and support for all aspects of pharmacy management both strategically and on a day-to-day basis. In addition; he is the plan representative for various committees with Prime Therapeutics (the plans' Pharmacy Benefit Manager) and the Blue Cross Blue Shield Association.





Conor Hanrahan, PharmD, BCPS, CPHIMS, CPPS

Medication Policy, Outcomes, and Stewardship Director Intermountain Healthcare

Conor Hanrahan practiced as a drug information specialist for several years and now serves as the Director of Medication Policy for Intermountain Healthcare where he coordinates the activities of the Drug Information Center, manages the system-wide formulary, leads the outcomes management program, and facilitates policy and procedure development for Pharmacy Services. He completed a PGY1 Pharmacy Practice Residency followed by a PGY2 Drug Information Specialty Residency at the Medical University of South Carolina and has also completed postgraduate training in conflict mediation and dispute resolution. He is in the process of obtaining a Masters in Comparative Effectiveness Research.



George Jaresko

Director, US Medical Value and Access Communications Amgen, Inc.

George Jaresko currently leads US
Medical Value and Access at Amgen
where he has been for past two years.
His prior ten years of managed care
experience has included negotiation
and management of drug rebate and
pharmacy network contracts, drug
pricing/reimbursement (e.g. ASP+,
MAC), and coordination and creation of
P&T Committee materials. He has also
been a full-time academic for fifteen
years and has past experience in critical
care and infectious diseases therapy.



Stephen Jung, PharmD, BCPS

Principal Pharmacist Blue Shield of California

Stephen Jung currently develops formulary and utilization management recommendations to the P&T committee at Blue Shield of California. He is a graduate of the University of Southern California School of Pharmacy and has completed residencies at the Long Beach VA and Kaiser Permanente Drug Information Services. In previous roles, he has also supported the P&T committees at OptumRx and MedImpact.





Jeremy Lee, PharmD, BCPS
Director of Drug Information
MedImpact Healthcare Systems

Jeremy Lee has over 20 year of experience working in health systems and managed care. He has managed inpatient pharmacies, infusion centers, primary care clinics, and retail and specialty pharmacies. He has also negotiated risk-based agreements with health plans for specialty pharmacy services. He has presided over more than 100 P&T committee meetings over the course of his career. Currently, he is serving as the Director of Drug Information at MedImpact Healthcare Systems. In this role, he is responsible for conducting the national P&T committee meetings, as well as for providing drug pipeline intelligence and analysis to client health plans.



Mandy Leonard, PharmD, BCPS
System Director, Drug Use Policy and
Formulary Management
Cleveland Clinic

For the past 20 years, Mandy Leonard has been in charge of the Pharmacy Drug Information Service at Cleveland Clinic. Additionally, she is a Board-Certified Pharmacotherapy Specialist. She has adjunct faculty appointments at the Colleges of Pharmacy at The Ohio State University, University of Toledo, Ohio Northern University, and NEOMED. She is an Assistant Professor at Cleveland Clinic Lerner College of Medicine and is the Pharmacology Thread Director and is responsible for coordinating all Cleveland Clinic pharmacy residency programs. Finally, she is responsible for drug shortages, drug recalls, REMS programs and formulary management for the Cleveland Clinic Health-System.



Craig Mattson, MS, MBA, RPh
Former Senior Director,
Formulary Development
Prime Therapeutics LLC

Craig Mattson recently retired from Prime Therapeutics, where he was Senior Director of Formulary Development for 14 years. He led the clinical evaluation of new drugs, and the critical positioning of all drugs within their therapeutic class or indication. He presented these results to the Prime Therapeutics Pharmacy and Therapeutics Committee and worked interdepartmentally to assist in developing the clinical vision, strategy and management of drug therapy within the pharmacy and medical benefit. He also worked nearly 20 years in hospital pharmacy at Tufts Medical Center in Boston and the Mayo Clinic in Rochester.





Lynn Nishida, RPh, FAMCP
Vice President of Pharmacy Programs
WithMe Health

Lynn Nishida is the Vice President of Pharmacy Programs at WithMe Health, a new technology company that provides medication guidance solutions for payers. In her role, she leads the development of programs across the prescription and medical benefit spectrum to ensure service offerings are based on nationally-recognized best practices for evidence-based medication review. Her experience spans over 30 years of working and consulting in the healthcare industry for health plans and PBMs. She has provided thought leadership at the national level for organizations, such as AHRQ and BCBSA. Her professional contributions have earned her recognition as a Fellow of AMCP.



Vincent Pacileo
Director, Federal Affairs
Arthritis Foundation

Vincent Pacileo is the Director of Federal Affairs for the Arthritis Foundation, where he leads the federal legislative and regulatory affairs programs. He joined the Foundation from the American Psychiatric Association (APA), the oldest medical association in the country. Prior to APA, he worked at West Health on policy and analytic projects to advance the organization's mission to lower the cost of health care. Previously, he provided policy and research support to the government affairs teams at Vertex Pharmaceuticals. He earned his Master of Public Policy degree from The George Washington University and Bachelor's degree from The University of Connecticut.



Swati Patel, PharmD, MBA Senior Manager Deloitte Consulting

Swati Patel leads the Provider Pharmacy practice at Deloitte, which focuses on redesigning and improving performance of inpatient, outpatient, and post-acute pharmacy operations. Provider clients include cancer centers, academic medical centers and large multi-hospital health systems. She has over 15 years of experience leveraging a pharmacy background to assist over 80 clients with sustainable margin and cost transformational engagements: drug expense management, supply chain optimization and strategic outpatient services. She also uses her expertise to assist pharmaceutical manufacturers, PBMs, specialty/drug distributors and retail pharmacy chains. Her full range of pharmacy capabilities allows her to provide advisory to the entire Pharmacy Value Chain.





Anne Pugh, PharmD, FCSHP
Formulary Management
Kaiser Permanente

Anne Pugh began her work in Drug Information Services at Kaiser Permanente in 2001, overseeing formulary management and the forecasting process in the areas of Ophthalmology, Nephrology, and Urology. Currently, she manages the National Medicare Part D Formulary and Southern California Permanente Medical Group Commercial Formularies working closely with the Formulary team, Drug Use Management and Pharmacy Benefits departments, along with health care leaders across Kaiser Permanente's eight regions. In 2017, she co-developed the Kaiser Permanente Emerging Therapeutics Strategy Program, an evidence-based program that offers a unified approach in the provision and management of emerging therapies.



Alynn Purdum, PharmD
Chief Compliance Officer
EnvisionRxOptions

Alynn Purdum has held health system and integrated managed care management roles for over fifteen years. She started her career as Chief Pharmacist with Kaiser Foundation Health Plan and has worked at EnvisionRxOptions for two years. Her responsibilities include complete operational direction of the Compliance and Ethics Department, including Audit Services and Risk Management. She holds a Bachelor of Science in Pharmacy from The Ohio State University and a Doctor of Pharmacy from the University of Florida.



Eileen Sakai, PharmD, MSHI
Director, Drug Information Services and
Outcomes Research, National Pharmacy
Programs and Services
Kaiser Permanente

Eileen Sakai has a diverse background, including Hospital Pharmacy, Clinical Consulting, Group Purchasing Organization (GPO) Consulting, Managed Care/Pharmacy Benefits Management (PBM) Leadership, and healthcare informatics. She leads multidisciplinary groups by setting clearly defined, realistic goal, scope, direction, and guides the team to work collaboratively towards the common goal. At Kaiser Permanente, she promotes and supports the safe, appropriate, and cost-effective use of pharmaceuticals throughout the Kaiser Permanente program improving national pharmaceutical utilization/costs, while achieving highest possible therapeutic outcomes and quality.





Elizabeth Sampsel, PharmD, MBA, BCPS

Vice President, Payer Strategy and Relations Dymaxium

Elizabeth Sampsel is currently responsible for payer strategy and growth planning, evidence and value content collaboration, and payer engagement and relations. With over 28 years of pharmacy experience, she has worked in IDN/health system and managed care settings, including at Sharp Healthcare System, MedImpact, and San Francisco Health Plan. She also worked for AMCP and represented managed care pharmacy on key ACA issues. She has been involved with the Format Executive Committee and a judge for the AMCP Foundation National P&T Competition since 2011.



Christine Strahl, PharmD, MBA
Director, Clinical Services
HealthPartners

Christine Strahl guides the clinical pharmacy services provided to insured members of HealthPartners, an integrated health care delivery and financing organization. This includes management of the formulary, rebate and specialty pharmacy programs with a single goal of improving the Triple Aim for members using drugs reimbursed on both medical and pharmacy benefits. Prior to joining HealthPartners in 2010, she led product development and account management teams at Prime Therapeutics. She is a graduate of the University of Minnesota College of Pharmacy and The Carlson School of Management and is a registered pharmacist in Minnesota and Wisconsin.



Iris Tam, PharmD, FAMCP
Director, Outcomes Research &
Quality of Care
Achaogen

Iris Tam has over 25 years of experience in health care, including hospital pharmacy, managed care, and the biopharmaceutical industry. Currently as Director, Outcomes Research and Quality of Care, she leads clinical and health economic strategies and tactics to support the value of Achaogen's product portfolio for patient access. Previously, she held similar roles at Otonomy and Genentech. Since 2008, she has been active on the AMCP Format Executive Committee which oversees the AMCP Format for Formulary Submission, and currently serves as the Committee's Chair.



Hai Tran, PharmD, BCPS
Associate Director, Drug Use Policy
Cedars-Sinai Medical Center

Hai Tran is the Associate Director for the Drug Use Policy at Cedars-Sinai Medical Center, an 863 bed acute tertiary care, teaching institution in Los Angeles. She oversees the Antimicrobial Stewardship Program, formulary management and leads the hospital pharmacy clinical program. She is also responsible for developing and implementing cost saving strategies in collaboration with Medical and Nursing Leadership.



Robin Turpin, PhD
Value Evidence and Health Outcomes
Scientific Lead
Takeda Pharmaceuticals, USA

Robin Turpin spent the first half of her career in health services and outcomes research for hospital and health care systems, including a period with the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to lead the reliability and validity testing of performance metrics. Her industry experience includes HEOR positions with Merck, Baxter, and Takeda, With 30 years of experience in health care evaluation and outcomes research, she has coauthored more than 100 books. book chapters, and journal articles on health economics, health behavior, and population health management.



Joe Vandigo, PhD
Director, Policy and Research
Pharmaceutical Research and
Manufacturers of America (PhRMA)

Joe Vandigo is a health services researcher with a background in patient and stakeholder engagement and claims database analysis. As a Director in the Policy and Research department at Pharmaceutical Research and Manufacturers of America (PhRMA), he manages a research portfolio focused on demonstrating the value of medicines. His research areas include innovative contracting arrangements, the non-retail pharmaceutical value chain, solutions to address cancer financial hardship, and biopharmaceutical manufacturer communication with payers and health professionals.





Laurie Wesolowicz, PharmD, FAMCP

Vice President, Clinical Programs and Services Archimedes/EpiphanyRx

Laurie Wesolowicz is serving as clinical leader on formulary, specialty drug and utilization management strategies at Archimedes/EpiphanyRx. Most recently, she served as clinical director for a regional Blues plan for ten years. Laurie is an active member of the Academy of the Managed Care Pharmacy and was recognized with fellow status. She has served as Chair of the Professional Practice Committee and has presented nationally on clinical drug evaluation and program development. Laurie holds an appointment as Adjunct Clinical Assistant Professor at the University of Michigan College of Pharmacy.



Adam D. Wilson, PharmD, BCGP Senior Director, Formulary Management MagellanRx Management

Adam Wilson is Senior Director, Formulary Management at MagellanRx (MRx). Prior to the business acquisition of Veridicus Health (VRx) by MRx, he was a Formulary manager at VRx. MRx is a full service PBM that incorporates PBM functions, P&T/formulary management, Medication Therapy Management (MTM)/Integrated Care Management (ICM), and government functions for commercial, Medicare Part D, and Medicaid lines of business across employer groups and health plans. At MRx, he directs formulary management (commercial, Medicare, and Managed Medicaid), formulary benefit design, analyzes drug rebates, etc. He participates in the P&T process and is a member of the MRx Value Assessment Committee. He also helps support and manage the residency programs previously with VRx and currently with MRx.

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THANK YOU

To our distinguished participants and guests.

The Academy of Managed Care Pharmacy
looks forward to holding more partnership forums
focused on issues of greatest importance to our 8,000 members,
the more than 270 million Americans covered by the pharmacy benefit,
and other health care stakeholders.

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