# HEALTH CARE

## IN SEARCH OF VALUE

The U.S. health care system's efforts to incentivize "value"—i.e., achieving better patient outcomes at lower cost—have been too slow for the Trump administration to accept.

The federal government and the health care industry have tried for decades to pay for outcomes and improved health rather than volume of care. In a December 2018 multi-agency report headlined by the U.S. Department of Health and Human Services, the Department of Labor, and the Department of the Treasury, the administration blamed state and federal regulations that "inhibit adequate choice and competition" for the current state of affairs.

"Lawmakers and executive agencies under both Republican- and Democrat-led administrations want the transition to happen. Nonetheless, they continue to struggle to find common ground on the mechanics of cutting national health care expenditures without being seen as rationing care or stifling innovation," says Stephanie Willis, a counsel in Crowell & Moring's Health Care Group and a former attorney at the HHS Office of Counsel to the Inspector General.

With these conflicts unresolved, it's no wonder the U.S. spends more than any nation on health care, whether measured as a percentage of the economy (a whopping 17.9 percent) or on a per capita basis ($9,892). (Both figures are for 2016.)

The pace of change may soon accelerate.

### SOMETHING OLD AND SOMETHING NEW

The Trump administration is pursuing a dual approach of pressing some strategies dating back to earlier presidencies and proposing innovations to the regulatory landscape. In both cases, it's acting aggressively to speed progress.

"A good example is financial incentives for value in the form of rewards and penalties, which have long been part of the health care regulatory regime," says Troy Barsky, a partner in Crowell & Moring's Health Care Group and a former senior official at HHS's Centers for Medicare & Medicaid Services (CMS). "While the current administration continues to offer bonuses for desired outcomes, it's placing more emphasis than previous administrations on downside risk, which means penalizing providers that don't deliver value," he says. "We expect a stronger push for the implementation of downside risk over the next couple years."

One of the Trump administration's top candidates for value-based reforms involves prescription drugs, many of which have seen dramatic price increases in recent years. Congress and the president frequently single out drug prices for disapproval and have been progressively taking more actions to achieve pricing transparency and payment reform. The president's late October suggestion that Medicare pay for certain drugs based on their prices in other advanced industrial countries—where average prices are significantly lower, according to a new government study—appeared to be a trial balloon that faces heavy industry and political opposition.

Nevertheless, Willis notes, "The administration is heavily focused on using price transparency in a variety of forums to change the cost landscape for prescription drugs, such as in television ads, the 340B Drug Discount Program, and Medicare Part C and D benefits."

Ironically, anti-fraud statutes specific to health care are now considered obstacles to achieving value. Foremost is a series of fraud and abuse laws designed to limit the ability of health care providers to refer patients to care-providing entities with which they have an ownership, investment, or other financial relationship—indicating potential conflicts of interest. These statutes have the unintended effect of dis-

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couraging an administration priority: coordination among individual health care providers and institutions, which could reduce costs and improve outcomes.

## THE CHALLENGE OF PROMOTING COORDINATED CARE

HHS declared its intent to rectify the problem last June by launching the Regulatory Sprint to Coordinated Care, with the first of two requests for information. As the first request (which involved the physician self-referral law, also known as the Stark Law) put it, "Addressing unnecessary obstacles to coordinated care, real or perceived, caused by the physician self-referral law is one of CMS's goals in this Regulatory Sprint."

The second RFI came two months later and dealt with Section 1128B(b) of the Social Security Act, better known as the federal Anti-Kickback Statute (AKS). As with the Stark Law, there is some irony in efforts to revise the AKS, which imposes restrictions intended to protect federal health care program beneficiaries against overutilization, increased costs, and low-quality services—precisely the kinds of things that coordinated care could also prevent if certain requirements under the AKS were relaxed.

"The challenge of promoting coordinated care while complying with the Stark Law and the AKS is very real for health care players, whether they're hospitals, insurers, physician groups, medical technology companies, or investors," Barsky notes. "These players are strong advocates for the Regulatory Sprint and might even succeed in prodding Congress to address the challenge with new legislation in 2019."

## STATE VS. FEDERAL: THEY'RE JUST GETTING WARMED UP

The administration's enthusiasm for deregulation isn't always shared at the state level, particularly where government officials are concerned that such actions could make health care consumers more vulnerable. Some states that consider the administration's business-friendly approach detrimental to patients and consumers have taken action against it. For example:

- Eleven states and the District of Columbia filed suit in the D.C. District Court last July to stop a Department of Labor rule that created association health plans. These plans were established to make health insurance more affordable to small businesses but were exempted from providing essential benefits mandated by the Affordable Care Act.
- Eighteen states and the District of Columbia brought suit in the Northern District of California against the Trump administration's 2017 decision to stop making federal payments for insurer cost-sharing reductions that the ACA requires. The court dismissed the suit without prejudice in July.
- In August, HHS announced a new rule that loosened some of the restrictions on "skinny" health insurance plans, which offer limited coverage at low cost and are heavily circumscribed under the ACA. Several states have cracked down on sales practices associated with these policies.
- California enacted its Consumer Privacy Act in June. While the law is broad and not specifically directed at federal health care initiatives, it may enable consumers to limit health care providers' access to certain medical data—which could hurt efforts to promote coordinated care.

"Our sense is that the state-versus-federal battles over health care issues are far from over," says Barsky. "Ultimately, though, it's clear that all parties are invested in making the system more value-driven. Value delivery should be a win-win for everyone involved."

## KEY POINTS

### Quantity over Quality

The U.S. health care system is slowly shifting toward quality of care over quantity of treatment.

### Risk-Bearing Arrangements

The Trump administration is aggressively pursuing risk-bearing strategies to push the system toward value-based reimbursement models.

### Coordinated Care Barriers

Anti-fraud laws effectively discourage the coordination of care among individual health care providers and institutions.