

Systemic Market and Organizational Changes: Impact on P&T Committees

F. Randy Vogenberg, RPh, PhD; Rita Marcoux, RPh, MBA; and Martha M. Rumore, PharmD, JD, MS, LLM, FAPhA



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How We Got Here— The Post-PPACA Marketplace

In 2004, Balu et al. reviewed the changing role of the P&T committee from its beginnings in acute-care hospitals.¹ Traditionally, P&T committees limited the impact of their decisions to the populations associated with their hospital or health plan; however, as hospitals transformed into larger health systems and even integrated payer organizations, P&T committees had to begin to consider inpatient, outpatient, and/or ambulatory care settings. The primary function of the P&T committee had not necessarily changed, but its scope expanded to other health care entities, such as health plans and pharmacy benefit management (PBM) firms.

After passage of the Patient Protection and Affordable Care Act (PPACA) and the implementation of health reform, Vogenberg and Gomes revisited the landscape of changes affecting P&T committees in 2014.² Market and regulatory changes since then have resulted in more significant modifications to

health care delivery models in 2016, a short two years later.

Today, P&T committees routinely deal with chronic drug shortages and become involved in ethical discussions on medication rationing. Still evolving, the committee's role in hospitals, payer organizations, and other entities has to meet the needs of a market that has further changed with new reimbursement pressures in both quality and cost in care delivery accelerated by the PPACA; the emergence of large, robust health care systems; and the proliferation of biotechnology-based drugs, diagnostic tests, and devices. While the defining task of the P&T committee has remained intact—the evaluation of the clinical use of medications and development of guidelines for managing access to them to ensure safe drug use and administration—concerns around decision-making independence are more commonly heard.³ The use of clinical effectiveness data that integrate overall costs and offer comparisons among therapies for the sake of public health remains imperative for the P&T committee;² however, conflicts of interest in patient care when making decisions or creating guidelines from such comparisons have emerged as a concern. Now it is more important than ever for P&T committees to use these data as they make decisions for a larger volume of patients who have been incorporated into larger health systems. For example, not only does a health system have to consider the medications that patients need while in the hospital, it must also consider the drugs that its patients will need at home to sustain positive health outcomes and avoid readmission.

Stakeholders in Care Delivery and Decision-Making

Pharmacists, physical therapists, nurses, and physicians are assuming new leadership responsibilities, making them partners with P&T committees in improving clinical care and cost performance for health systems. The formation of formal and informal care teams tasked with

holistic care places drug therapy at a higher level of scrutiny and accountability.

P&T committees offer a perceived sense of comfort and independence in protecting patients using prescribed drugs. However, various institutional entities may be perceived as using the formulary as leverage for economic gain. Complicit or not, health care professionals and manufacturers can be tainted by perceptions that question the integrity of health care entities—and by extension their P&T committees.

Decision-making across the health care spectrum is under fire, and economic pressures are reshaping the landscape of care delivery. Professionals in the stakeholder mix are closest to patients and, therefore, have the most credibility to lose during the rapid transitions. As members of P&T committees, health care professionals necessarily need to redouble efforts to represent the interest of patients for safety and efficacy in drug therapy.

Focus on Cost and Quality

Considerations of quality, cost (reimbursement), and access (accreditation) affecting P&T committees over the past decade will become even more important as new drugs and biologic therapies enter the market and the shortage of primary care physicians intensifies.

Therapy costs, having skyrocketed in the last few years, escalate the focus of attention on cost but also on the achievement of good outcomes. The tension among key attributes of a health care system—cost, quality, and access—is reverberating rapidly, causing further stress that impacts the care of patients.

Efforts to identify key drivers in quality to empower decision-making are underway in an effort to moderate the system tension that has opened access without consideration of cost. As seen in health care reform efforts in Massachusetts, addressing cost rapidly emerges as a priority. Pharmacotherapies today will continue to engage P&T committees in challenging issues beyond traditional population health.

Dr. Vogenberg is Principal at the Institute for Integrated Healthcare and National Institute of Collaborative Healthcare in Greenville, South Carolina, and Adjunct Professor of Pharmacy Administration at the University of Rhode Island, College of Pharmacy, in Kingston, Rhode Island. Ms. Marcoux is a Clinical Associate Professor of Regulations and Managed Care and Director of Pharmacy Outreach Programs at the University of Rhode Island College of Pharmacy. Dr. Rumore is Associate Professor of Social, Behavioral, and Administrative Pharmacy at Touro College of Pharmacy in New York, New York; and Of Counsel at Sorell, Lenna & Schmidt, LLP, in New York, New York.

Convergence in Care Delivery

The financial pressures to demonstrate revenue growth and innovation in the post-PPACA era has resulted in an accelerated merger and acquisitions trend that began in 2014 and continues even now. Hospitals and providers merged to address the threats by more efficient and cost-effective outpatient facilities as well as changes in reimbursement. Regional hospitals and health systems also afford greater negotiating power with insurance companies. These acquisitions or partnerships offer the integration of technology, clinical practice, and providers needed to address the developing models of care.

In 2015, the pharmaceutical and insurance sectors joined in the merger and acquisitions activity. The pharmaceutical sector's acquisitions and divestitures attempted to capitalize on revenue growth, specialty pipelines, and distribution opportunities provided by the PPACA. Some of the higher-profile deals included Actavis and Mylan. Actavis purchased Allergan for \$70 billion and Kythera Biopharmaceuticals for \$2.1 billion and divested its generics line to Teva.⁴ Mylan purchased a division of Abbott, then inverted to the Netherlands for tax benefits. Pfizer made a bid for Allergan, but when the Obama administration introduced rule changes in 2016, the value of this overseas purchase diminished. The new rules limited Pfizer's ability to shed corporate citizenship in an effort to move income and avoid taxes.⁵

Finally, national insurance market activity has been delayed by the federal government. In 2014, five companies represented 83% of the national insurance market share. In 2015, Anthem announced plans to purchase Cigna for \$54 billion, while Aetna made a \$37-billion offer for Humana.⁶ The government has argued that this consolidation to three insurers would reduce competition, especially in the Medicare segment, as well as limit quality initiatives and the control of premiums. The Anthem-Cigna judicial review is under way. The Aetna-Humana merger was set for a judicial hearing in December 2016 and a decision is expected mid-January 2017.⁷

While entities in all health care sectors work to report revenue growth and innovation to financial markets, payers are working to redefine the reimbursement algorithms. Value-based reimburse-

ment is being driven by the Centers for Medicare and Medicaid Services (CMS). CMS continues its work to replace fee-for-service with episode-of-care payments and increase quality-based payments. Hospital value-based purchasing and physician-based value modifier programs reward providers for quality of care. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provided a new approach that aligns payment with quality and value of care. MACRA supports two paths: the merit-based incentive payment system (MIPS), which adjusts fee-for-service payments, and advanced alternative payment models (APMs), which include patient-centered medical homes, accountable care organizations, and bundled payment-of-care initiatives.

The availability of data is imperative to manage utilization and cost within these new paradigms of reimbursement. In 2018, MIPS will consolidate existing quality programs into a unified reimbursement that assesses quality, resource use, technology, and clinical practice. Payment adjustments will be made based on individual composite scores. The advanced APMs require that providers meet the criteria for technology and quality measurement, and assume more than nominal financial risk. Hospitals receiving bundled payments will be required to manage inpatient and post-acute-care costs for up to 90 days.

Since the implementation of MACRA, CMS has proposed additional bundles for episodes of care, including the comprehensive care for joint replacement model for hip and knee replacement, the oncology care model, and the cardiac bundled payment model for heart attacks and bypass surgery.⁸ To avoid costs shifting to the private sector, private insurers are monitoring and implementing similar bundled payment programs and quality measures. Anthem Blue Cross and Blue Shield of Ohio introduced a reward program for providers who received the Joint Commission's Integrated Care Certification.⁹ The Integrated Care Certification program focuses on the integration of technology, sharing of information, and transition of care for patients, and the best practice standards elements require that providers must be working toward improving outcomes through coordination of care, be accredited, and highlight risk sharing.¹⁰

These new models of care require integration and collaboration among all sectors of the industry. As health systems and providers are pushed to assume risk, pharmaceutical industry participation and assumption of risk for outcomes is being discussed. Physicians will be integral to reducing postacute treatment and managing patient behaviors to ensure positive outcomes. The integration models must align incentives and payment while including patients as key stakeholders. As the burden of cost continues to shift to the consumer in the form of premiums, cost-sharing, and deductibles, consumers will demand transparency in the pricing model.

For integrated health care systems with multiple service lines, managed care negotiations can be complex. "While payers often focus on negotiating with the hospital, an integrated system needs to think about the bigger picture," says Paula Dillon, Director of Managed Care at Rockford Health System in Rockford, Illinois. "For example, increased rates in certain settings can offset decreased rates in others. By looking at the net changes across the organization, you can negotiate more effectively and realize a robust agreement for the entire organization. That includes incorporating other entities, such as ancillary providers and physicians in the negotiations."¹¹

Impact on P&T Committees

P&T committees are currently in a state of flux with regard to commercial plans, Medicare Part D, Medicaid, the Veterans Health Administration/Department of Defense, hospitals, long-term care, and various submarkets. For example, PBMs and their P&T committees are shifting toward formularies that lower costs for employers and plans while passing those costs to employees. Over the last few years, emerging P&T consequences of rising drug costs have dominated the health care landscape, affecting patient accessibility to medications and giving rise to concerted patient advocacy, pharmacy benefit discrimination cases, and legislative action.

The increasing costs of most generic and brand-name medications have prompted concerns about future sustainability for state governments and insurers to shoulder the absolute costs of medications. Emerging trends for

Table 1 Emerging Formulary Restriction Strategies

Tiering	Adverse tiering	Increasing multiple specialty tiers
	Increased tier numbers	Increasing number of generic drugs (higher prices)
Utilization management	Increased cost-sharing	Drug-specific deductibles
	Increasing use of closed formularies	Increase in prior authorizations and quantity limits
Medication exclusions	Especially where no lower-cost generic alternative	
	Trend to exclude rather than tier brands for “therapeutic equivalents” that are chemically and pharmacologically different	
	The lists keep getting longer (e.g., Express Scripts excluded 80 drugs in 2016, up from 66 in 2015)	
	Alignments differ—each PBM is aligned with a different insulin maker	
Specialty drugs	Different approaches being taken by different PBMs	
PBM = pharmacy benefit manager		

health plan strategies for medication formulary restrictions are detailed in Table 1. From 2006 to the present, medication cost-sharing for brand-name medications has increased. Such practices comport with the traditional role of P&T committees, where cost is a legitimate factor that can be taken into consideration but cannot be the only or overriding factor for P&T decisions. P&T committees cannot make formulary decisions negligently or recklessly based upon nonlegitimate criteria. Participating physicians are often encouraged to conform their prescribing practices to align with health insurer policies, to consider the cost of treatment to the health plans, and to prioritize patients accordingly. Should an unfavorable result occur as a result of a medication substitution, the patient only has to prove negligence somewhere along the chain of responsibility for those who assemble the formulary.

P&T committee collusion lawsuits have emerged as plaintiffs have increasingly pressed a “formulary influence” theory of liability, alleging that off-label promotion or kickbacks caused states to wrongfully place drugs on formulary or give them preferred formulary status. In the high-profile Avandia (rosiglitazone maleate, GlaxoSmithKline) case, the plaintiffs alleged the drug was included on formularies in reliance on representations made by the pharmaceutical manufacturer.¹² Pharmaceutical companies have been forced to pay millions to resolve kickback allegations related to PBM formulary placement, inappropriate influence, or

illegal inducements of P&T formulary decisions in state hospital systems.

Cases Allege Pharmacy Benefit Failure to Provide Adequate Care

P&T formulary decisions can create possible legal dilemmas. Beginning with *Wickline v State of California* in 1986, courts have ruled that health plans could be liable for improper cost-control decisions.¹³ Courts have granted substantial awards to patients from health plans that failed to treat patients fairly.¹⁴

New medications for hepatitis C—with cure rates exceeding 90%, significantly fewer side effects compared with older treatments, shorter lengths of treatment, and increased ease of administration—have met with health plan restrictions due to the high cost of these drugs over the past two years. The restrictions have generated many consumer lawsuits against insurers in California, Washington state, and New York, as well as the Medicaid program in Washington state and the Massachusetts prison system.

In New York, the Attorney General sued a health insurer for denying coverage for hepatitis C drugs unless patients had an advanced stage of disease, such as moderate-to-severe hepatic scarring. The lawsuit accuses the insurer of failing to advise beneficiaries in plan documents that cost was a factor in its formulary decision-making processes for “medically necessary” treatment.¹⁵ The complaint states the restrictions are contrary to prevailing medical guidelines and gener-

ally accepted treatment standards and are based exclusively on cost considerations. The insurer claims its guidelines for coverage were developed by an independent P&T committee utilizing evidence-based medicine. However, the reversal of claim denials by external medical reviewers during the appeal process has provided strong evidence that cost-based rather than evidence-based formulary decisions are being made. The New York case is based upon consumer fraud, deceptive business practice, and insurance law violations.^{16–18} In at least one case, the Attorney General threatened to sue a manufacturer for violating consumer protection laws if it refuses to lower its prices. In other cases, the health plan has settled by loosening formulary restrictions.

In several cases involving prisoners, the claims involved a denial under the state’s formulary for the prisoner’s medication. In *Whipple v Schofield*, the allegation was made that “having the P&T committee stacked with employees from private contractors, which have a profit motivation to cut costs, puts the financial needs of those contractors above the medical needs of the prisoners.”¹⁹

Legislative, Regulatory, and Judicial Deterrents

Over the past few years, state legislatures introduced and passed numerous bills regarding drug formularies. The PPACA requires all qualified health plans (QHPs) to provide prescription drug coverage as an essential health benefit (EHB) and such plans must cover at least the greater of: 1) one drug in every United States Pharmacopeia (USP) category and class, or 2) the same number of prescription drugs in each USP category and class as the state’s EHB-benchmark plan.¹⁹ A QHP that fails to meet the EHB standard can be decertified if the plan employs a discriminatory benefits design.

Formulary rankings, known as tiers, have traditionally been used by health care plans. Can formularies designed by P&T committees be considered discriminatory? Over the past few years, the cost consideration factor has transformed into a process of structuring formularies to discourage patients with certain disease states from enrolling.

Adverse tiering—the placing of all medications (including generics) for

a particular disease on a specialty or high-cost tier—has flourished. When an insurance plan charges more for common human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) medications than other insurers, the company may be trying to discourage high-cost patients from choosing its plans on the PPACA exchange marketplace. Adverse tiering is explicitly prohibited under the antidiscrimination provisions of the PPACA; a plan “may not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.”²¹

The PPACA also includes annual limits on cost-sharing, which means that patients with chronic conditions should not pay high coinsurance once they reach maximum out-of-pocket spending. While the PPACA rule has been the basis for complaints to state and federal regulators, insurers have countered with the “Safe Harbor Provision,” which protects insurers in “underwriting risks, classifying risks, or administering such risks that are not inconsistent with state laws.”²² The Safe Harbor provision cannot be a subterfuge to circumvent antidiscrimination provisions inasmuch as “limits must be based upon actual or reasonable predictable risks.” All that is required is the showing of a “rational nexus” between the higher tier and cost-sharing, including copayment and coinsurance for certain classes of medications and risks.

A 2015 study published in the *New England Journal of Medicine* reported adverse tiering for HIV and AIDS drugs in 12 of 48 plans.²³ Enrollees in adverse-tiered plans had a yearly per-drug cost that was almost \$4,900 versus about \$1,600 for those in nonadverse-tiered plans. About half of the adverse-tiered plans had a deductible that was drug-specific. CMS has issued various letters regarding cost-sharing and adverse tiering and its intent to conduct outlier analysis as part of QHP certification or recertification.^{24–26} The Department of Health and Human Services’ examples of potentially discriminatory plan designs include: adverse tiering of HIV prescription drugs; formularies or services that fail to meet recognized treatment guidelines or the standard of care for a certain condition; applying age limits to services found to be

effective at all ages; requiring prior authorization for all medications in certain classes; and whether limitations and exclusions are based on clinical guidelines and medical evidence.

In May 2016, CMS issued the final rule implementing Section 1557, the anti-discrimination provision of the PPACA.²⁷ The rule prohibits plan designs that place “most or all drugs that treat a specific condition on highest cost tiers” and “charge more for single-tablet regimens than for treatments that require patients to take multiple tablets.” Although it will take years for the scope of Section 1557 to be established by the courts and provisions for health plan benefit design will not take effect until January 2017, the rule authorizes private right to action. Increased plan benefit litigation will be on the horizon as courts are already authorizing Section 1557 lawsuits. A number of states, such as Florida, have warned that plans found to be discriminatory will not be recommended as QHPs that can be sold in the state.

Over the past two years, we have witnessed the divergence of P&T formulary trends in the new PPACA exchange market, employer-sponsored plans, and Medicare Part D plans. One study of the exchange market in eight states revealed significant drug access and cost-sharing differences in exchange plans versus employer and Medicare Part D plans. For example, exchange plans cover fewer specialty drugs and have three times the utilization management rates. Specialty coinsurance is often more than 30% for single-source drugs for HIV/AIDS, hepatitis, cancer, and multiple sclerosis.²⁸

One of the duties of P&T committees is to assign products to formulary tiers. Over the past few years, health care plan formularies have gone from the typical three tiers (i.e., generic, preferred brand, nonpreferred brand) to four-, five-, and even eight-tier formularies. Most plans have created two tiers for generic drugs, and some have tiers for generic drugs used to treat certain conditions, such as diabetes, Parkinson’s disease, and epilepsy. The new tiers most often pertain to higher-cost generics and specialty medications. The trend toward more tiers warrants close attention.

The Medicare Part D approach to medication access applies to participating health care insurers. Medicare designates

six classes of medications as protected and mandates at least two medications in every drug category.²⁹ CMS also has a rule for the independence of P&T committee members that requires at least two members to be independent of the plan sponsor or manufacturer (but not the PBM). There are now two tiers for generic medications in most Medicare Part D plans. The scope of formulary medication coverage for these plans varies widely; some plans list all drugs from the CMS drug reference file, while others list as few as 65% of these drugs. Even if on formulary, utilization management rules, including step therapy, prior authorization, and quantity limits may restrict a beneficiary’s access to the medication. On average, prior authorization applies to 22% of medications.³⁰

Perhaps the balance between savings and wellness has tipped too far toward savings. A more equitable health care system for patients with chronic disease is required.

P&T: Dealing With Convergence in a Transitional Marketplace

While much of what has been discussed in this column is unlikely to change, the post-presidential election fallout has already begun in many economic sectors, including health care. During the campaign, the PPACA was targeted for elimination. Now that the campaign is over, it has become apparent that incremental change is more likely, and that not much will change in 2017. That being said, commercial market impacts could be felt in 2017 and are much more likely to be seen along with public sector shifts for the 2018 plan year.

This transitional marketplace makes some P&T committee decisions more difficult based upon the myriad of commercial or public plans covered while maintaining some simplicity for others that only deal with one type of plan, such as Medicaid or Medicare. For example, closed or preferential-based formularies may become less favored over more-open formularies depending on the plan type and progress of legal or regulatory change being implemented around prescription drug coverage. Other similar impacts may result from the pricing furor in 2016 leading to fewer-to-no rebates or contract incentives through managed care middlemen. Such uncertainty around specifics

will continue through 2017, epitomizing the nature of transition.

With the complexity of today's health care organizations, how can P&T committees most effectively deal with pharmaceutical decision-making alongside care delivery issues over the next few years? Understanding the purpose and actions to be taken by a P&T committee will provide a touchstone for examining formulary or policy decisions. Maintaining an awareness of health policy and legal trends will be more critical for the P&T committee and its individual members for making decisions on drug use. Avoiding obvious legal infringements or conflicts requires effective continuing education of P&T committee members and support staff.

Given the pace of change and calls for efficiency, what will the future P&T landscape look like by 2020? Based on trends to date in market stakeholder consolidation, market-driven efficiency demands, public and commercial plans' drive for value, consumerism, and legal enforcement of patient rights related to access to appropriate drugs, P&T committees will have their hands full balancing the issues when making decisions. The rise in shared-risk arrangements, high-deductible insurance plans, and litigation will create an increasingly tangled environment in which to maintain legitimacy, focus on clean execution of purpose, and find persons willing to serve on such a high-profile committee.

Individuals who can lead P&T committees into the new decade of care will be in high demand and can help deliver on the promise for better outcomes, better quality care processes, and fiscally responsible action. The need for P&T committees will only grow in urgency, but most urgent is the authenticity, credibility, and reliability of future P&T committees to maintain their core mission of providing safety and efficacy guidance to prescribers or users of drugs in their organizations.

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