AMCP | PARTNERSHIP FORUMS

Building the Foundation for Patient-Reported Outcomes: Infrastructure and Methodologies

OCTOBER 25, 2018 | ORLANDO WORLD CENTER MARRIOTT | ORLANDO, FL

HOSTED BY THE ACADEMY OF MANAGED CARE PHARMACY IN PARTNERSHIP WITH

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WELCOME

Building the Foundation for Patient-Reported Outcomes: Infrastructure and Methodologies

Welcome to the Academy of Manage Care Pharmacy's (AMCP) Partnership Forum on **Building the Foundation for Patient Reported Outcomes: Infrastructure and Methodologies**.

This event is a follow-up to last year's Forum on patient reported outcomes (PROs) and the role they can play in defining health-care value. Last year's attendees achieved consensus on two overarching issues: (1) the importance of PROs in improving patient care and implementing value-based payment models, and (2) the need for strong organizational systems to fully adopt and use PROs in health care decision-making.

Our job now is to put these findings into practice by identifying specific methods and infrastructure around the ideal use of PROs in practice. Once again, we are fortunate to draw on a wide range of perspectives, with stakeholders representing patients, payers, providers, government, and biopharmaceutical companies. In light of the Food and Drug Administration's plans to propose guidance on incorporating PROs in the regulatory process, our Forum will focus on:

- Describing the current state of using PROs for FDA regulatory and value-based coverage decisions;
- Defining a process for collecting and sharing PROs with the FDA and managed care organizations for value-based decisions;
- Identifying the necessary infrastructure needed support the ideal use of PROs; and
- Identifying the health information technology strategies needed to support PRO use across managed care stakeholders.

From here, we will identify a path forward to implement Forum recommendations. Like all of AMCP's Partnership Forums, this one has the potential to directly improve the U.S. health care system. I thank you for your participation and would like to thank our generous sponsors who helped make this event possible: **Allergan, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Merck, Novo Nordisk, Pharmaceutical Research and Manufacturers of America (PhRMA), Sanofi, Takeda and Xcenda**.

Sincerely,

Susan A. Cantrell, RPh, CAE
AMCP CEO

MODERATOR

Caleb Alexander, MD, MS
Co-Director,
Johns Hopkins Center for Drug Safety
and Effectiveness
Johns Hopkins Bloomberg School of Public Health

Caleb Alexander is an Associate Professor of Epidemiology and Medicine at the Johns Hopkins Bloomberg School of Public Health, where he serves as founding co-Director of the Center for Drug Safety and Effectiveness and Principal Investigator of the Johns Hopkins-FDA Center of Excellence in Regulatory Science and Innovation. He also is co-founder of Monument Analytics, a health care consultancy, and a practicing primary care physician. He is internationally renowned for his work in pharmacoepidemiology and is the author of over 250 scientific articles examining prescription drug utilization, safety and effectiveness. He received his Bachelor of Arts cum laude from the University of Pennsylvania, a Medical Doctorate from Case Western Reserve University, and a Master's of Science from the University of Chicago.

AGENDA

THUR, OCT 25

7:30 am – 8:15 am

Welcome and Introductions

8:15 am – 8:45 am

Presentation

Ideal State for PROs — An Overview of the 2017 Partnership Forum, "Patient Reported Outcomes: The Missing Link in Defining Value"

8:45 am – 9:00 am

Break

9:00 am – 9:45 am

Panel Discussion

Current State of Incorporating PROs into Drug Development, Approval and Value-Based Contracting Coverage Decisions

- Reflections on FDA plans for implementing PRO provisions of 21st Century Cures Act (see Pre-Reading)
- Recommendations for the FDA, Life Science Companies and Managed Care Organizations

9:45 am – 11:15 am

Breakout Session #1 *(followed by 40-minute Report Out)*

Describe a Streamlined Process for Collecting and Sharing PROs with FDA, Life Science Companies and Managed Care Organizations

- Describe a process for collecting PROs for drug development (i.e., confirming clinical endpoints) and reporting PROs to the FDA
- Describe a streamlined process for collecting PROs to support value-based contracting between managed care organizations and life science companies

11:15 am – 12:30 pm

Lunch / Panel Discussion

What Type of Infrastructure is Needed to Support the Ideal Use of PROs?

- Data Repositories
- Accessible EHR data (Health IT strategy)
- Patient engagement
- Manufacturer/Life Science Company research and initiatives
- Managed Care Organizations

AGENDA

THUR, OCT 25

Breakout Session #2 ***(followed by 20-minute Report Out and 15-minute Full Room Discussion)*** — **12:30 pm – 1:45 pm**

Identifying Health IT Strategies to Support PRO Use Across Managed Care Stakeholders

- Table 1: Patient Engagement
- Table 2: Life Sciences Companies and Researchers
- Table 3: Managed Care Organizations
- Table 4: Healthcare Providers

Break — **1:45 pm – 2:00 pm**

Breakout Session #3 ***(followed by 40-minute Report Out)*** — **2:00 pm – 3:15 pm**

Creating a Plan to Promote Implementation of Forum Recommendations

- Identified next steps for each stakeholder
- Identify the role for AMCP
- Suggested partners for implementing Forum approaches
- Pilot/Project conceptualization

Forum Summary and Conclusions — **3:15 pm – 3:30 pm**

PARTICIPANTS

Amanda Bain, PharmD, MPH, MBA

Director, Pharmacy and Care Management
The Ohio State University Health Plan, Inc.

Amanda Bain is the Director of Pharmacy and Care Management for The Ohio State University Health Plan, Inc. in Columbus, Ohio. In her role, she leads the creation, implementation, and evaluation of nursing and pharmacy care management programs. Additionally, she acts as the clinical liaison to the Office of Human Resources, the OSU Wexner Medical Center, and the PBM vendor in support of pharmacy benefit program designs, services and communications for The Ohio State University. She has served on numerous national committees regarding pharmacy education, quality, and technology.

Joel V. Brill, MD, FACP

Chief Medical Officer
Predictive Health

Joel V. Brill is the Chief Medical Officer of Predictive Health. Board certified in Internal Medicine and Gastroenterology, he is an executive clinician with over 30 years of experience providing strategic leadership and medical oversight to large data-driven health organizations. He is skilled in strategy, development and implementation of innovative health programs, products and payment systems, with extensive experience in clinical practice, research, coverage, reimbursement, quality improvement, data analysis, bundled and episode payments and accountable care.

H. Eric Cannon, PharmD, FAMCP

Assistant Vice President,
Pharmacy Benefit Services
SelectHealth

H. Eric Cannon is Assistant Vice President of Pharmacy Benefit Services for SelectHealth, an Intermountain Healthcare company in Salt Lake City, Utah. He has responsibility for SelectHealth Prescriptions, a full service pharmacy benefit management group. He has worked in pharmacy for over 25 years. He was awarded the Fellow of the Academy of Managed Care Pharmacy recognition, and was awarded the 2013 Professional Achievement Award by Idaho State University, where he received his Doctor of Pharmacy degree. He also served on the Institute of Medicine of the National Academies Committee, Preventing Medication Errors.

PARTICIPANTS

Nikki Carrico, PharmD

Pharmacist
Epic

Nikki Carrico is a pharmacist at Epic, a health care software company. Carrico received her Bachelor of Science in Biochemistry and her Doctor of Pharmacy from the University of Wisconsin. She completed a Pharmacy Practice Residency at the Monroe Clinic, where she then worked as a clinical pharmacist and pharmacy manager in the clinic and hospital. At Epic, she works across several teams on medication use, with a primary focus on creating and improving tools to support ambulatory pharmacy practice.

Alana Clemens-Saliba

Associate Director, Patient Advocacy and Professional Relations
Boehringer Ingelheim

Alana Clemens-Saliba is the Associate Director of Patient Advocacy and Professional Relations at Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT. In her role, she is focused on the respiratory therapeutic area and is responsible for building and maintaining collaborative partnerships with key patient advocacy groups and professional medical associations. She has held a variety of roles at Boehringer Ingelheim over the course of her 15 years with the company.

Joseph Couto, PharmD, MBA

Data Science Director
Cigna Healthcare

Joseph Couto is a Data Science Director at Cigna, where he supports Cigna Pharmacy Management with health economics and outcomes research aligned with their quality improvement and pharmacy utilization management initiatives. He currently is the Vice Chair of the AMCP/AMCP Foundation Joint Research Committee, and serves on the editorial board for American Health and Drug Benefits, and the Specialty Consultants Panel for Pharmacist's Letter. He holds a Bachelor of Science in psychology from Furman University, a PharmD and MBA from SUNY Buffalo, and completed a fellowship in Health Economics and Outcomes Research at Thomas Jefferson University.

PARTICIPANTS

Gwen Darien

Executive Vice President,
Patient Advocacy
Patient Advocate Foundation and National Patient Advocate Foundation

Gwen Darien is Executive Vice President of Patient Advocacy at the Patient Advocate Foundation (PAF) and National Patient Advocate Foundation (NPAF). She is a longtime patient advocate who has played leadership roles in some of the country's preeminent nonprofit organizations. Darien leads programs that link PAF's patient service programs to NPAF initiatives, with the goal of improving access to affordable, quality health care. As a cancer survivor herself, she came into health advocacy expressly to change the experiences and outcomes for the patients who came after her and to change the public dialogue about cancer and other life-threatening illnesses.

Jessica Daw, PharmD, MBA

Senior Director, Clinical Pharmacy
UPMC Health Plan

Jessica Daw is the Senior Director, Clinical Pharmacy at UPMC Health Plan. Her primary responsibilities include managing the pharmacy clinical programs for Medicare, Special Needs, Medical Assistance, Commercial, Exchange, and the Children's Health Insurance products. Her role includes formulary and utilization management as well as clinical program, quality, and pharmacy care management program development. She participates as a member of the Educational Affairs Committee for the Academy of Managed Care Pharmacy (AMCP).

Diana Graalum, PharmD, BCPS

Clinical Pharmacy Manager
MedSavvy

Diana Graalum is MedSavvy's Clinical Pharmacy Manager and brings clinical experience in direct patient care to MedSavvy. She is a strong advocate for analyzing and interpreting the best available evidence, bringing it to life for patients, helping them understand their treatment options and identify what's important for them. Her primary responsibilities include: process and standards development, pharmacist team training, physician and patient consultation, disease and drug therapy evaluation, and clinical program management. In addition to ambulatory care and medication therapy management, she has over 20 years of experience as a clinical pharmacist in hospital and ambulatory practice settings. She has worked as a clinical pharmacy specialist in cardiology, orthopedic surgery, neonatal and pediatric medicine, labor and delivery, postpartum care, and adult intensive care.

PARTICIPANTS

Mark Gregory, RPh

Director, Pharmacist Consultant
Med Adherence Division
Omnicell

Mark Gregory joined Omnicell/Ateb in July 2014 as Vice President Healthcare Solutions. Omnicell is a healthcare solutions company focused primarily on medication adherence. Before joining Omnicell, he served as Senior Vice President of Store Operations for Kerr Drug, Inc. based in Raleigh, North Carolina. Responsibilities included all store operations, oversight of pharmacy systems and automation, managed care contracting, pharmacy administration, operational policies and procedures, patient care and compliance programs, university relationships and government affairs activities. He also served as Kerr Drug's Privacy Officer and Chairman of Kerr Drug's PAC.

Carolyn Ha, PharmD

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

Carolyn Ha is a Director in the Policy and Research Department at PhRMA, where she provides clinical expertise to shape policy development and advocacy related to population health and chronic disease management, improvement of medication use and clinical and quality management strategies. As a clinician, she is passionate about patient care and translating research into actionable policies that will ensure patients get the most out of their medications and creating a sustainable health care delivery system that incentivizes innovation. Prior to joining PhRMA, she spent time as a practitioner in a community pharmacy and advocated on behalf of independent pharmacy owners.

Jonathan Hamrick, MBA

President and Chief Operating Officer
Therigy, LLC

Jonathan Hamrick oversees the daily operations of Therigy, setting strategic goals for performance and growth and implementing business strategies, plans and procedures. He also leads Therigy's pharma consulting division. He joined Therigy as a Principal Partner in 2011, bringing with him more than 25 years of pharmaceutical, medical device, payer industry, and senior leadership experience. Prior to his appointment as Chief Strategy Officer, he was Therigy's Executive Vice President of Biotech and Specialty Services, where he led the company's pharma consulting practice, sales, marketing, client services, and corporate business development activities. Before joining Therigy, he was Vice President of Business Development at Priority Healthcare. He went on to be a senior member of the leadership team at CuraScript, a subsidiary of Express Scripts.

PARTICIPANTS

Amvrosios Ioannidis

Vice President,
Payer Sales and Account Management
Onco360

Amvrosios Ioannidis is the Vice President of Payer Sales and Account Management for Onco360 Oncology Pharmacy. In this role, he is responsible for the strategic development and execution of all Managed Care initiatives for Onco360, including national business development, contracting, and account management.

Patricia Jacob, PharmD, MS

Director, Managed Care Scientific
Allergan

Patricia Jacob is a Director, Managed Care Scientific at Allergan. Prior to joining Allergan, she was an Assistant Professor of Clinical Pharmacy at Xavier University of Louisiana, a Senior Medical Science Liaison at GlaxoSmithKline, and MAP Pharmaceuticals. Dr. Jacob completed her BSc Pharmacy and Doctor of Pharmacy degrees at Howard University. She completed her Master of Science degree (Clinical Trial Sciences: Regulatory Affairs) at Rutgers University. She also completed a one-year clinical residency at the University of Southern California and a two-year Postdoctoral Drug Development fellowship at the University of North Carolina at Chapel Hill and Glaxo Inc.

Mark Kosinski

Vice President of Life Sciences and
Patient Insight/Senior Scientist
QualityMetric/Optum

PARTICIPANTS

Greg Low, RPh, PhD

Director, MGPO Pharmacy Quality & Utilization Program
Massachusetts General Hospital

Greg Low is the Director for the Massachusetts General Physicians Organization's (MGPO) Pharmacy Quality and Utilization Program at Massachusetts General Hospital (MGH), Boston, MA and a member of the Massachusetts Drug Utilization Review Board. At the MGPO, he works with leadership to develop, implement, and evaluate ambulatory pharmacy programs. His efforts include addressing pharmacy's contribution to total medical expense, physician variation reporting, ACO reporting, and academic detailing. He began his training with a B.S. in Pharmacy from the University of Rhode Island, followed by a residency in clinical informatics with Ohio Northern University. He later completed a doctorate in pharmacoepidemiology and pharmacoeconomics at the University of Rhode Island.

Dana McCormick, RPh

Director of Pharmacy
Blue Cross Blue Shield of Texas

Dana McCormick currently is the Director of Pharmacy Sales and Account Management for Blue Cross Blue Shield of Texas. She has worked in many areas of pharmacy practice, including health plans, PBMs and pharmaceuticals. Most recently, she was with Sanofi working on the account management team and in medical affairs. Dana is actively involved with the Academy of Managed Care Pharmacy, recently serving as President of AMCP's Board of Directors. Dana earned her pharmacy degree from the University of Texas.

Trent McLaughlin, BS, PhD

Vice President, Real World Evidence
Xcenda

Trent McLaughlin is Vice President of Real World Evidence (RWE) at Xcenda. He leads a team that partners with manufacturers to develop best-in-class RWE, health economic, and market access activities for successful product commercialization. He has over 20 years of health economic and outcomes research (HEOR) experience, both as a consultant at Xcenda and NDCHealth, as well as a member of global HEOR departments at Abbott/Abbvie, Janssen Alzheimer Immunotherapy, and Elan. Additionally, He was responsible for establishing the Clinical Analytics and Outcomes department at Stanford Hospital & Clinics in 2005. Originally from Halifax, Nova Scotia, he received his pharmacy degree from Dalhousie University in 1995 and his PhD from the University of South Carolina in 1999.

PARTICIPANTS

Leslie S. Ritter, MA

Senior Director,
Federal Government Relations
National Multiple Sclerosis Society

Leslie S. Ritter manages the National Multiple Sclerosis Society's federal research advocacy portfolio of issues. In this capacity, she works within the legislative, regulatory and executive branches of the government to build relationships and communicate the needs of people with MS. She earned her Master of international Commerce and Policy from the Schar School of Policy and Government at George Mason University and a Bachelor's degree in political science from Middle Tennessee State University.

Kenneth Schaecher, MD, FACP, CPC

Associate Chief Medical Officer
University of Utah Health Plans

Kenneth Schaecher has been active in managed care for nearly 20 years, initially involved in utilization management, credentialing, formulary management and appeals for several managed care organizations. Employed by Intermountain Healthcare/SelectHealth from 1998 until 2017 and subsequently by University of Utah Health Plans, his responsibilities have included quality improvement, medical policy development/implementation and new technology assessment. He has assisted with benefit design, fee schedule development, medical coding and auditing, provider relations liaison and value-based programs. He has worked closely with pharmacy services at both plans in developing the plan formulary and has been active in the Pharmacy and Therapeutics committee, working to align formularies so as to reduce administrative complexity and cost yet assuring appropriate patient access to important therapies. Prior to joining SelectHealth, he was Chief of Staff at Pioneer Valley Hospital.

Tracy Spinks, BBA

Senior Director,
Quality Innovation
National Quality Forum

Tracy Spinks is the Senior Director, Quality Innovation at National Quality Forum in Washington, DC. She leads the NQF Measure Incubator™, which promotes efficient measure development and testing through collaboration and partnership. She also leads NQF's Learning Collaborative, whose members are committed to innovation and ideation to improve quality measurement. Previously, she provided management, financial and litigation consulting services before focusing on oncology-focused health policy, quality metrics, and alternative payments. She holds a Bachelor of Business Administration in Management Information Systems from the University of Houston and a Certificate of Public Health from The University of Texas School of Public Health.

PARTICIPANTS

Meredith Strozier

Director,
Practice Advocacy
American College of Rheumatology

Meredith Strozier is the Director of Practice Advocacy for the American College of Rheumatology (ACR), a professional membership organization committed to improving the care of patients with rheumatic disease and advancing the rheumatology subspecialty. The ACR serves over 9,600 physicians, health professionals, and scientists worldwide. She is responsible for monitoring trends in payer policy that impact the practice of rheumatology. She guides payer outreach by advocating for patient access to high quality care and treatments and fair and consistent reimbursement for providers.

Penny Surratt, BSN, MBA, RN

Senior Director, Trade Relations
ReCept Healthcare Services

Penny Surratt is the Senior Director, Trade Relations at ReCept Healthcare Services, with 34 years in health care that encompasses diverse, inter-related roles such as: UT Southwestern Medical Center Heart/Lung Transplant Coordinator and Cardiovascular Staff researcher, Pharmaceutical National Accounts Manager, Medicare Sponsor PBM team member, and Specialty Pharmacy Services Contract Manager. She received a BSN, from the University of Texas HSC, with Sigma Theta Tau honors, and an MBA, from the University of Dallas.

Sheila M. Thomas, RPh, PharmD

Senior Director,
Health Economics and Value Assessment
Sanofi

Sheila M. Thomas is Senior Director, Global Health Economics and Value Assessment, Value Frameworks Engagement at Sanofi. She joined Sanofi as the Senior Director, National Accounts Outcomes Liaisons, Evidence Based Medicine in 2013. She has more than 18 years of professional health economics and outcomes research (HEOR) experience in pharmaceutical industry, building and leading field-based and in-house Medical and HEOR functions responsible for U.S. and global evidence generation and communicating the value of health technology to various key stakeholders for pipeline and marketed products across multiple therapeutic areas. She is also an Assistant Clinical Professor at The Ohio State University College of Pharmacy, her alma mater.

PARTICIPANTS

Margaret K. Vernon, PhD

Vice President,
Patient Centered Research
Evidera

Margaret K. Vernon is Vice President and Senior Research Scientist for Evidera's Patient Centered Research (PCR) practice area. Responsible for the general management of the PCR global practice, she oversees all business aspects of the group. She has extensive applied research experience in designing and executing outcomes research studies and expertise in regulatory strategy and PRO clinical trial implementation and analysis. She has been responsible for validation and regulatory submissions of three PROs which have achieved U.S. labeling claims in rare disease indications. She holds a PhD in developmental psychology from the Pennsylvania State University.

Wendy Weingart, RPh, MS

Senior Vice President, Managed Care Services
Visante, Inc.

Wendy Weingart has over 25 years' experience with hospitals, health plans and pharmacy benefits management (PBM). For the last 13 years, Wendy has been a member of the Visante, Inc. team of consultants and serves as a practice leader in Visante's Managed Care/ Government Programs division. She is experienced in formulary and benefit administration, rejected and paid claims analyses, Part D transition program claims administration, Part B vs. Part D billing issues, hospice, and protected class drugs. Before joining Visante, she was Director, Pharmacy Services, for Assurant Health. In that position she oversaw Assurant's prescription drug card programs, pharmacy and PBM contracting, and pharmacy benefit program compliance as well as formulary and benefit administration and pharmacy clinical operations for the health plan's one million members nationwide.

ADDITIONAL PARTICIPANTS

Kristin Borowski

Senior Manager,
Federal Payment Agencies, Quality
Bristol-Myers Squibb

Kristin Borowski came to Bristol-Myers Squibb (BMS) from a career in government, having spent time at the Social Security Administration and the National Institutes of Health. Prior to coming to BMS, she was at the Centers for Medicare and Medicaid Services where she worked on Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) implementation and quality measure development for the Merit-Based Incentive Payments System (MIPS). At BMS, she is engaged on increasing the company's expertise and participation in identifying quality gaps and improving the quality of care for patients. This includes partnership with stakeholders both internal to the BMS matrix team and external engagement on quality activities, including quality improvement initiatives and measure development support.

Steven Smith, PharmD, MBA

Health Systems Medical Affairs Director
Merck and Company, Inc.

Steven Smith is a Health Systems Medical Affairs Director of Merck in Ohio. He has been with Merck for 18 years in US Medical Affairs in various capacities. In his present role, he provides scientific support across the Merck portfolio to payors and integrated delivery systems (IDNs) leaders, in support of appropriate access on formularies, protocols or pathways. He is the health economics point person for the team, and as such had done research and presented to the team on patient reported outcomes. Prior to Merck, he spent nearly a decade with United HealthCare of Ohio in Pharmacy Management.

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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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