Challenges to the U.S. Health Care System From Legal and Regulatory Changes in the Donald Trump Era

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Introduction

During the past 20+ months, the U.S. market has seen dramatic changes in health care, and they continue at a deeper and more rapid pace than ever before. One significant aspect is the trends of purchasers seeking greater value for their health care spending (“value-based medicine”), mergers and acquisitions within the industry, and technology-driven innovation. Some examples include: the formation of the Health Transformation Alliance, the Amazon/Berkshire Hathaway/Citibank health start-up; CVS Health seeking Aetna, CIGNA seeking Express Scripts, Amazon purchasing Pill Pak; faster and more efficient FDA approvals; the use of gene therapeutics and immunologic therapies; and health care artificial intelligence, to name a few.

Despite a slow legislative start by President Donald Trump, federal regulatory initiatives in health care have continued at a faster pace as a result of the administration’s new policies. A major emphasis has been rolling back key provisions of the Patient Protection and Affordable Care Act (ACA), in addition to shifting more decision-making responsibility to the states. Regulatory change, in a politically deadlocked Washington, D.C., has emerged as the path for change and a way to circumvent the complexities involved in creating legislation in multiple areas of the U.S. economy.

The federal and state regulatory shift in health program changes that continue to occur will likely be more state-driven than federally driven under this administration.

Various state-implemented or federally supported programs, such as Medicaid, are more likely to reflect state or regional requirements. The current administration may establish fewer federal restrictions on their operations but federal agencies like the Centers for Medicare & Medicaid Services (CMS) will impose funding caps.

With the backdrop of rapid-based market change and shifting governmental policies left to the discretion of states, this article will explore perspectives on select federal and state policies into 2020 that will be important for Pharmacy and Therapeutics (P&T) committees, medical executive committees, and health care administrators or executives in various health care organizations.

Federal Health Policy and Regulatory Trends Affecting P&T Committees

During the Obama administration, the health care market was focused on implementing the ACA, passed in 2010, along with its annual mandated implementation adjustments from 2012 to 2016 to today. The changes in health care were driven by many presidential policies and agency regulations that pushed the public and commercial sector markets into a population health orientation and value-seeking approach, as opposed to the traditional fee-for-service structure. What remained in place was mostly a federally driven governmental approach that built upon previous administrations’ efforts to address the ever-growing issues of health care cost and quality. Components of the ACA are continuing into 2019, but with incrementally strategic shifts by CMS, increasing in type and frequency of change, in order to address the value-based nature of population health. Such strategic shifts will have an impact on providers in Medicaid and Medicare programs, along with third-party payers, significantly as regulatory-driven change is implemented.

During this same time, commercial insurance plans saw rapid growth in high-deductible health plans (HDHPs), including in the self-insured plans offered through employers. The use of Health Spending Accounts (HSAs) grew faster than Health Reimbursement Agreements or the declining Flexible Spending Accounts (FSAs); and higher out-of-pocket insurance costs for patients occurred with both pharmacy and medical benefits. These market dynamics place additional pressures on key health care stakeholders.

With the election of Donald Trump as President, the market is now in the midst of readjusting to an ACA regulatory pullback and start of the new American Patients First Plan (APFP, released in May 2018). Despite the current media

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Abbreviations: Affordable Care Act (ACA 2010), American Patients First Plan (APFP), Average Manufacturer Price (AMP), Centers for Medicare & Medicaid Services (CMS), Clinic Laboratory Improvement Amendment (CLIA), Fiscal Year (FY), Food and Drug Administration (FDA), Health and Human Services (HHS), Health Spending Account (HSA), Health Reimbursement Agreement (HRA), High-Deductible Health Plans (HDHPs), Pharmacy Technician Certification Board (PTCB), Pharmacy and Therapeutics Committee, P&T, Point-of-Service (POS), Risk Evaluation and Mitigation Strategies (REMS).
discussion about APFP, most insurance market trends continue in the same patterns as a result of the long decision cycles and processes required for change in the insurance market. However, 2020 looks to be a significant year of potential change resulting from the APFP policy pillars that are likely to be implemented in both public and private sector health benefit plans or programs (Table 1). A review of these pillars is useful for market stakeholders.

The four key pillars, goal categories or policy pillars in the APFP by the Trump administration (led by U.S. Health and Human Services Secretary Alex Azar), to watch for in the 2019 and 2020 fiscal years are increasing competition; improving negotiations; lowering list prices (drugs and other related items); and lowering out-of-pocket costs for patients.

According to an EY-Parthenon Analysis of drug channels, there are more than 50 regulatory and legislative measures to reduce drug costs for American consumers in the APFP. Some of the APFP implementation mechanisms, directives or policies important for health care professionals, executives, and P&T committees include the following:

1. Increasing competition
   a. Increase generic and biosimilar market share (FDA and Health and Human Services [HHS]).
   b. Provide guidance on how manufacturers use Risk Evaluation and Mitigation Strategies (REMS) to delay or block competition.
   c. Support biosimilar development.
   d. Accelerate FDA approvals.
   e. Educate/inform all stakeholders and drive interchange.
   f. Improve the Purple Book (biosimilars).

2. Improving negotiations
   b. Fiscal Year (FY) budget proposals should reflect savings resulting from improved negotiations.
   c. Provide plans with full flexibility to negotiate drug prices paid.
   d. Cap price increases.
   e. Update Drug Plan Consumer Service Star rating methodology.
   f. Implement site-neutral payment policies for prescriber-administered drugs and Part A inpatient versus Part B outpatient settings.

3. Lowering list prices for drugs and other related items
   a. Ensure discounts and rebates are passed along to patients.
   b. Re-examine 340B program and review impact on market competition/pricing.
   c. Increase price transparency in Medicare and Medicaid.
   d. Implement CMS programs—drug price dashboard tool for better informing consumers about drug prices.
   e. Exclude certain payments, rebates or discounts from Average Manufacturer Price or “best price” calculation.

4. Lowering out-of-pocket costs for patients
   a. Help patients to understand drug prices, rebates, and treatment alternatives.
   b. Move to Point-of-Service (POS) rebates/subsidies, including 340B or low-income patients.
   c. Implement FY2019 budget proposals to eliminate cost-sharing for generic drugs for low-income beneficiaries and require Part D plans to apply a substantial portion of rebates at the point of service.
   d. Force payers and pharmacies to drive low-cost alternatives for patients, preempt gag clauses, and Part D year-end drug price statements.

Although the specifics of all of these

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<tr>
<th>Table 1 Domains of Potential Changes for Health Care Stakeholders Resulting From American Patients First Plan</th>
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American Patients First Plan (APFP) key pillars are identified in bold in first row of table.

Resulting actions taken that impact various stakeholders are listed below each pillar, the result of changes being implemented.
pillar areas being targeted for change are minimal, they do represent active policies and issues for public discussion and debate. The pillars are also organized into mechanisms of action that can lead to goals or HHS directives to support new or future initiatives. In addition, many of these public sector changes are amenable to implementation in the private sector commercial insurance market, especially by employers.

State Legal and Regulatory Trends Affecting Pharmacists and P&T Committees

Today, pharmacists are integral members of the health care team. As their role continues to expand in the direction of more patient-focused activities, workflow and job functions of ancillary personnel must evolve as well. To achieve the full scope of many pharmacist-based initiatives, states’ boards of pharmacy have had to amend existing regulations or pass legislation that enables these practitioners to offer services beyond dispensing drugs. Modifications to regulations are often needed to allow current ancillary staff members, interns, and technicians the legal authority to perform some functions traditionally done by pharmacists in order to allow pharmacists the time required to manage their patients.

Prescription-writing authority is an area that is increasingly being delegated to pharmacists. The push for provider status by pharmacy organizations, as well as the lack of primary care services in many areas, has fueled such initiatives. A number of states have expanded the scope of pharmacist prescribing in various ways, depending on the goal of the initiative.

Statewide protocols are generally used for disease prevention and in cases of acute or self-limiting health care, such as dispensing and educating patients about naloxone, travel medications, and tobacco cessation products. Eight states—Arizona, California, Colorado, Idaho, Iowa, Illinois, Maine and New Mexico—allow pharmacists to prescribe smoking cessation products without a collaborative practice agreement. Six states—California, Colorado, Hawaii, Maryland, New Mexico and Oregon—have approved statewide protocols for pharmacist prescribing of hormonal contraceptives that offer women greater access to contraceptive agents. A number of other states, including New Hampshire, Rhode Island, Illinois, Missouri, and Minnesota have legislation or regulations submitted to include hormonal contraceptive prescribing as part of a pharmacist’s scope of practice. The states vary in the types of products that may be prescribed but collectively include contraceptive pills, patches, rings, and injections.

Some states are also reviewing pharmacists’ use of the Clinic Laboratory Improvement Amendment (CLIA) test to care for their patients. A number of states are considering legislation that would allow protocol-driven prescribing based on CLIA test results. In April 2018, the Idaho Board of Pharmacy sent a letter to its licensees addressing their prescribing authority for the treatment of cold sores, influenza, urinary tract infections, and the prescribing of statins and short-acting beta agonists. The letter included templates outlining which patients are appropriate for management by a pharmacist. Although these templates are available, the Board’s letter stresses the importance of each pharmacist practicing in accordance with nationally accepted guidelines and maintaining their clinical expertise. As of January 1, 2018, Oregon pharmacists have full autonomy to prescribe and dispense drugs and devices that are on a state board of pharmacy—approved formulary.

The ability of organizations to offer expanded pharmacists’ services will depend on the extent to which they can effectively manage pharmacists’ time and limit their distribution activities. Skilled ancillary personnel will be needed to assume those responsibilities while maintaining high quality standards. The National Healthcareer Association and the Pharmacy Technician Certification Board (PTCB) offer national certification. These organizations are also developing advanced training modules to ensure technicians have the necessary skills. PTCB recently announced that 300 technicians had passed their advanced certification program in compounded sterile products. Boards of pharmacies have been updating their regulations to allow technicians increased responsibilities as pharmacists delegate their responsibility for many distribution functions to their technicians. Seventeen states allow technicians to take verbal orders and transfer prescriptions.

Currently, 45 states and the District of Columbia regulate pharmacy technicians. Twenty-three states require national certification in their regulations. Other states regulate technicians through licensing and registration. Arizona, Louisiana, North Dakota, Texas, and Wyoming require technicians to pass the Pharmacy Technician Certification Exam, which is administered by PTCB. National certification requires 20 hours of continuing education every two years. In 2019, PTCB will require technicians to register with NABP so that states may access their CEUs through NABP’s CPE monitor.

The expansion of duties for technicians and pharmacists requires organizations to assess the impact of these changes on staffing requirements, salaries, and liability. As the technicians’ scope of practice and certification requirements increase, there will be a corresponding demand for higher compensation. The Bureau of Labor reports the mean salary for technicians is $33,000 with a high of $47,000. Technicians training and continuing education will be crucial to maintain the level of care.

Figure 1 Practice Restriction Regulatory Trend

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<th>Patient-specific collaborative practice agreements</th>
<th>Population-collaborative practice agreements</th>
<th>Statewide protocols</th>
<th>Unrestricted category-specific prescribing</th>
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<td>Restrictive</td>
<td>Less Restrictive</td>
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of expertise needed for quality assurance. The shift toward diagnosing and prescribing will require pharmacists to maintain their clinical skills and may require increased specialization and/or certification. However, regulations may be moving at a faster pace than the reimbursement shifts for pharmacists who take on the role of providers. The ACA requires payment for family counseling for providers but pharmacists may not be allowed to bill for their services without provider status. This has been identified as a potential barrier to patients accessing pharmacists’ services for hormonal contraceptives in California. In Oregon, Medicaid is required to pay pharmacists for this service.14 Medicare and Medicaid are leading the country in payment for pharmacists’ services; 14 Medicaid programs require payment for some direct pharmacists’ services. Medicare allows reimbursement for medication therapy management (MTM) under Medicare Part D.15 However, all insurance companies and health plans will need to recognize pharmacists for billing if this new definition of pharmacy services is to be financially viable for organizations.

Work flow and distribution practices will need to be ironed out as pharmacists begin to spend more time counseling patients, administering the CLIA waived test, assessing patients for pharmacist-approved prescribing and monitoring adherence. These activities will be performed as independent providers, which will create greater liability for pharmacists and their organizations.

Traditionally, the courts have held pharmacists to a standard of error-free dispensing of prescribed medications. The learned intermediary doctrine protected the pharmacists from adverse clinical decisions made by the prescriber. However, the courts have been expanding pharmacists’ accountability for negligence outside of the dispensing function when they have demonstrated specific knowledge that could have prevented adverse outcomes. In a number of cases, including Baker v. Arbor Drug, Inc., Klasch v. Walgreen Co. and Whiting v. Rite Aid, attorneys have attempted to shield pharmacies and pharmacists using the learned intermediary doctrine, but the courts allowed these negligence cases to proceed.16 The courts ruled that pharmacists, as medication experts, have a duty, when given specific information by the patient, system or prescriber, to consult with the prescriber or patient to prevent adverse events. The Massachusetts Supreme Court recently ruled in Correa v. Schoeck and other cases that a pharmacist owes a reasonable duty of care to inform the prescriber and patient of the need for a prior authorization. The courts are increasingly recognizing pharmacists’ expert knowledge of the effects of medications they dispense. This level of accountability will grow as pharmacists, among other mid-level professionals, take on expanded new role as prescribers. Organizations and their P&T committees must consider these expanded functions when developing their risk management strategies and determine whether their current liability coverage protects their organizations from legal jeopardy.

Implications for P&T Committees and Health Care Executives

P&T committees are not only faced with increasing demands on their compliance with ever-changing regulations and accreditation standards, but also with rapid increases in new biologics and specialty drugs approved by the FDA, making their work more important than ever. Their responsibilities include making informed decisions about innovative biologic-based branded drugs/medications, biosimilars, and gene therapies. In addition, diagnostics (companion or stand-alone), and devices are similarly being approved at a faster pace as a result of greater FDA efficiencies that are tied to diagnoses and monitoring of new drug therapies. All of these basic P&T committee responsibilities are likely to become more complex over the next several years.

All of these developments reinforce the importance for pharmacists and health care professionals to stay abreast of advances in drug therapies while maintaining their decision-making independence by avoiding conflicts of interest. This has been particularly true since the Office of Inspector General Report in 2013 and the 2015 CMS Rules regarding P&T committees that affect hospitals, health systems, medical groups, managed care organizations, and clinics. Although this places an obvious burden on P&T committees in terms of time and expertise required, these legal and regulatory changes are also occurring in an increasingly cost-conscious environment when little free time exists for such work.

Medical and other executive committees in health care organizations will be similarly challenged as their P&T committees are dealing with the rapid pace of market innovation in drug development and in all areas of health care delivery. The subsequent economic burden on providers, purchasers of care, and patients represents a major challenge to balance offering the best available treatments versus those that can be delivered/provided to a patient due to private or public sector insurance challenges. Inevitably, this struggle fuels the public policy discourse around access and care coverage that continually seems to escalate with every new advance in health care.

More state-level change will increase the impact on P&T committees in terms of local-level implementation; the scope of professional practice changes; and increased regulatory oversight. These state-level regulatory changes may include all supply chain stakeholders (manufacturer, wholesaler, retailer, managed care organization or others) and traditional group purchasing entities (GPOs, collaboratives, etc.) that likely will need to adjust their business models and/or membership in the coming years.

Federal and state changes in policy, regulation, and laws need to be on the P&T committee’s radar as these types of changes will present significant challenges for the regular committee deliberations and will affect the scope and nature of their role in health care coverage for patients in the next decade and beyond.

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