Perspective

The Changing Roles of P&T Committees

A Look Back at the Last Decade and a Look Forward to 2020

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ABSTRACT

Market and regulatory changes in the last 10 years, as well as the Affordable Care Act, have resulted in significant modifications to health care delivery models. Traditionally, P&T committees limited the impact of their decisions to the populations associated with their hospital or health plan; however, as hospitals have begun to transform into larger health systems and even integrated payer organizations, P&T committees must consider both inpatient and outpatient needs of patients in multiple hospitals and ambulatory care settings. The function of the P&T committee has not necessarily changed, but its scope has expanded. 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 biotech therapies enter the market and the shortage of primary care physicians intensifies. 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.

Keywords: P&T, pharmacy and therapeutics committee, Affordable Care Act (ACA), quality of care, access, accreditation, hospital, health system, reimbursement models, biologic drugs, accountable care organizations (ACOs), transitions of care, collaborative care, leadership, physical therapists, nurses, pharmacists, physicians

INTRODUCTION

The health care environment is undergoing rapid change, posing an increasing number and mix of challenges for health care professionals. As the health care system evolves, the pharmacy and therapeutics (P&T) committee is adapting in step.

Initially, the P&T committee arose in the hospital setting, spreading later to managed care payers. In P&T in 2004, Balu et al^{1,2} reviewed the changing role of the P&T committee:

Pharmacy and therapeutics (P&T) committees evaluate the clinical use of medications and develop policies for managing access to them and for ensuring effective drug use and administration. ... From the focus on rational medication choices to the practice of monitoring adverse drug reactions and operating within an organization's budgetary limits, the duties of P&T committees have been continuously expanding and evolving. 1.2

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Who would have thought that by 2014, P&T committees would be dealing with chronic drug shortages and becoming involved in ethical discussions on medication rationing? In the past decade, the committee's role in hospitals, payer organizations, and other entities has also evolved to meet the needs of a market that has changed with the implementation of the Affordable Care Act (ACA); the emergence of large, robust health care systems; and the proliferation of biotechnology-based drugs, diagnostic tests, and devices. Yet the defining characteristic of the P&T committee has remained intact: It evaluates the clinical use of medications and develops guidelines for managing access to them to ensure safe drug use and administration. In addition, the use of clinical effectiveness data that integrate overall costs and offer comparisons among therapies remains imperative for the P&T committee.

Today, however, it is more important than ever for P&T committees to use this 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 medications that patients need while in the hospital, it must also consider drugs that its patients will need at home to sustain positive health outcomes and avoid readmission.

This article will explore how P&T committees' activities have changed since *P&T* reviewed their role in 2004 and will detail the challenges that the committees face today. These changes and challenges have become particularly acute within the last four years or so, mirroring hospitals' transitions to health systems and, in some markets, to integrated payer organizations. Interestingly, these changes have initiated a "retro focus" from a regulatory and reimbursement perspective. As a result, the P&T committee now deals with old and new issues—increasingly complex—that fall into three basic categories: cost (or reimbursement), quality, and access to care (or accreditation).

DRIVERS OF CHANGE OVER THE PAST DECADE Cost (Reimbursement)

Although the traditional variables in a triangular paradigm of population health involve *cost* versus quality and access, we use the term *reimbursement* to connote the evolution of third-party payment and its impact on the other two factors. Shulkin pointed out that as hospitals consolidate and grow into larger health systems, formulary decisions will likely be based on clinical predischarge and postdischarge outcomes.³ Ultimately, this approach will improve health outcomes for hospitals as well as the integrated entity as a whole. Payment methodologies are predicted to focus on gainsharing, bundling, and value-based reimbursement as opposed to traditional fixed-payment schedules. Bundling, for instance, allows physicians to share in savings and engages them in understanding the effects of drug choices

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on costs of care. With the evolution of the P&T committee, members will need to understand the hospital's role as the core of an integrated system in addition to understanding contracts and reimbursement strategies. The P&T committee must also consider itself part of an integrated team that manages episodes of illness, and it must include professionals from outside the hospital, such as primary care physicians and data analysts.4

Medicaid expansion through the ACA has greatly increased the number of nonelderly adults (ages 19 to 64) eligible for the program,⁵ including both healthy and chronically ill adults. Research by Hill et al indicates that newly eligible adults, as well as those previously eligible but not enrolled, are healthier than pre-ACA enrollees in both expansion and nonexpansion states. 6 If nonexpansion states later choose to join in Medicaid expansion, the authors suggest, they "could provide coverage to millions of healthier adults as well as to millions who have chronic conditions and who need care."6 Thus, nonexpansion may have great implications for uncompensated care, assuming that many of the uninsured have at least one chronic condition. This is just one example of how cost and reimbursement considerations make P&T committees' decision-making more complex.

New dispensing-assistance technologies, such as automated dispensing systems (ADSs), have helped to improve medication distribution practices in both inpatient and outpatient settings. However, the need to understand how the pharmacy department develops a decision matrix and operating rules for ADSs is another new matter for the P&T committee. Optimal clinical use of ADSs by approved personnel follows a policy and has implications for drug costs. Data collected from ADSs are factored into utilization review practices and reported through P&T committees, as with any drug-dispensing recordkeeping.

With more and more specialty medications on the market, new considerations arise. P&T committees must now decide whether a drug such as sofosbuvir (Sovaldi, Gilead Sciences) for hepatitis C is worth \$1,000 per tablet when Medicaid might not cover it. The extraordinary costs of many specialty drugs can bankrupt families and expand pharmacy budgets for employers and state Medicaid agencies. Comparative effectiveness data can be essential for evaluating the worth of these drugs, yet such data are largely lacking—a problem that has not been resolved in the past decade.

Heterogeneity in patient characteristics has led to greater utilization of targeted drugs, and the cost of these products is causing greater scrutiny of formularies. Hospitals that consolidate into a health system are responsible for more lives—a phenomenon that may alter a formulary's cost-effectiveness, depending on the health of the newly enlarged population. In a model by Truong, heuristics for drug selection that employ average or incremental cost-effectiveness ratios can perform very poorly. Cost-effectiveness improved considerably when physicians were kept informed about the relative effectiveness of drugs and were allowed to prescribe on the basis of individual patient characteristics, as opposed to restricting the formulary for quality-control purposes.⁷

Quality

Unlike cost and access, quality has remained largely untouched as decision-makers struggle to develop standard terminology to identify what worked to deliver satisfactory out-

comes, either in the eyes of the patient or the entity paying for care. With the emergence of new biotech drugs, the expertise and knowledge of the P&T committee may be further tested in the context of quality. The challenges of deciphering research data generated by these drugs in clinical trials and in real-world experience presents P&T committees with a conundrum: Should the P&T committee engage experts on "big data," or would a doctor of pharmacy or medicine on the committee suffice? Currently, P&T committees may evaluate new drugs by comparing them with agents already on the formulary used for the same purpose. When no comparable agent is on the formulary, the new drug may be compared with medications historically used for the same indication. In addition, the P&T committee will review the incidence and severity of reported adverse events and side effects associated with the agent. This should be done with great caution, however, because some new drugs might not have been studied in large patient populations. The P&T committee's evaluation of drugs in a new pharmacological class might be delayed for one year after the drug's release.8

According to the newly revised vision statement of the Joint Commission of Pharmacy Practitioners (JCPP), "Pharmacists will have the authority and autonomy to manage medication therapy and will be accountable for patients' therapeutic outcomes."9 This statement serves as a goal in attempting to address problems created by an aging population, a shortage of primary health care professionals, and a shift in the emphasis of care from acute to chronic disease. Pharmacists face several barriers in achieving this goal:¹⁰

- · Inadequate, erroneous, or compromised decision-making by the prescriber
- Lack of integrated and shared electronic medical records and computerized order-entry systems
- The patient's inability to afford the medication or part of its cost (e.g., a copayment)
- Limited access to medical information and technologies that improve medication safety, particularly during transitions of care¹⁰

In Pharmacy Forecast 2014–2018: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation identified five themes that will affect health-system pharmacy practice over the next several years. All are relevant to P&T committees:11

- Enterprise in hospitals and health systems will be greatly affected by the ACA.
- Pharmacy can aid the success of patient-centered medical homes (PCMHs) and accountable care organizations (ACOs) that engage with institutions.
- The reformation of the pharmacy practice model—including more observance of ambulatory care, actively working to improve the quality and continuity of care, participating in interdisciplinary patient-care teams, and enhancing the technician workforce—will aid in organizational success.
- Pharmacy practice leaders should help leaders within their organizations evaluate outsourcing and insourcing options for medication-related activities, such as operating an outcontinued on page 768

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- patient pharmacy, improving compliance among discharged patients, and preparing sterile compounded products.
- Pharmacy departments and formulary committees should prepare for the marketing of biosimilars over the next few years.

Access (Accreditation)

Much as reimbursement has become almost synonymous with cost, *accreditation* has become a driver of access to care. The Centers for Medicare and Medicaid Services requires Medicare Part D sponsors to have an established medication therapy management (MTM) program that "ensures optimum therapeutic outcomes for targeted beneficiaries through improved medication use;" however, efforts have not focused on documenting improved outcomes. Prescription drug plans, Medicare Advantage programs, and other payers have instead looked to cost reduction and surrogate process measures, such as outbound calls, interventions, and identification of medication therapy issues. According to the American College of Clinical Pharmacology, there is no definitive evidence that there has been an improvement in quality of health outcomes. ¹⁰

The PCMH and the ACO have emerged to fulfill patient needs through a team-based approach that relies on the skills, knowledge, and time of an interdisciplinary care team. ¹⁰ In instances when members of the team are unable to interact and provide appropriate MTM, electronic access to medical, medication, and scientific information is critical. Ideally, Zarowitz and colleagues write, third-party payment would compensate all members of the team on the basis of "the cost and clinical outcomes of accurate, appropriate medication therapy choices for all medical conditions." ¹⁰

Transitions of care are a significant concern in managed care today. Sinvani et al recently published the first study to look at three transition points in a large health care system and the medication discrepancies associated with each. In a review of subacute patient medication records from hospital admission to discharge (transition time 1), hospital discharge to skilled nursing facility (SNF) (transition time 2), and SNF admission to discharge home or to long-term care (transition time 3), medication discrepancies were prevalent at each point. The authors recommended that the medication reconciliation processes be re-evaluated to ensure that geriatric patients with complex health issues make transitions safely through levels of care. ¹² Such a re-evaluation would be consistent with the spirit of the JCPP vision statement.

Under Joint Commission accreditation requirements, medication reconciliation is accomplished if a "good-faith" effort is made to collect information about the medications a patient is prescribed and actually takes. A new Joint Commission National Patient Safety Goal requires organizations to ask patients to bring an up-to-date list of medications each time they visit a doctor.¹³

It is important for today's P&T committee to understand that the linkage between accreditation standards and economics extends beyond participation in Medicare or Medicaid. Commercial plans, along with specialty services or safety net programs, generally require advanced certifications. For example, URAC has a community pharmacy certification that incorporates many of the principles from MTM and other outcomes-focused domains. Patient-satisfaction surveys create additional considerations for P&T committees, while ACA-related patient-care

requirements compel provider organizations to deliver excellence or face potential medical-legal and economic damages.

DRIVERS OF FUTURE CHANGE

To achieve team-based care in which the pharmacist is not solely the distributor of medications but is also responsible for optimal medication-prescribing management, steps should be taken to develop a novel economic model of pharmacy practice. Potential conflicts in drug procurement, sales, or distribution should be anticipated and avoided. P&T committees have a vital role in decision-making economics in hospitals and other health care settings. Effective use of the P&T committee is a safeguard that can mitigate conflicts of interest that may develop between drug-acquisition activities and economic and accounting procedures. There must be written policies, procedures, and oversight by appropriate bodies to manage conflicts that may arise, for instance, between federal or state laws and regulations versus operational efficiencies in providing optimal and timely care. Protections such as separation and/or systematic oversight of medication-selection processes and sales must be effective no matter who the prescriber is or what organized health care setting the prescriber represents.

In addition, payment systems should recognize the efforts of interprofessional teams to achieve desired clinical, economic, and humanistic outcomes through the delivery of safe and effective patient-centered, evidence-based care. Pharmacists, for instance, should be compensated for their time with a professional fee for predispensing prescription review, patient education and consultation, and optimal medication-therapy prescribing and management. ¹⁰ The goals of the JCPP vision statement will be reached only when the profession and the health policy community initiate broad discussions about pharmacy practice economic models and implement a compensation framework that encourages integrated, evidence-based care. ¹⁰

Trends in Pharmacy Leadership

In a survey of 164 "forecast panelists," ASHP's Pharmacy Forecast 2014–2018 predicted the prevalence of several health-system pharmacy department operations by the year 2018 (Table 1). Notably, 90% of the forecast panelists believed that more than half of the hospitals in their regions will charge P&T committees with developing a formal process for evaluating biosimilars by 2018. Thus, as biosimilars reach the market, pharmacists will face a new challenge—proactively educating P&T committee members about these medications and helping to establish a valid process for evaluating them.

In suggestions that stress the importance of engaging legal and risk-management staff in formulary development, the ASHP report recommends that leaders assess options for serving their institutions' need for sterile compounding services; strongly encourage nearby pharmacy colleges and technician training programs to offer more extensive specialized training in sterile compounding; and assess barriers in state laws or regulations applicable to centralized packaging and preparation services.¹¹

To implement these types of programs and changes successfully, pharmacy leaders must be able to interpret economic and regulatory requirements and foresee their implications for their own organizations. Key activities anticipated during the next four years for implementing organizational change,

| Table 1 Pharmacy Forecast Panelists' Predictions of Operational Changes in Their Markets by 2018 ¹¹ | | | | | | |
|--|----------------|--------------------|----------------------|------------------|--|--|
| Description | Very Likely | Somewhat Likely | Somewhat Unlikely | Very Unlikely | | |
| Pharmacy departments in at least 50% of hospitals will be responsible for compounding all high-risk sterile products needed by the hospitals' patients (versus outsourcing this function). | 30% | 31% | 29% | 10% | | |
| At least 25% of hospital-based sterile compounding operations will be accredited by a quality-improvement organization that has a specific program for sterile compounding (e.g., Pharmacy Compounding Accreditation Board). | 29% | 48% | 20% | 3% | | |
| At least 25% of hospital-based sterile compounding operations will contract to provide this service to other hospitals. | 21% | 44% | 22% | 13% | | |
| At least 50% of health systems will conduct centralized drug preparation, repackaging, and distribution for multiple hospitals within their system. | 42% | 39% | 15% | 4% | | |
| In at least 25% of hospitals, individuals employed by the pharmacy department will be responsible for administration of medications to patients and for documentation of administration. | 3% | 12% | 41% | 44% | | |
| At least 50% of small hospitals (50 or fewer beds) will have a contractual relationship with a pharmacy department of a larger institution to provide operational advice and support (including after-hours order verification). | 39% | 44% | 16% | 2% | | |
| The P&T committee in at least 50% of hospitals will have a formal process for evaluating biosimilars. | 42% | 48% | 7% | 3% | | |
| At least 75% of hospitals will require conflict-of-interest disclosures by members of P&T committees and by clinicians who propose new agents for formulary addition. | 76% | 18% | 5% | 1% | | |

| Description | Very Likely | Somewhat Likely | Somewhat Unlikely | Very Unlikely |
|---|----------------|--------------------|----------------------|------------------|
| At least 50% of health systems and hospital networks will assign to a specific pharmacy leader/manager responsibility for managing medication-use issues (including formulary and purchasing issues) for the entire system or network. | 55% | 39% | 5% | 1% |
| Systematic strategic planning (including establishment of explicit goals for the next 2–5 years) will be conducted by at least 50% of hospital pharmacy departments. | 61% | 32% | 6% | 1% |
| In at least 50% of hospitals, pharmacy leaders will be evaluated and financially compensated based primarily upon the pharmacy department's contribution to successful achievement of organizational long-range strategic objectives (rather than based primarily upon departmental success in routine operations). | 34% | 43% | 18% | 5% |
| At least 75% of hospital pharmacy department leaders will be "fiscally literate" in the sense that they understand and can clearly discuss fundamental financial challenges facing their institution and department. | 51% | 40% | 7% | 1% |
| In at least 50% of hospitals, brochures that describe the institution's services to patients and visitors will mention the patient care services of pharmacists. | 29% | 49% | 19% | 3% |
| At least 50% of hospital pharmacy departments will assertively ensure that patients accurately recall if they interacted with a pharmacist. | 23% | 43% | 29% | 5% |
| The pharmacy department in at least 50% of hospitals will have made contingency plans for potential future downsizing of staff. | 24% | 45% | 28% | 3% |
| At least 25% of pharmacy departments in hospitals will have a succession plan for key leadership positions. | 16% | 50% | 31% | 3% |

as described in Pharmacy Forecast 2014–2018, are listed in Table 2.¹¹ ASHP forecasters characterize contingency planning as highly important for ensuring that essential patient-care services are maintained in the event of revenue-related downsizing and that hospitals maintain an effective leadership presence in an evolving landscape. Succession planning for key leadership positions will help.¹¹

While such surveys identify important operational issues, the ASHP results reveal a focus on the short term. Pharmacy and P&T committees must deal with day-to-day issues while planning for the health system of the future. ASHP recommends that pharmacy leaders in an organization make time to review current management of the medication-use process in all patient-care areas, step by step; analyze health care regulations and trends; develop and implement a staff-development curriculum on financial issues; create a pharmacists' patient-care activities portfolio; devise a plan to increase pharmacists' patient-care activities across the continuum of care; and prepare the pharmacy staff for possible downsizing as part of contingency planning.¹¹

Trends in Medicine, Physical Therapy, and Nursing

P&T committee responsibilities will be shaped not only by influences on the pharmacy profession but by influences on all patient-care professionals. Access to better data in real time allows for thoughtful medical-staff practice through development of procedures and review of care delivery. Improvements in data collection and analysis allow for collaborative care-protocol enhancements, quality management, and integrative care team support.

Physicians

Among the top issues discussed at the 2014 American Medical Association (AMA) House of Delegates Annual Meeting was maintenance of certification (MOC). Physicians believe that current MOC requirements, as well as those of osteopathic continuous certification (OCC) and maintenance of licensure (MOL), need thorough scrutiny. Delegates concurred that the implications of MOC, OCC, and MOL extend beyond physician practices, leading delegates to recommend a study of their effect on practice costs, patient access, patient safety, and patient outcomes. This recommendation expands current work on these issues; the AMA, for instance, continues to work with the American Board of Medical Specialties to understand why physicians continue or discontinue their certifications. The AMA will also work with the Federation of State Medical Boards to gain a better understanding of physician decisions to retire because of MOC and MOL factors. AMA delegates also voted to oppose making MOC mandatory as a condition of licensure.¹⁴

With many hospitals requiring their physicians to be board certified and managed care plans reconfiguring the composition of physician networks to include only board-certified physicians, many physicians are closing their practices. Many physicians cannot afford board recertification fees or do not pass exams in one sitting. These trends may add to the shortage of primary care physicians, particularly those who treat elderly and pediatric patients. P&T committees could be affected significantly by falling numbers of these experts in their fields.

Other measures enacted at the AMA's annual meeting in 2014 included a plea for better electronic data interchange to serve

physician and patient needs. The meaningful use provisions of the ACA require all pharmacies to accept e-prescriptions, but the AMA supports suspension of this requirement until all pharmacies are able to comply. ¹⁵ The AMA has begun to advocate for improvements in the electronic health record through its Professional Satisfaction and Practice Sustainability initiative. ¹⁵

Physical Therapy

Many specialists, including physical therapists, now utilize such innovations as collaborative-care models (e.g., ACOs and PCMHs) and bundled payment models to address staff shortages, payment barriers, and the rise in physician-owned physical therapy practices. PCMHs, which provide comprehensive and coordinated primary care services to the patient, are becoming more common among physical therapists.

To bring physical therapists together with physicians, large health systems, and policy makers to discuss the role of physical therapy in integrated models of care, the American Physical Therapy Association (APTA) hosted a March 2013 event called the Innovation Summit: Collaborative Care Models. One outcome was Innovation 2.0, a project designed to promote and further define the role of physical therapy. For institutions developing innovative patient-care and reimbursement models, APTA mentors will provide advice on such topics as evidence-based practice, health care issues, health care policy, data management, and dissemination of outcomes. ¹⁶ In these ways, physical therapy has made strides in advocating for its role in health-system improvement and patient care. P&T committees must recognize these efforts, as their outcomes will ultimately guide P&T committee decisions affecting collaborative-care models.

Nursing

Nurses also play meaningful roles on P&T committees. As patient advocates with hands-on responsibilities in all care-delivery settings, nurses help to facilitate P&T decision-making in cost, reimbursement, and drug-quality deliberations. To make recommendations for the progress of the nursing profession as health care settings and the health care system evolve, the Institute of Medicine (IOM) created the Committee on The Robert Wood Johnson Foundation Initiative on the Future of Nursing. In the committee's subsequent report—The Future of Nursing: Leading Change, Advancing Health—one key message was that nurses should be full partners with physicians and other health care professionals in redesigning U.S. health care.

In this report, nurses' leadership, dedication to promoting patient health, and desire to work collaboratively with leaders across health care disciplines are evident. For nurses, leadership responsibilities could include: identifying areas of waste and recommending or implementing improvements; participating in decision-making related to the implementation of health care reform; and taking part in policy decisions by serving on advisory boards. The IOM report is another example of how comprehensive organizational improvements arise from collaboration across the spectrum of health professionals. ¹⁷

Ancillary practice considerations for a P&T committee in 2014 take into account the work of multiple health professions that have assumed additional responsibilities aimed at coordinating care-team practices for an evolving health care market. Effective, practical, and economically sound collaboration of multiple profes-

sionals is not new, but in today's regulatory and reimbursement environments, collaboration has assumed greater prominence in both traditional and nontraditional settings of care.

DISCUSSION

The provider-related issues outlined above, which stem from the rapid evolution of our health care system, compel clinical professionals to forge a closer relationship with those who evaluate effectiveness as a means of improving system performance. In recent years, changes in the health care environment have sensitized P&T committees to the importance of a balance between clinical and financial concerns; as the clinical delivery side works more closely with the financial effectiveness side of the health system, operational gaps that may adversely affect the P&T committee may close. The ACO, which oversees administrative staff (including the pharmacy), and the medical staff and its committees, including the P&T committee, will need to align by using directors of each specialty in an integrated fashion. ACOs may also require more cross-functional reporting to achieve specific patient outcomes. The pharmacy director will be a vital force for bridging this gap, as he or she must educate the rest of a system's staff about new drugs and other options for achieving optimal treatment outcomes across a continuum of care. In addition to drugs, diagnostic tests and medical devices will increasingly need to be considered.

New responsibilities have been added to the pharmacist's workload at a time when senior physicians are choosing to limit their scope of practice or simply retire. Thus, pharmacists will need to provide strong leadership, making their voices heard on optimal drug use. As the number of nurse practitioners and physician assistants increases, pharmacists must be ready to support their expanded roles while ensuring safe, effective utilization of contemporary drug therapies.

In these ways, not only can pharmacists on the P&T committee help to control costs, they can also assure that formulary drug decisions consider patients in the hospital, patients who have been discharged, and patients who receive care through a PCMH or affiliated providers in an ACO. With the right expertise and leadership from all members of the health care team, P&T committee decisions will take into account changing market and regulatory forces. For example, the recent decision by the Department of Health and Human Services to delay implementation of the ICD-10 medical code set will result in extra costs to large health plans that were on track for a compliance date of October 15, 2014; P&T members may have to revert to previous formularies and decisions based on the ICD-9-CM code set. On the positive side, however, an additional year to implement ICD-10 gives health systems an opportunity to improve diagnosis-related groups, reimbursement, and quality measurement and reporting proficiencies.¹⁸

Continued implementation of the ACA through 2020 will raise additional considerations for P&T committees. As of mid-2014, the ACA has been characterized by dysfunctional implementation that has had unintended effects beyond its goal of increasing health insurance coverage. Unlike regulatory initiatives that don't depend on an obliging political landscape, the ACA has been implemented in pieces, hampered by a divided government and country. While health care reform has brought changes such as risk-sharing safe harbors and

transparent quality metrics into the insurance market, it has also added responsibilities and pressures for P&T committees.

Hospitals, as part of broad systems of care, may now have a corporate-level P&T committee. Additional roles relating to care coordination, risk-sharing, or risk-taking may now rest with higher corporate entities rather than individual hospitals. That places more pressure on both corporate- and hospital-level P&T committees to deliver positive results.

ACOs will focus on economic outcomes that extend beyond the cost of an individual drug. Some ACO-like organizations may be set up and/or supported by insurance carriers in a formal partnership, not just an informal collaboration.

Beyond the ACA's effects on the public sector, market-driven change or innovation has altered the roles of most stakeholders. For example, commercial insurers are increasingly shifting financial risk to care providers or the organizations that manage them, even as health systems market themselves to health care purchasers. Competition at multiple levels, including consumer choice, has continued to drive such change.

As the ACA introduced public exchanges beyond Massachusetts, private exchanges have emerged in the commercial market. Private exchanges have taken some of the lessons learned from health maintenance organizations, public sector programs, and insurance principles to package a businessfriendly product that manages or shifts risk to meet the demands of clinical and economic performance.

These shifts and the objectives of purchasers, providers, and payers all affect the role and responsibilities of an organization's P&T committee. Given the newness of health care reform, it remains to be seen what will really occur in the marketplace and how it will affect P&T committees.

CONCLUSION

Clearly, P&T committees have faced, and will continue to face, numerous challenges related to multiple factors: changes in health system organization and access to providers, the proliferation of biologic therapies, and an aging population, to name a few. To deal with these factors, it is important that pharmacists on P&T committees educate themselves and other committee members about new therapeutic agents. Pharmacists should be compensated for the increased responsibilities associated with these factors.

Ultimately, all health professionals must adapt to new functions and responsibilities induced by market changes and the ACA. Over the next two to four years, the leadership and expertise of each specialty on the P&T committee will be critical. For example, P&T committees will have to budget their efforts appropriately as they temporarily revert to ICD-9-CM codes and then resume work on ICD-10 codes to meet a new compliance deadline of October 15, 2015. With the next presidential election two years away, we are likely to see continued gridlock in Washington until the end of 2016. In that time, we could see numerous changes to the ACA, depending on the political landscape—and health professionals must be prepared. Such changes could affect the nature of the entities that deliver health care. If ACOs (or organizations like them in the commercial sector) gain prominence based on clinical effectiveness and performance in integrating administration and medical staffing, then ACOs or health systems will become the main risk-holders. That risk would likely include drug decision-

making and utilization review overseen by a P&T committee.

By 2020, traditional commercial insurers and the new private exchanges may have little influence in the health system and patient decision-making. Beneficiaries will likely look toward systems of care for guidance on managing the cost of care, not just clinical or drug-use advice. P&T committees must begin now to prepare for these types of changes, looking at pharmacy directors as part of P&T leadership to manage the health of the new populations they will serve.

One thing is certain: The P&T committee will continue to play an important role in the rapidly evolving U.S. health care system. Exactly how that role will change remains to be seen.

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