Health Law Daily

Wolters Kluwer

February 7, 2018

As Congress struggles with ACA repeal, Trump Administration moves forward with regulatory reform

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The Trump administration and Republican-led Congress spent substantial time and political capital in 2017 on efforts to repeal and replace the Affordable Care Act (ACA) and enact sweeping Medicaid reform. By the end of the year, their efforts yielded a more modest but symbolically important repeal of the ACA's individual mandate to purchase health insurance. While comprehensive reform—with a slim Republican majority in Congress during an election year—appears unlikely, health care is certain to be an ongoing policy and political battleground in 2018, with numerous pending proposals awaiting action. In the meantime, the administration has moved aggressively on its health care reform and deregulation agenda.

Congress Makes High-Profile but Limited Progress on ACA Repeal

The House of Representatives passed a sweeping bill that not only called for repealing and replacing the ACA but also for making fundamental changes to Medicaid by converting it from an entitlement program to a largely state-run block grant. The legislation foundered in the Senate without the 50 votes needed to pass it through the budget reconciliation process. Republicans were successful, however, in including a repeal of the individual mandate in the Tax Cuts and Jobs Act, which President Donald Trump signed into law on December 22, 2017.

Significant unfinished business for 2018 includes bipartisan proposals sponsored by Sens. Lamar Alexander, R-Tenn., and Patty Murray, D-Wash., to stabilize health insurance markets through a replacement of the cost-sharing reduction payments that the administration ended in 2017 (a proposal made all the more important by repeal of the individual mandate, which will reduce the number of younger, relatively healthy individuals participating in the ACA markets) and a long-term extension of the Children's Health Insurance Program (CHIP), which provides supplemental coverage for children in need who don't qualify for Medicaid. CHIP enjoys bipartisan support and is expected to be funded.

Administration Moves Aggressively on Health Care Regulatory Reform

While Congress struggled to enact sweeping health care reform, the Trump administration has begun to flex its regulatory muscles to reform several segments of the health care industry. On October 12, 2017, the president signed an executive order directing a trio of federal agencies to (1) craft rules to allow more employers to band together and purchase association health plans across state lines that are less regulated than those on the ACA marketplaces, (2) allow employees to use health

reimbursement arrangement funds to pay for health care premiums, and (3) increase the availability of coverage under short-term, limited-duration health insurance.

The administration also pushed forward with payment model reforms begun under President Barack Obama. The Centers for Medicare and Medicaid Services (CMS) scaled back mandatory payment models for orthopedic and cardiac care procedures in favor of alternative, volunteer models and has plans for other market-driven reforms. More Medicare payment model changes are likely in 2018. CMS Administrator Seema Verma has stated her intention to provide states with greater flexibility under Medicaid, encouraging the type of innovations she implemented in Indiana's Medicaid program.

FDA Acts to Expand Access to Drugs and Expedite Medical Device Approvals

One area of significant regulatory action has been at the Food and Drug Administration (FDA) under its new commissioner, Scott Gottlieb. He has consistently stated that the FDA's public health mission includes evaluating how high drug prices impact patient access to care. Commissioner Gottlieb has committed the agency to lowering regulatory barriers and speeding up the approval of generic drugs to foster more price competition—and ultimately lower prices—for high-cost specialty drugs. This includes speeding the pathway for biosimilars and generic drugs that can compete with off-patent orphan drugs, the latter having seen significant price hikes and drawn criticism from the administration, Congress, and patient and provider groups alike. It remains to be seen whether Congress will authorize CMS to negotiate drug prices directly, which President Trump called for during the 2016 presidential race.

The FDA also announced changes to expedite the pathway to market certain medical devices, including by allowing some devices to go to market with only initial approvals (with further performance assessments coming later) and by implementing a voluntary program under which companies will be able to secure device approval by meeting the FDA's "objective safety and performance criteria." Industry observers predict this will reduce the cost and time to bring devices to market.

President Declares Opioids a National Health Crisis as DOJ and States Pursue Enforcement

The nationwide opioid crisis was another top policy priority in 2017, and President Trump declared it to be a nationwide public health emergency. Earlier in the year, the Department of Health and Human Services laid out a comprehensive five-point strategy to combat opioid abuse, and the Department of Justice (DOJ) announced increased federal prosecution efforts, initiated scheduling of certain fentanyl-related substances under the Controlled Substances Act and expanded grants to states to increase enforcement efforts. The FDA also has been active in addressing the opioid crisis, which Commissioner Gottlieb has named a top priority. The FDA's actions have included seeking the withdrawal of an approved opioid medication whose benefits the agency believes no longer outweigh its risks, requiring manufacturers of certain opioids to increase their physician education efforts via an FDA-required risk evaluation and mitigation strategy, and utilizing its regulatory authority to commission a number of studies designed to better understand the causes of the crisis. The FDA continues to believe that abuse-deterrent formulations are an important tool to make opioids safer for patients and physicians alike.

These efforts, however, fell short of what Democrats and some Republicans have said is needed to combat the crisis, and Congress is likely to face demands to expand drug education and treatment efforts in 2018.

Industry Awaits Direction of Enforcement Under New Administration

In fiscal year 2017, the DOJ recovered $2.4 billion in civil actions under the False Claims Act (FCA) involving health care companies, accounting for 66 percent of the overall FCA recoveries in this period. Four settlements exceeded $100 million (two involving drug manufacturers, one against a health care provider and another with a health information technology vendor). This is the eighth consecutive year that the department's civil health care fraud settlements and judgments have exceeded $2 billion.

The Trump administration's deregulatory agenda may have some impact on enforcement activity going forward. A senior DOJ official recently said that the DOJ intends to move away from prosecutorial enforcement of what are often technical regulatory violations or matters that do not pose a substantial risk of harm under the Food, Drug and Cosmetic Act. The recent U.S. Supreme Court ruling in *Universal Health Services, Inc. v. United States ex rel. Escobar* has already led to dismissal of many FCA cases that previously might have survived a challenge. Nevertheless, recent trends indicate that relators are willing to pursue cases even where the DOJ declines to intervene.

While the political environment in Washington, D.C. and beyond is likely to remain unsettled, health care companies are all but certain to face continued whistleblower suits under the FCA and tough scrutiny by criminal and civil enforcement personnel.

Looking Ahead

Congress will start 2018 with a full health care to-do list. While CHIP reauthorization is likely, and some form of insurance market stabilization possible, other more far-reaching legislation seems doubtful. House Speaker Paul Ryan stated that House Republicans will turn their attention back to health care and other entitlement reform in early 2018, but Senate Majority Leader Mitch McConnell quickly nixed hopes for such legislation due to the slim majority Republicans hold in Congress and the lack of consensus within his own caucus. According to press reports, Sen. McConnell seems unwilling to force his caucus to take tough votes on proposals unlikely to become law as he confronts the electoral map in the 2018 midterm elections.

The leaders of CMS and the FDA have already pushed out major regulatory reform actions, and more are likely in 2018 in the areas of alternative payment models, use of technology to improve care and hold down costs, speedier drug and medical device approvals, and market-driven payment model reforms to increase competition and keep prices down. Virtually every major area within the health care sector—physicians and providers, hospitals and health systems, insurers, and manufacturers and supplies—will be the subject of legislative and regulatory action. Increased efforts to combat the opioid crisis are likely to pass, as are reforms that can be achieved through regulatory action.

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This article originally published on January 23, 2018, as part of Skadden's *2018 Insights*, an annual collection of commentaries on the critical legal issues in the year ahead.