AMCP | PARTNERSHIP FORUMS

Designing Benefits and Payment Models for Innovative High-Investment Medications

JULY 24–25, 2018 | BALTIMORE MARRIOTT INNER HARBOR AT CAMDEN YARDS
BALTIMORE, MD

HOSTED BY THE ACADEMY OF MANAGED CARE PHARMACY IN PARTNERSHIP WITH

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WELCOME

Designing Benefits and Payment Models for Innovative High-Investment Medications

Welcome to AMCP's Partnership Forum, **Designing Benefits and Payment Models for Innovative, High-Investment Medications**. Your presence here will help answer a crucial question of our time: How can health care payers design models to help patients afford the many innovative treatments coming to market each year?

The pace of biopharmaceutical innovation is rapidly bringing to reality the promise of cures or "near-cures" to many long-intractable diseases. While this is great news for society, the challenge for payers is how to ensure broad coverage and patient acess for these products in an era of constrained budgets. The challenge is compounded by the dynamic nature of our insurance system, in which patients may switch among carriers before the full effects of a therapy are realized.

This forum will get to the heart of today's conundrum by exploring new, non-traditional models for designing benefits and payment. Developing such models is imperative if we hope to maintain our health care system's financial viability, and more importantly, maintain patient access to the very best health care possible.

Over the next day and a half, we will examine the question of how to manage high-investment medications from many different angles. We will ask: What's changing and what can stay the same? What methods and best practices currently are under consideration?; What are the strengths and potential weaknesses of these methods?; How will payment systems have to adapt to new models?

At the end of this Forum, we will produce:

- A user-friendly overview of current financial payment models, and outline specific challenges inherent in each model when it comes to high-investment therapies.
- A priority list of potential solutions, including short-term work-arounds and long-term solutions, to help spread both the risk and cost of drugs for patients and risk-bearing entities.
- A priority list of legal, regulatory and operational hurdles that must be considered in the development of potential solutions.

This is just a taste of the activity that will result from our work this week. I would like to extend a warm thank you to our sponsors who made this event possible: **AbbVie, Alnylam, Amgen, AstraZeneca, Celgene, Gilead, National Pharmaceutical Council, Pharmaceutical Research and Manufacturers of America, Takeda and Xcenda**. I look forward to a very interesting and productive Forum.

Sincerely,

Susan A. Cantrell, RPh, CAE
AMCP CEO

MODERATOR

Susan C. Winckler, RPh, Esq.

President
Leavitt Partners Consulting

As President of Leavitt Partners Consulting and Chief Risk Management Officer of Leavitt Partners, a national health-care consulting firm, Susan Winckler advises corporate executives on policy and business matters, such as Medicare/Medicaid, FDA practices and alternative payment models. As CEO of the Food & Drug Law Institute from 2009–2014, she provided attorneys, regulators, industry leaders and consumers with journals, meetings and a neutral forum for addressing domestic and global issues. As FDA Chief of Staff from 2007–2009, she managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, Ms. Winckler served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations and allied groups. Over the prior 9 years, she held several policy and practice-related jobs.

She earned a B.S. from the University of Iowa College of Pharmacy and her J.D. magna cum laude from Georgetown University Law Center. She is an APhA Fellow.

AGENDA

TUES, JULY 24

2:00 pm – 2:30 pm — **Welcome and Introductions**

2:30 pm – 3:00 pm — **Presentation**

Setting the Stage — Challenges Facing Managed Care in Handling High-Investment Medications

Objective: To set the foundation for the forum's discussions. Understanding the challenges facing managed care stakeholders in meeting the demands of high-investment medications that are currently on the market and moving through the FDA pipeline.

3:00 pm – 3:45 pm — **Panel Discussion**

Rethinking Benefit Designs for Chronic versus Curative High-Investment Medications

Objective: Panel members will share their unique perspectives on how managed care stakeholders view high-investment medications for chronic diseases versus those that are curative in nature. Participants will discuss the challenges of the two modalities which sets the stage for further breakout discussions throughout the next day and half.

3:45 pm – 4:00 pm — **Break**

4:00 pm – 5:30 pm — **Breakout Session #1**

Innovative Payment Strategies for High-Investment Medications

Objective: Explore ways to implement possible alternative reimbursement contracting models that will be necessary to gain optimal coverage for these high-investment medications. Forum participants will identify:

- Traditional and non-traditional contracting solutions for high-investment medications for both curative and chronic conditions
- How to appropriately collaborate with providers who may have their own policies and contracts involving high-investment medications
- Ways in which to work with CMS and state Medicaid officials to be innovative and accommodating in their acceptance and coverage of these high-cost medications
- Alternative reimbursement models for high-investment medications that could be considered and solutions to overcome obstacles (i.e. annuity based, amortization, etc.)

5:30 pm – 5:45 pm — **Recap Day 1 with Reception Immediately Following**

WED, JULY 25

8:00 am – 8:15 am — **Welcome**

8:15 am – 9:00 am — **Panel**

Reflections and Considerations When Designing Benefits and Payment Models for High-Investment Medications

Objective: Panel members will reflect on the Day 1 Breakout Session, *Innovative Payment Strategies for High-Investment Medications*. Panelists will additionally share their experiences in dealing with high-investment medications through non-traditional contracting models. New dynamics must be considered

WED, JULY 25 [CONT'D]

when contracting, reimbursing and paying for such medications. Each participant will answer moderated questions on their successes and lessons learned when accounting for both high-investment curative and chronic medications.

Presentation — 9:00 am – 9:30 am

Overview of Traditional Benefit Designs, Value Assessment and High-Investment Medications

Breakout Session #2 — 9:30 am – 10:45 am

Rethinking Benefit Designs for High-Investment Medications

Objective: Gain insights and identify solutions for stakeholders within managed care to design appropriate benefits for high-investment medications that may be curative or chronic in nature. Forum participants will identify:

- What new and different benefit designs may need to be considered by payers, employers, and CMS to ensure adequate benefits are provided to patients that need these medications
- How to define value for these high-investment medications
- Ways to identify appropriate patients for these medications
- Patient engagement activities to address coverage and cost concerns for high-investment medications

Break — 10:45 am – 11:00 am

Breakout Session #3 — 11:00 am – 12:15 pm

Tackling Other Critical Issues Impacting Benefit Design and Payment/Reimbursement of High-Investment Medications

Objective: To address potential legal, regulatory and policy barriers that may impede implementation of innovative benefit designs for reimbursing high-investment medications. Forum participants will identify:

- Any *legal* barriers to the adoption/acceptance of new benefit designs for high-investment medications in managed care settings, and what opportunities exist to address these barriers
- Any *regulatory* barriers to the adoption/acceptance of these benefit designs and what opportunities exist to address these barriers
- Ways to advocate via collaboration with other stakeholders (i.e. AMCP, advocacy, etc.)
- How to affect payer internal policy restrictions

Networking Lunch — 12:15 pm – 1:00 pm

Breakout Session #4 — 1:00 pm – 2:15 pm

Best-Case Ideas to Support the Use of High-Investment Medications in Managed Care

Objective: Participants provide "best case" solutions for managed care stakeholders to overcome potential challenges with managing high-investment medications. Secondarily, participants will determine which solutions could be supported by AMCP's involvement. The forum participants will deliver achievable solutions for managed care stakeholders.

Recap Day 2 and Adjournment — 2:15 pm – 2:30 pm

PARTICIPANTS

Jane Barlow, MD, MPH, MBA

CEO
Jane Barlow & Associates

Dr. Jane Barlow is a clinical and strategic executive with over 25 years of healthcare leadership experience. She currently serves as Senior Advisor to the MIT Center for Biomedical Innovation project on Financing of Curative Therapies and is Chief Clinical Officer of Real Endpoints. Dr. Barlow focuses on evaluating the economic impact and value of pharmaceuticals and diagnostics to aid in defining access and coverage strategies. Dr. Barlow previously held senior leadership positions at CVS Health, Medco Health Solutions and IBM.

Cynthia Bens

Senior Vice President, Public Policy
Personalized Medicine Coalition

Cynthia Bens leads the Personalized Medicine Coalition's (PMC's) policy development and government relations efforts and serves as its primary liaison with the U.S. Congress and federal regulators. She is responsible for implementing research, regulatory and reimbursement policy strategies that promote the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system. Before joining PMC, Bens was the Vice President of Public Policy at the Alliance for Aging Research.

Tim Brent

Senior Director, Business Development
National Hemophilia Foundation

Tim Brent operates within the External Affairs Division of the National Hemophilia Foundation (NHF) where he is responsible for special project contracting and engagement as well as part of a team representing the foundation with employer groups, third party administrators, and employer benefits consultants. Tim has held previous positions as National Accounts Director for a national biologics distributor, Executive Director of a hemophilia treatment center, and responsible for overseeing operations of two 340B pharmacy programs.

PARTICIPANTS

Michael Ciarametaro, MBA

Vice President of Research
National Pharmaceutical Council

Michael Ciarametaro focuses on public policy issues with potential impact to the biopharmaceutical industry. His work on value, pricing, health spending and budget management, and access has been published in *American Journal of Managed Care*, *Value in Health*, and other publications. At National Pharmaceutical Council (NPC), he plays a key role in developing and delivering NPC's portfolio of health policy research projects. Mr. Ciarametaro has 19 years of health care industry experience with both pharmaceutical manufacturers and payers.

Collin Conway, PharmD

Manager, Pharmacy Product Development & Business Analysis
Kaiser Permanente Washington

Michelle Drozd, ScM

Deputy Vice President, Policy and Research
Pharmaceutical Research and Manufacturers of America (PhRMA)

Michelle Drozd works on a range of cross-cutting issues, including value-based contracting, Medicare Part B, transparency, and the pharmaceutical supply chain. Prior to joining PhRMA, she worked in quality improvement and business planning at Partners Healthcare, an integrated delivery system in Boston. She also worked at RTI International, implementing demonstration projects for the Centers for Medicare & Medicaid Services.

PARTICIPANTS

Jeremy Fredell, PharmD, BCPS

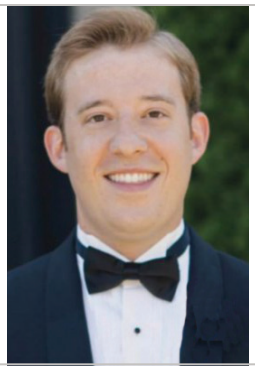
Director, Trend Solutions
Express Scripts

Jeremy Fredell is a pharmacist overseeing commercial trend strategies for Express Scripts. Jeremy is responsible for the commercial utilization management offering that Express Scripts provides to tens of millions of its members. With over 15 years in pharmacy benefit management, Jeremy has also worked on electronic prior authorization, improving patient medication adherence, and developing population-specific concurrent drug utilization review programs.

Stephen George, PharmD, MS

Senior Consultant
Milliman

Stephen George serves as a senior consultant assisting clients in various areas including health care plan pharmacy operations, management of physician administered and specialty drugs, integration of pharmacy and medical outcomes analysis, and developing ROI evaluations on medical interventions. Stephen has experience in a variety of patient care and management settings — managed care, hospital, care management, and clinical trials. He also has experience with health policy analysis, pharmacoeconomics and outcomes research, auditing PBM/specialty pharmacy contracts, 340B pricing models, implementing disease management models, drug/device pricing, assessing pharmacy MTM programs, and developing "best in class" clinical applications.



Matthew Harman, PharmD, MPH

Director of Pharmacy
Employers Health Coalition

As the Director of Pharmacy at Employers Health, Matthew Harman provides clinical expertise to support the coalition's member organizations focusing on overall plan performance, clinical recommendations, analytic consultations and customer engagement and retention. Additionally, he is responsible for managing and executing the Employers Health pharmacy residency and flu immunization programs.

PARTICIPANTS

Barbara Henry, RPh

Lead Clinical Pharmacy Specialist
Harvard Pilgrim Health Plan

Barbara Henry has nearly thirty years of managed care experience and is currently a Lead Pharmacy Specialist at Harvard Pilgrim Health Care serving members in Massachusetts, Maine, New Hampshire and Connecticut. In this role her responsibilities focus on the development and management of multiple formularies, including drug tier placement and utilization management programs. She also provides leadership in the creation and execution of pharmacy strategy including comprehensive drug cost management initiatives and monitoring medical and pharmacy drug trends. She also evaluates the clinical and operational components of creative contracts.

Paul Jeffrey, PharmD

Director of Pharmacy, Office of Clinical Affairs / Associate Professor
MassHealth / University of Massachusetts Medical School

Paul Jeffrey is Director of Pharmacy in the Office of Clinical Affairs for Mass-Health (Massachusetts Medicaid) and is responsible for the state's pharmacy benefit for approximately 1 million of MassHealth's 1.85 million members. He is also Associate Professor of Family Medicine and Community Health at the University of Massachusetts Medical School. He currently serves on the Board of Directors of the Academy of Managed Care Pharmacy.

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Laura Koontz, PhD

Personalized Medicine Staff
Food and Drug Administration

Laura Koontz is a member of the Personalized Medicine Staff at the Food and Drug Administration in the Center for Devices and Radiological Health. Prior to joining the FDA, she was the Director of Policy for the Ovarian Cancer National Alliance, where she oversaw Congressional and regulatory policy. Prior to that, she was an ASHG-NHGRI Genetics and Public Policy Fellow from 2012–2013 and worked in the House of Representatives.

PARTICIPANTS

Johanna Liu, PharmD, MBA

Director of Quality & Pharmacy
Santa Clara Family Health Plan

Johanna Liu oversees the quality program and pharmacy benefit at Santa Clara Family Health Plan in San Jose, CA. She specializes in managed care, quality and health care strategy for health systems and health plans. She is a Fellow of the California Health Care Foundation Leadership Program. Her interest in pharmacy advocacy has led her to serve on the CA Department of Health Care Services Global Medi-Cal Drug Use Review Board, and the Board of Trustees for California Pharmacists Association.

Lisa Logan

Director, Americas Compensation & Benefits
InterContinental Hotels Group

Lisa Logan provides strategic leadership in the design and delivery of all compensation and benefit programs at IHG, including merit and bonus processes, relocation and health & welfare plans serving over 14,000 colleagues. She joined IHG in 1998 and is now Director of Compensation & Benefits after working as Senior Benefits Consultant, Benefits Manager and Benefits Director. Before joining IHG, she worked for nearly 15 years at Georgia-Pacific Corporation in various benefits roles. She was an American Cancer Society IMPACT Steering Committee member has been a guest speaker at various conferences.

Genia Long

Senior Advisor
Analysis Group, Inc.

Genia Long is a Senior Advisor at Analysis Group and focuses on the economics of innovation in the life sciences, particularly policy and competitive developments affecting the pharmaceutical, biotech and medical device industries. Her analysis of trends in pharmaceutical competition, the impact of biosimilar entry, the value of innovation and its impact on human health, and other topics has been published in *Health Affairs, the Journal of Health Politics, Policy and Law, the Journal of Medical Economics, Nature Reviews Drug Discovery, the American Journal of Managed Care, the Encyclopedia of Health Economics*, and the *Seton Hall Law Journal.*

PARTICIPANTS

Sunil Majethia, PharmD

Associate Director, Medical Sciences
Gilead Sciences

Sunil Majethia currently serves as an Associate Director, Medical Sciences, Managed Care and Government Accounts. He began his professional career working in retail pharmacy. Since then he has gained experience working in Acute Care, Managed Care, Ambulatory Care, Home Infusion and Skilled Nursing Facilities in the Washington, DC, and Baltimore Areas. He began his industry experience with Wyeth and has worked for Biogen, Centocor and Abbott/Abbvie with a focus in Managed Care.

Donna Mancuso, MS, RN

Director, Payer & Employer Outreach Programs
National Comprehensive Cancer Network (NCCN)

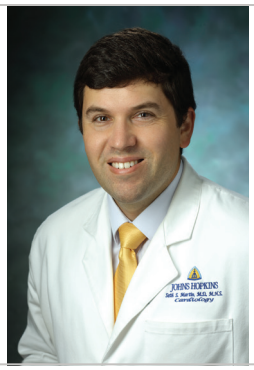
Donna Mancuso has leadership and consulting experience across key healthcare sectors. Her expertise is in health systems/care delivery, informatics, managed care, reimbursement, research & analytics, health policy, and biotech. As NCCN's point of contact for payer outreach, Donna is responsible for program-related relationships with payers, payer-technology vendors, PBMs/SPMs, and employers, and is accountable for payer and payer-HIT licensing of NCCN Guidelines and Content.

Bill Martin

Chief Commercial Officer
Accredo, an Express Scripts Company

Bill Martin is responsible for guiding the development and growth of Accredo's overall specialty business with payers, pharmaceutical manufacturers, and distribution partners. He leads a team that is heavily focused on growth through strategic initiatives, innovative clinical programs, and market development efforts.

PARTICIPANTS



Seth Martin, MD, MHS, FACC, FAHA, FASPC

Assistant Professor of Medicine
Johns Hopkins University
School of Medicine

Dr. Martin is a preventive cardiologist at Johns Hopkins Hospital. He directs the Advanced Dyslipidemia Clinic and Mobile Health Program for the Ciccarone Center for the Prevention of Cardiovascular Disease. Dr. Martin also serves as an Associate Faculty member in the Welch Center for Prevention, Epidemiology, and Clinical Research, and as an Affiliate Faculty member in the Malone Center for Engineering in Healthcare. Dr. Martin has published more than 200 articles in leading cardiology and medicine journals. He serves as Associate Editor for the ACC.org Dyslipidemia Clinical Community and as an Associate Editor for the *Journal of Clinical Lipidology*.

Jeff Myers, MBA

Chief Executive Officer
Medicaid Health Plans of America (MHPA)

Jeff Myers is the President and CEO of Medicaid Health Plans of America (MHPA), the trade association representing at risk managed Medicaid plans. MHPA's members are large, multistate commercial insurance companies that have Medicaid lines of business; multistate insurers that focus primarily on Medicaid and Blue Cross/ Blue Shield plans; and single state nonprofits that provide full risk contracts to manage state Medicaid populations. Prior to MHPA, Jeff had extensive experience in the provider side of health care with his work at the American Health Care Association, which represents post-acute institutional providers.

Annette Powers, PharmD, MBA

Executive Director, Health Economics and Outcomes Research
Celgene

Annette Powers is Executive Director, Health Economics and Outcomes Research at Celgene. Prior to joining Celgene, she held various positions of leadership at Eisai and Bristol Myers Squibb (BMS). At Eisai, her most recent responsibilities included overseeing the National and Regional Payer teams, the US HEOR Department and the Payer Marketing Teams across the neurology and oncology business units. She has also led the Oncology Key Account Sales team and Reimbursement Services. Annette started her professional career as a clinical infectious disease and critical care pharmacist at Newark Beth Israel and held faculty positions at Rutgers College of Pharmacy and Seton Hall University.

PARTICIPANTS

Shirley Reitz, PharmD

Clinical Pharmacist Client Manager
Cambia Health Solutions

Shirley Reitz, serves as Clinical Pharmacy Client Manager, providing strategic responsibility for developing, communicating, and reporting the outcomes of clinical initiatives impacting both cost and quality of care to members and clients. Previously, she served as Director of Pharmacy Clinical Services at Group Health Cooperative (now Kaiser Washington).

William Rogers, MD

Chief Medical Officer
Applied Policy

Dr. Rogers is the CMO at Applied Policy, a healthcare consultancy, and practices full time as an emergency physician at the VA medical center in New Orleans. He worked at the Centers for Medicare and Medicaid Services until January of 2017. During his 15-year tenure at CMS, he was director of the Physicians Regulatory Issues Team which worked to minimize the regulatory burden for clinicians who cared for Medicare patients. Dr. Rogers served on the Recovery Audit Contractor new issues review board. During the transition to ICD-10 Dr. Rogers was the ICD-10 ombudsman for CMS.

Bonnie Shaul, MBA

Director, Payer Strategy
AbbVie

Bonnie Shaul has responsibilities for identifying opportunities and risks to AbbVie's current and future therapeutic areas across all US payer types. She leads the development of brand-agnostic payer strategies to inform business development decisions, product strategic plans and long-range planning. Bonnie joined Abbott/AbbVie in 1992 and has held sales, marketing and general manager positions of increasing responsibility. She held the position of Country General Manager for 5 years, three years in Europe and two in Latin America.

PARTICIPANTS

Kyle Skiermont, PharmD

Chief Operating Officer
Fairview Pharmacy Services

As COO of Fairview Pharmacy Services, Kyle Skiermont is responsible for strategy and overall operations of specialty pharmacy, retail, MTM, mail order, long term care, compounding, home infusion and community infusion business units. Kyle has spent 20+ years in pharmacy including traditional retail, clinic-based retail, outpatient pharmacy at an academic health center, community and home infusion, specialty, and mail order. In addition, he is a frequent media and professional spokesperson on a variety of pharmacy topics.

Jason Spangler, MD, MPH

Executive Director of Value, Quality, and Medical Policy
Amgen, Inc.

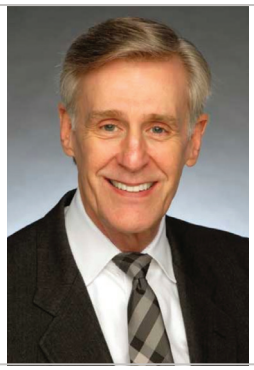
As Executive Director of Value, Quality, and Medical Policy at Amgen, Inc., Jason Spangler serves as the lead in representing the company on value policy, healthcare quality issues and Federal agency engagement. Previously, he was chief medical officer at Partnership for Prevention and was a public health and health policy consultant at Pfizer Inc. He is a Fellow of the American College of Preventive Medicine (ACPM) and serves on the Board of Regents of ACPM.

Ana Stojanovska

Vice President, Reimbursement & Policy Insights
Xcenda

Ana Stojanovska has over 15 years in the health care industry, providing reimbursement strategy and health policy consulting services for biotech, pharmaceutical, and medical device clients. She has significant experience in developing strategic recommendations and implementing tactical plans in the reimbursement space, taking into account payer benefit designs, provider perceptions, and patient needs. She has extensive expertise working with key stakeholders in motivating local coverage of new products by both public and private payers. She also provides strategic compendia analyses and ongoing coding support to help maximize patient access of current and emerging products.

PARTICIPANTS



Louis Tharp

Executive Director
Global Healthy Living Foundation

After running a successful international public relations, advertising and marketing company for nearly 20 years, taking equity positions in tech companies during the '90s, and working at international PR and marketing agencies, Louis Tharp became a social entrepreneur in 1999, co-founded and acted as the initial funder for CreakyJoints, an international organization for people with arthritis. In 2007 CreakyJoints became part of the Global Healthy Living Foundation (GHLF), which he also co-founded. GHLF focuses on health policy, advocacy, research, education and patient support issues. In addition to his work with the foundation, he is also CEO and co-founder of TGI Healthworks, a healthcare research company.

Susan Trieu, PharmD

Director, Enterprise Specialty Clinical Solutions
MedImpact Healthcare Systems, Inc.

Dr. Trieu is the Director of Enterprise Specialty Clinical Solutions for MedImpact and is responsible for clinical aspects of the MedImpact Specialty Programs. She previously led surveillance and strategy for pipeline compounds for the Emerging Therapeutics Strategy Team at MedImpact. In this role, she tracked pipeline agents in development, developed budget impact models for high-interest pipeline agents and new drugs, and for provided clinical strategy for pipeline agents and recently approved drugs. Prior to joining MedImpact, Dr. Trieu spent 10 years working for various large pharmaceutical companies in Medical Affairs.

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 healthcare systems, including a period with the 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 co-authored more than 100 books, book chapters, and journal articles on health economics, health behavior, and population health management.

PARTICIPANTS

Michael West, PhD

Director, Contract and Channel Strategy
AstraZeneca

Michael West brings over eighteen years of pharmaceutical industry experience including sales, field medical, health outcomes, health policy and managed markets support. His current focus is the creation, implementation and analysis of innovative value-based agreements.

Melanie Whittington, PhD, MS

Research Faculty
University of Colorado
Anschutz Medical Campus

Melanie Whittington has a research faculty appointment in the University of Colorado Skaggs School of Pharmacy and is a member in the Center for Pharmaceutical Outcomes Research. The theme of her research is to use economic evaluation methodologies to identify high value healthcare interventions to improve the quality and efficiency of healthcare delivered. She serves as the health economic methodologist for the Denver/Seattle Center of Innovation for Veteran-Centered and Value-Driven Care.

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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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