



PARTNERSHIP FORUM

No.1 — 2019

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

MARCH 28, 2019 | MARRIOTT MARQUIS SAN DIEGO MARINA | SAN DIEGO, CA





Welcome



Matt Lowe

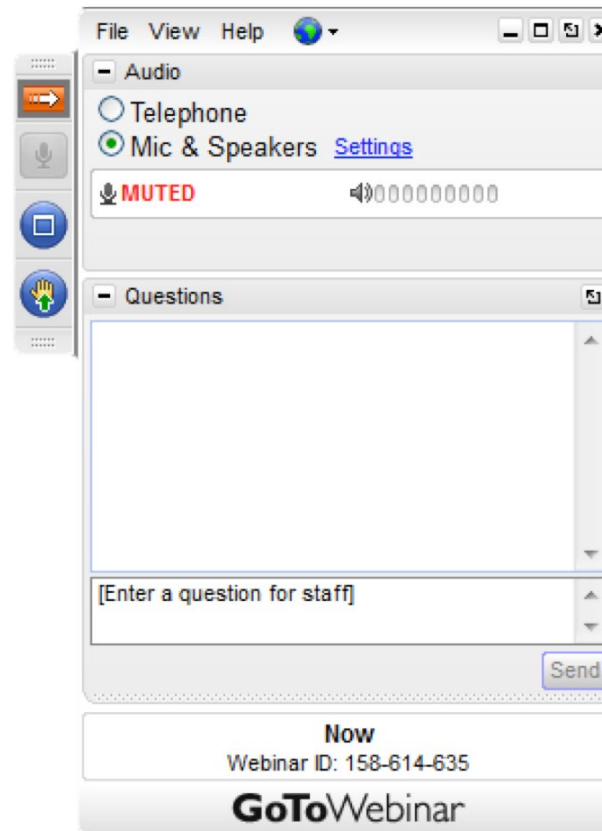
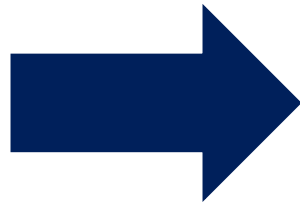
Vice President, Business Strategies
AMCP

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How to Ask Questions





AMCP Partnership Forums

Collaboration for Optimization



The live, hands-on AMCP Partnership Forums bring key decision makers in managed care, integrated care, the pharmaceutical industry, and others together to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes in integrated care and managed care.

AMCP Partnership Forums

- Adopt a proactive, collaborative approach
- Provide a voice
- Gain consensus and remove barriers
- Allow stakeholders to work together on common goals and interests
- Garner high visibility
- Find common ground and actionable results

2019 AMCP Partnership Forums



- **Pharmacy and Therapeutics (P&T) Practices: What's Next?**
March 28 | Marriott Marquis, San Diego, Calif.
- **Optimizing Prior Authorization for Appropriate Medication Selection**
June 25–26 | Hilton Mark Center, Alexandria, Va.
- **Digital Therapeutics: What Are They and Where Do They Fit in Pharmacy and Medical Benefits?**
Sept. 17–18 | Hilton Mark Center, Alexandria, Va.
- **What's Next for Specialty Medication Benefit Design and Reimbursement**
Dec. 10–11 | Hilton Mark Center, Alexandria, Va.



2020 AMCP Partnership Forums

Live Forums in Alexandria, Va.

- Helping Patients Anticipate and Manage Drug Costs | March 12–13
- Preparing for and Managing Rare Diseases | September 8–9
- Biosimilars: Policy, Practice, and Post Marketing Surveillance to Support Treatment and Coverage Decisions | December 15–16

Workgroup

- Addressing Barriers to Value-based Payment Models in Integrated Delivery Networks

Faculty



Mandy Leonard, PharmD, BCPS

System Director, Drug Use Policy and Formulary Management
Cleveland Clinic



**Conor Hanrahan, PharmD, BCPS,
CPHIMS, CPPS**

Medication Policy, Outcomes, and Stewardship Director
Intermountain Healthcare

Agenda

- P&T committee: Responsibilities and process evolution
- Forum findings and recommendations
- Q&A
- Next steps and action items

P&T Committee: Responsibilities and Process Evolution



Principles of a Sound Formulary System

Guiding Principles

- Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost-effective drug therapy.
- The formulary system encompasses drug selection, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, and monitoring of outcomes.
- The P&T committee, or equivalent body, comprised of actively practicing physicians, pharmacists, and other health care professionals, is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of drug products.

Principles of a Sound Formulary System

Guiding Principles

- Physicians, pharmacists, and other health care professionals provide oversight of the formulary system.
- The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members.
- The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities.
- The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.

P&T Committee Responsibilities

Primary Function

- The central role of the P&T committee is to maintain the drug formulary to promote treatment safety, efficacy, and value to organizations.

Additional Roles

- Developing clinical care plans
- Setting treatment guidelines
- Establishing critical pathways
- Instituting disease management protocols



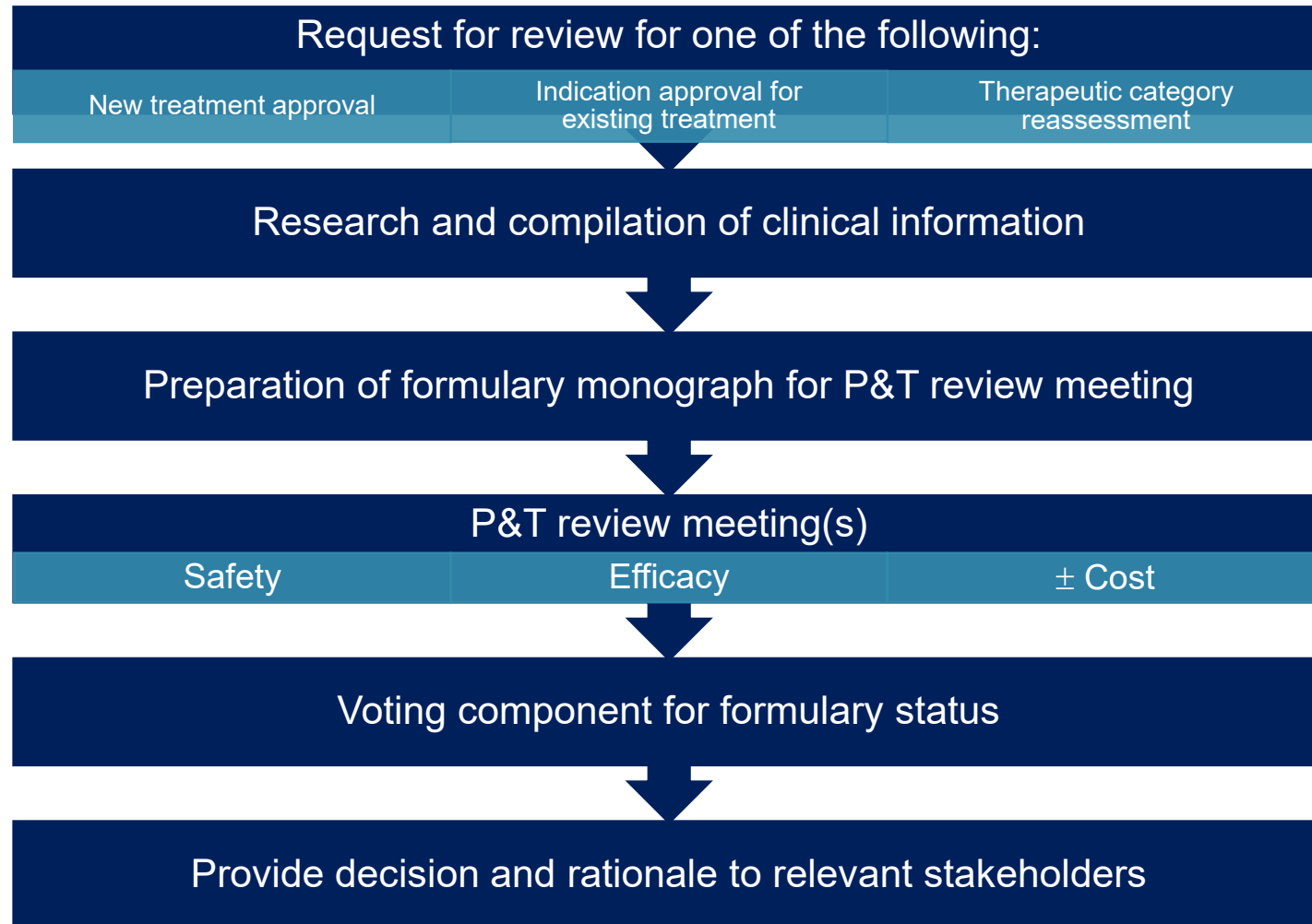
P&T Committee Stakeholders

Physicians	Pharmacists	Nurses	Other health care professionals
Administration	HEOR	Leadership (Chairs or department leads)	Specific clinical specialties, as needed
Medication use process experts	Patient representatives	Safety and quality-improvement professionals	

Caveat for Medicare

- Requirement for “an independent practicing physician and independent practicing pharmacist”

P&T Committee Decision Making



Objective Evaluation of Key Characteristics

- Clinical
- Economic
- Humanistic



Guideline and Evidence Assessment



Research and Assessment

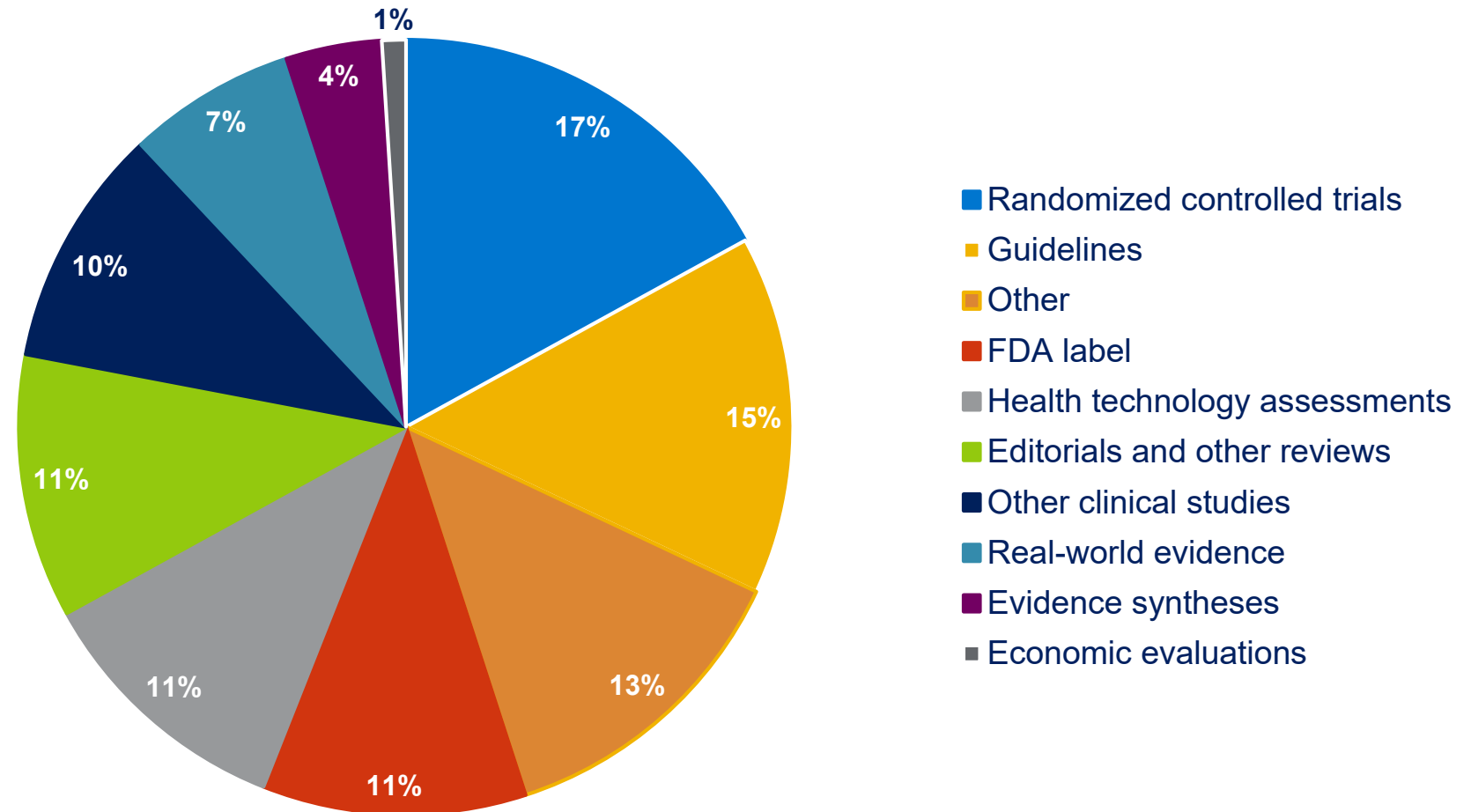
Types of Evidence Supporting the Creation of an Objective Formulary Monograph

- Randomized controlled trials (RCTs)
- Network meta-analyses
- Clinical and treatment guidelines
- Manufacturer dossiers
- Other published literature

Coverage Evidence Cited

Evidence cited in coverage policies

- SPEC Database comes from 17 Payers covering 130 million covered lives



Other Sources of Information

Additional Types of Information that are Gaining Traction

- Health technology assessments
- Economic evaluations
- Real-world evidence
- External groups or expert opinion publications
- Patient advocacy group reports

Best Practices of Successful P&T Committees



Team and Meeting Logistics

Key Considerations

- Broad inclusion of competencies
- Specific roles for each participant
- Clear definition of “value”
- Maintained objectivity
- Standardized process
- Anonymity and confidentiality
- Protected time

Evidence for P&T Committees to Include and Consider

Recommendations Regarding Evidence

- Assess results of randomized clinical trials objectively
- Review claims information and real-world data if available
- Factor in cost-effectiveness research and modeling
- Include patient perspectives in the evidence case
- Leverage patient-reported outcomes within studies
- Consider expert opinions and reports from external organizations

Training and Education

Training and Development Considerations for all P&T Committee Members and Supporting Staff

- Present fair and relevant information
- Provide training various types of research approaches
- Develop clinical data interpretation skills

Key Barriers and Challenges



Disclosing and Managing Potential Conflicts of Interest (COIs)

- *COIs are often financial in nature, but may have several layers of complexity as activities can change over time*

Guidance for Managing COIs

- Set clear definitions and policies for COIs
- Hold all members equally accountable
- Establish timeframes for COI disclosures

Transparency of Rationale for Formulary Decisions

- *P&T committee meetings are confidential in nature, but stakeholders often want more information about formulary decisions*

Suggestions on Approaches to Formulary Transparency

- Establish annual compliance training
- Share background information on literature used
- Provide information about the general background of committee members
- List the rules and mandates followed during the P&T processes
- Note potential COIs for P&T committee members



Principles and Best Practices:

Committee Composition and Meeting Logistics

The P&T committee, comprised of actively practicing physicians, pharmacists and other health care professionals, is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of drug products.²

Principles and Best Practices

Committee Composition and Meeting Logistics *cont'd*

Best practices for the P&T committee:

- Include a broad range of member expertise (e.g. specific clinical specialties, medication use processes, safety and quality-improvement) to provide unique perspectives
- Designate specific roles to be included in P&T committee (e.g. administration, HEOR, chair or department lead, nursing lead, and patient representation)
- Align on a clear working definition of value for the P&T committee
- Maintain objectivity within the P&T committee, holding each member accountable in the decision-making process
- Standardize and formalize P&T committee processes
- Develop protocols around anonymous voting and confidentiality for the P&T process
- Provide administrative time for data/monograph review prior to meetings and ample time during the P&T meeting for review and discussion

Principles and Best Practices

Evidentiary Considerations

Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost-effective drug therapy.²

Consider or include the following types of evidence in reviews:

- Randomized clinical trials, making sure to assess the study design and results objectively
- Real-world data, to provide additional context in coverage decision reassessments and formulary updates
- Cost-effectiveness research and modeling, to assess the value of a therapy
- Patient perspectives, to provide insight into the practical use of therapies and impact on quality of life outcomes.
- Expert opinions and reports from external organizations are helpful for reevaluations, new indications, and instances where limited data are available

Principles and Best Practices

Training and Education

The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities.² Consider building educational programs to support the competencies of new stakeholders.

Provide training to all committee members and staff on the following:

- How to develop and present fair and relevant information in an accessible manner
- Methods, benefits, and limitations of various types of research approaches like health technology assessments, cost-effectiveness research, and economic evaluations
- Clinical data interpretation skills
- Value and cost-benefit assessments

Future Opportunities

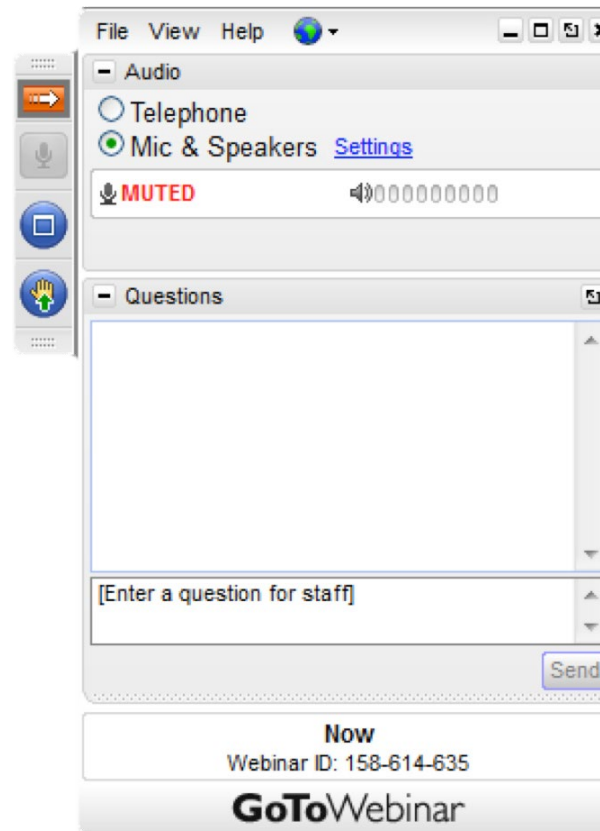
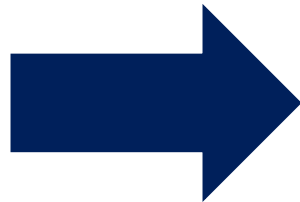
Key Opportunities for P&T Committees

- Education and training on new data sources
 - Real-world evidence
 - ICER reports
 - Patient-reported outcomes
- Incorporation of new data into formulary decisions
- Development of best practice case studies

Summary

- Evaluating P&T committees processes and the usage of new types of evidence and perspectives continuously is critical.
- Training P&T committee members is also important, which can include guidance on how evidence should be used and viewed, as well as policies and protocols.
- Establishing organizational policies on transparency around P&T committee processes and decisions are crucial for establishing successful P&T committees.

How to Ask Questions



Next Steps



PROCEEDINGS

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

ABSTRACT

It has been nearly 20 years since the Academy of Managed Care Pharmacy (AMCP) and other stakeholders adopted the Principles for a Sound Formulary System. Since that time, best practices for pharmacy and therapeutics (P&T) committees have matured throughout the health care system. On March 28, 2019, AMCP convened a group of thought leaders representing clinicians, academia, patient advocacy, payer organizations, and the pharmaceutical industry to consider P&T committee best practices in today's evolving health care system. Specifically, the group provided perspectives on (a) P&T committee composition and relevant stakeholders, (b) evaluation of emerging evidence for formulary decisions and recommendations around training of P&T committee members, and (c) characteristics and best practices of successful committees.

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The formulary system, when properly designed and implemented, can promote rational, clinically appropriate, safe, and cost-effective drug therapy. The pharmacy & therapeutics (P&T) committee is responsible for developing, managing, updating, and administering the drug formulary system for a managed care organization (MCO) or hospital.¹ The informed decisions that stem from the P&T committee's scientific assessment of products allow organizations to ensure that 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.^{2,3} However, as health care dynamics change, it is important to advance P&T committee best practices to meet the future needs of population health decision making.

To address these issues, the Academy of Managed Care Pharmacy (AMCP) convened a forum on March 28, 2019, at the AMCP Annual Meeting in National Harbor, MD. With a goal of gathering stakeholder input, forum participants provided their perspectives on (a) P&T committee composition and relevant stakeholders, (b) evaluation of emerging evidence for formulary decisions and recommendations around training of P&T committee members, and (c) characteristics and best practices of successful committees.

■ P&T Committees: Composition and Relevant Stakeholders

committee is to objectively appraise, evaluate, and select drugs for the formulary.^{1,4}

In addition to this core responsibility, P&T committees establish policies and procedures to educate and inform health care providers about drug products, usage, and committee decisions. P&T committees may also help support adoption of appropriate medication therapies through the development of clinical care plans, treatment guidelines, critical pathways, quality improvement programs that employ drug use evaluation, and disease management protocols.¹ As an overview, a typical P&T committee review process is described in Figure 1.

A P&T committee is usually composed of actively practicing physicians, pharmacists, and other health care professionals,^{5,7} but forum participants added that a well-structured committee also includes members with the following roles and/or expertise:

Organizational Roles

- Administration
- Health economics and outcomes research (HEOR)/pharmacoeconomist
- Leadership, chair, or department lead
- Nursing lead
- Patient representation

Expertise

- Medication use processes
- Safety and quality improvement
- Specific clinical specialties, as needed (e.g., oncology and pediatric endocrinology)

Generally, P&T committee members with clinical backgrounds provide guidance on standards of care and usual treatment approach. Having a variety of perspectives and expertise is crucial to ensuring that the review of evidence for formulary decisions is conducted in an unbiased manner and is inclusive of relevant stakeholder perspectives. In the case of Medicare programs, the Centers for Medicare & Medicaid Services require at least 1 independent practicing physician and 1 independent practicing pharmacist who are "independent and free of conflict" and do not have any financial arrangements with pharmacy benefit managers, drug companies, or other entities with vested interests.⁸ The inclusion of the patient perspective can also be a helpful component of the formulary evaluation process, since it provides additional insight into the practical use of therapies and effect on quality of life outcomes.

In addition, forum participants noted that continuous qual-

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To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.