Regulatory Change Versus Legislation Impacting Health Care Decisions and Delivery

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Introduction

On January 20, 2017, shortly after his inauguration, President Donald Trump signed an executive order for an immediate repeal of the Patient Protection and Affordable Care Act of 2010 (PPACA), encouraging the Secretary of Health and Human Services (HHS) and other department heads to “waive, defer, grant exemptions from, or delay the implementation of any provision or requirement” of the PPACA that would pose an economic burden on the American people and those involved in the health care industry. Since then, Congressional efforts to repeal the legislation have been repeatedly unsuccessful. In response, President Trump signed another executive order on October 12, 2017, to further dismantle the law. Key actions taken by the administration and department heads have resulted in delayed enforcement of the PPACA and relaxation of the law, despite the lack of Congressional legislation repealing and/or replacing the Obama-era act.

The new administration has also changed the health care landscape through the Food and Drug Administration (FDA) and its new commissioner, Scott Gottlieb, MD. The FDA has enacted various policies and plans to address issues such as high drug pricing, clearing the orphan drug request backlog, increasing drug review efficiency (particularly in markets with little or no competition), and driving digital health technology and medical device innovation. These policies, as well as other legislative and regulatory trends in several cabinet-level regulatory agencies, have often been done in an unprecedented manner.

This article will cover issues mentioned above and high-level trends of the new administration’s policy, legislative agenda, and regulations. In addition, the effects these changes may have on the marketplace, health care organizations, and P&T committees will be explored.

Relaxation of the PPACA

Certain actions taken by the new administration and its department heads have resulted in a gradual loosening and relaxing of the PPACA (Table 1). For example, the Internal Revenue Service previously intended to comply with the PPACA’s individual shared-responsibility provision by considering 2016 tax returns to be incomplete if they were submitted without health insurance coverage information. However, at the behest of the new administration, this decision was postponed until the 2018 filing season.

Moreover, actions by HHS also highlight the new administration’s desire to replace the PPACA. In August, the Centers for Medicare and Medicaid Services (CMS) cut funding for PPACA navigator programs by more than 90%. The CMS is also now requiring these programs to operate based on performance: That is, funding will be determined by their ability to meet previous years’ enrollment goals.

In addition, there was a significant delay in PPACA rate deadlines and coverage stemming from uncertainty related to the Trump administration. In a draft bulletin published in February 2017, the CMS extended deadlines for proposed premium rates of health plans that issuers were intending to sell on the 2018 PPACA market. The initial filing deadline for qualified health plans (QHPs) was moved from May 3 to June 21, with final deadlines on August 16. However, on August 10, the CMS announced that it would extend the final deadline to September 5. The delays and uncertainty, especially surrounding silver-level QHPs and the administration’s persistent threat to cut federal cost-sharing reductions (CSR) related to the silver-level plans, resulted in some issuers increasing rates to adjust for anticipated risks.

While the CMS had assured policyholders that it could continue to provide CSR payments on a monthly basis, on October 12 the President announced that the federal government would no longer subsidize insurance companies providing silver-level QHPs. He made this announcement along with his executive order for the Departments of Labor, Treasury, and HHS to take actions related to association health plans, short-term, limited-duration insurance plans, and health reimbursement arrangements. While this may destabilize insurance markets in the short term, it also puts the burden back on Congress to take legislative action.

FDA Policies That May Affect Drug Prices

Dr. Gottlieb, the new FDA commissioner, announced that he and the agency would address high prescription drug prices by improving the efficiency of reviews for abbreviated new drug applications (ANDAs) to increase competition on the market and in turn drive prescription prices down. In addition, the FDA has implemented policies and guidelines meant to curb price hikes for off-patent drugs without competition, implement the Orphan Drug Modernization Plan, and promote digital health technology and medical device innovation (Table 2). As part of its Drug Competition Action Plan, the FDA published a list of off-patent, off-exclusivity branded drugs without approved generics and enacted a policy to accelerate the review of generic drug applications when competition is limited. These steps were intended to improve transparency between the agency and manufacturers and to encourage the development of generic alternatives, increasing competition. Under the new policy, ANDA approval may be expedited if there are fewer than three approved...
### Table 1  Examples of Patient Protection and Affordable Care Act Relaxation by Government Departments

<table>
<thead>
<tr>
<th>Department</th>
<th>PPACA Regulation</th>
<th>New Administration’s Actions</th>
</tr>
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<tbody>
<tr>
<td>IRS(^a)</td>
<td>Reject tax returns that fail to comply with PPACA's individual shared responsibility provision by indicating either a full year of health insurance coverage or an exemption to the provision, or paying the tax penalty</td>
<td>Tax returns will continue to be filed as in previous years, though filers may still be required to pay penalty of $695 or 2.5% of income (whichever is greater)</td>
</tr>
<tr>
<td>CMS(^b)</td>
<td>$100 million for promotion and outreach to navigator programs for 2017 PPACA plan enrollment</td>
<td>$10 million (90% reduction) for 2018 enrollment; funding will be based on performance to meet enrollment goals</td>
</tr>
<tr>
<td>HHS</td>
<td>Cost-sharing reduction payments to insurance companies providing silver plans for low-income Americans (&lt; 250% of poverty level)</td>
<td>Cost-sharing reduction payments eliminated</td>
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<tr>
<td>Labor</td>
<td>Small employers (up to 100 workers) required to buy policies in small-group markets, which must meet PPACA essential health benefits requirement and premium rating restrictions (i.e., protection for those with pre-existing conditions)</td>
<td>Association health plans (AHPs) enable small businesses to collectively purchase insurance and be regulated as large employers</td>
</tr>
<tr>
<td>Treasury, Labor, HHS</td>
<td>Short-term health plans restricted because they do not meet coverage requirements under PPACA and may open an individual to tax penalties</td>
<td>Short-term, limited-duration insurance no longer restricted</td>
</tr>
<tr>
<td>Treasury, Labor, HHS</td>
<td>IRS requires tax-exempt employer contributions must comply with PPACA group health plans</td>
<td>Expanded use of health reimbursement arrangements, which may give employees flexibility in purchasing their own health care</td>
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\(^a\) Under the Department of Treasury; \(^b\) Under HHS.
CMS = Centers for Medicare and Medicaid Services; HHS = Department of Health and Human Services; IRS = Internal Revenue Service; PPACA = Patient Protection and Affordable Care Act.

### Table 2  Significant 2017 Food and Drug Administration Policies Related to Generic Drugs and Drug Prices

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>Description or Purpose</th>
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<tbody>
<tr>
<td>Published list of off-patent, off-exclusivity drugs without approved generics</td>
<td>June 27</td>
<td>Encourage generic drug development to increase competition and decrease prescription drug prices</td>
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<tr>
<td>New policy on prioritization of review of original ANDAs, amendments, and supplements</td>
<td>June 27</td>
<td>Agency may give priority to ANDA applications with fewer than three approved generics on market</td>
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<tr>
<td>Orphan Drug Modernization Plan</td>
<td>June 29</td>
<td>Eliminate backlog of about of 200 orphan drug designation requests within 90 days and guarantee timely approval for future requests within 90 days thereafter</td>
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<tr>
<td>“Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access”</td>
<td>July 18</td>
<td>Public meeting to solicit comments regarding increasing innovation and preventing “gaming” of procedures and regulations from hindering access</td>
</tr>
<tr>
<td>Digital Health Innovation Plan</td>
<td>July 27</td>
<td>CDRH plan to 1) issue guidance on FDA stance toward medical software; 2) launch Pre-Cert pilot program; and 3) build expertise in digital health unit</td>
</tr>
<tr>
<td>Draft guidance related to formal meetings between FDA and ANDA applicants for complex products under GDUFA</td>
<td>October 2</td>
<td>Assist ANDA applicants in setting up meetings to facilitate enhanced communications with the agency for efficient processing</td>
</tr>
<tr>
<td>Draft guidance related to ANDAs for certain highly purified synthetic peptide drug products that refer to listed drugs of rDNA origin</td>
<td>October 2</td>
<td>ANDA applications related to glucagon, liraglutide (Saxenda, Victoza, Novo Nordisk), nesiritide (Natrecor, Scios, Inc.), teriparatide (Forteo, Lilly), and teduglutide (Gatter, NPS Pharmaceuticals), which the FDA deems feasible due to technological advances</td>
</tr>
<tr>
<td>Draft guidance related to Breakthrough Devices Program</td>
<td>October 25</td>
<td>Facilitate more efficient approval pathway for devices related to life-threatening or debilitating conditions</td>
</tr>
<tr>
<td>Two final guidances related to 510(k) submissions</td>
<td>October 25</td>
<td>Advises when it is necessary to submit new pre-market notification (i.e., 510(k)) for a change to an existing advice</td>
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ANDA = abbreviated new drug application; CDRH = Center for Devices and Radiological Health; FDA = Food and Drug Administration; GDUFA = Generic Drug User Fee Amendment; rDNA = recombinant deoxyribonucleic acid.
Other FDA Approval Initiatives

The FDA also announced the Orphan Drug Modernization Plan to eliminate a backlog of about 200 orphan drug designation requests, which had steadily increased over the last five years, and to ensure a timely response for future requests.13 To do this, the FDA established the “Backlog SWAT Team,” which successfully cleared the logjam within the proposed 90 days.14 The FDA also created a new Designation Review Template, reorganized its review staff, and formed the FDA Orphan Products Council to increase efficiency and guarantee a 90-day response time for future requests.15 Moreover, to further encourage drug development in rare diseases and facilitate market competition, the agency for the first time awarded six grants to study the natural history of rare diseases, as well as 15 grants toward new clinical trial research in rare diseases.20,21

To encourage digital health technology innovation in line with the 21st Century Cures Act, the FDA published the Digital Health Innovation Action Plan. This document detailed the agency’s intention to clarify regulatory strategies for such technologies, launch an innovative pilot software precertification program (FDA Pre-Cert for Software), and increase its expertise in digital health technologies.22 The FDA intends to take a “new and pragmatic approach to digital health technology,” according to Dr. Gottlieb.22,23

The FDA also intends to use post-market real-world data to generate evidence for supporting these initiatives.24 Furthermore, in line with current approaches to regulating medical devices, the FDA intends to develop “modern tools and benchmarks for measuring the safety and performance of [these] devices.”24 The agency released three guidance documents related to the new Breakthrough Devices Program and improved clarity for device approval.25

With increased efforts to drive review efficiency through improved transparency and enhanced communication between the agency and industry, it is anticipated that a significant increase of approved products will flood the market. As of October 2017, the agency had approved 764 generic and 34 novel drugs in fiscal year 2017—more than on the same date in previous years.26,27 While increases in generic alternatives may help drive down costs, increased approval of orphan drugs may actually drive costs and budgets higher.

Drug-Related Legislation and Regulatory Trends

Under the new administration, the FDA has sought to adopt a “modern, risk-based, and efficient” stance toward its regulatory duties.18 In an unprecedented manner, the agency has implemented policies that improve efficiency, encourage innovation, and in some cases enforce further requirements in the interest of consumer and public health (Table 3).

Anna Abram, the FDA’s Deputy Commissioner for Policy, Planning, Legislation, and Analysis, recently stated that the agency is conducting a broad, comprehensive review of its policies and regulatory framework.28 As a result, the agency has increased efforts to engage the public on policy considerations and their public health implications by soliciting comments from health care providers, patients, industry, and other stakeholders.

The FDA hopes to enact policies or changes that have maximum impact while addressing relevant concerns.

Dr. Gottlieb also took steps to address the opioid crisis by establishing the Opioid Policy Steering Committee, with emphasis in preventing new cases of addiction and promoting opioid addiction treatment.29,30 The agency is evaluating the risk–benefit profiles of opioid products (which resulted in Opana ER [oxymorphone hydrochloride, Endo Pharmaceuticals] being withdrawn from the market in 2017) and incorporating “the public health effects of opioids into its regulatory decision-making framework.”31,32 The FDA now requires immediate-release opioid products to be subject to risk evaluation and mitigation strategy requirements, and for the first time, training will be extended to health care professionals beyond prescribers (i.e., pharmacists, nurses).33

In a similar manner, the FDA is imposing further regulatory requirements on tobacco products and stem cell research. In July, the agency announced a new regulation that will limit the nicotine levels in cigarettes; it also encouraged applications for innovative tobacco products.34 The FDA intends to implement clear regulations related to regenerative medicine, as well as increasing enforcement to ensure the safety and health of the public.35

The FDA under the new administration has promoted efficiency and innovation, as seen with generic drug approvals and novel digital health technology, and has taken steps to adopt and enforce policies it believes will addresses matters deemed to be significant threats to the public health.

Discussion

While no law has repealed or replaced the PPACA, changes made by department heads in response to President Trump’s executive orders are resulting in changes to the U.S. health care landscape.

It is anticipated that the new administration will continue to undermine the PPACA and attempt to nullify Obamcare legislation and/or executive orders. Reduced enrollment in the marketplace health plans due to the administration’s decisions has resulted in higher premiums, especially for sicker individuals. The new administration’s decision to eliminate CSRs has caused great uncer-
Table 3  Examples of Drug-Related Policy, Legislation, and Regulatory Trends of the Trump Administration

<table>
<thead>
<tr>
<th>Actions</th>
<th>Description</th>
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<tbody>
<tr>
<td>Increased engagement with public</td>
<td>Open for comments to solicit feedback from public regarding broad policy changes and modern regulatory framework</td>
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<tr>
<td>Increased generic review efficiency</td>
<td>Encourage generic drug development to increase competition on market and decrease prescription drug prices: 1) published list of off-patent, off-exclusivity drugs without approved generics; 2) new policy on ANDA review prioritization; 3) published draft guidances to help enhance review pathways for ANDA applications, particularly for complex drugs</td>
</tr>
<tr>
<td>Grants for rare disease research</td>
<td>FDA has awarded 15 grants for clinical trials and (for the first time) six grants to research the natural history of diseases</td>
</tr>
<tr>
<td>Opioid Policy Steering Committee</td>
<td>Established to address opioid crisis, particularly related to mandatory education, medication dosing, and review processes for these products; resulted in Opana ER (oxymorphone hydrochloride, Endo Pharmaceuticals) being withdrawn from market this year</td>
</tr>
<tr>
<td>Stem cell research</td>
<td>Increased enforcement and regulation related to regenerative medicine; warnings and judicial action taken on centers in Florida and California</td>
</tr>
<tr>
<td>Tobacco products</td>
<td>Limit nicotine amounts in tobacco products, while also encouraging innovation for alternative products</td>
</tr>
<tr>
<td>Compounded drugs</td>
<td>Further implementing and enforcing the Drug Quality and Security Act; posting new reports on drugs compounded in outsourcing facilities and relevant regulatory information</td>
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ANDA = abbreviated new drug application; FDA = Food and Drug Administration.

The FDA under the new administration is increasing procedural efficiencies and encouraging innovation through increased transparency and enhanced communications between the agency and industry. An anticipated increase in generic options, rare disease treatments, novel medical devices, and precertified software will be available on the market. Therefore, despite controversies surrounding pharmacy benefit managers, their P&T formulary activities will be valuable to minimize pharmacy expenditures for commercial and employer-sponsored health plans. Providers and committees should also keep track of generic drug approvals, particularly those that may significantly relieve patients’ high out-of-pocket costs.

**Conclusion**

Despite efforts in Congress to repeal and replace the PPACA, no legislative changes have been enacted. The focus now turns to administrative branch (regulatory) action for commercial and public-sector insurance. Uncertainty surrounding the actions of the administration and Congress may well continue past the mid-term elections in November 2018, while progressive loosening and changing of federal rules will likely go on. This will accompany a variety of state-level changes and administrative practices that are evolving in response to the new administration’s regulatory strategy.

P&T committees and other operating committees of the medical staff will need to keep abreast of what can or does happen at the federal, state, and local government levels. They should also examine generic and novel products that appear on the market as they consider cost-effective options for clients and patients. In addition, health care organizations and administrative bodies should monitor changing FDA regulations and policies that may impact their organizations.

**REFERENCES**


