Will Health Care Be Healthier in 2020?

Health Care



The legal landscape for U.S. health care is poised for significant change in 2020. Whether it's our health care system as a whole, the way Medicaid dollars are spent by states, or the rules governing health care providers' business practices, odds are good that reality will look very

different at the end of the year.

Yet amid so much uncertainty, one thing remains certain: Industry participants and their advisors will have to stay on top of developments, create contingency plans for different outcomes, and be ready to move forward as the dust settles.

Showdown for the ACA

2020 is shaping up as the year of go or no-go for the current system, at least as embodied by the Patient Protection and Affordable Care Act. The presidential election should, in part, be a referendum on voters' wishes and concerns about the ACA, and the law itself will likely get yet another day in court.

Crowell & Moring partner Xavier Baker expects *United States* v. Texas—in which the 5th Circuit upheld the Northern District of Texas's ruling striking down the ACA's "individual mandate" to have health insurance—to end up on the Supreme Court's docket. The stakes couldn't be higher. "The fate of health care as we know it in the United States is up in the air," Baker says, "because the 5th Circuit's ruling returned the case to the trial court to decide which parts of the ACA, if any, can remain and which must fall with the loss of the mandate.

"The trial court's original ruling held that the individual mandate was unconstitutional and the rest of the ACA was inseverable," he continues. "It isn't clear that the district court will reach a different conclusion this go-round and hold, for example, that the individual mandate, guaranteed issue, and

community rating provisions must fall but the rest of the ACA mav remain."

A New Medicaid Model?

Many states have long wanted greater control over how Medicaid funding is spent. Rather than the federal government paying a percentage of state health care costs for qualified recipients, some states support a block-grant system in which they would receive an annual lump sum to allocate as they please. A novel 2019 proposal from Tennessee may soon be the first to become reality. What's novel about the plan is that it would allow Tennessee to split any savings (i.e., the difference between what it spends and the amount of the block grant) with the federal government—savings not traditionally possible under federally administered Medicaid. The Tennessee proposal and others like it could act as a major incentive to reduce federal Medicaid spending, which was \$370.9 billion in fiscal 2018.

Crowell & Moring partner and co-chair of the firm's Health Care Group Chris Flynn expects the Centers for Medicare and Medicaid Services (CMS) to approve the Tennessee plan "because the Trump administration is encouraging block grants and wants to cut spending on entitlement programs such as Medicaid. And a plan with CMS's blessing would immediately become the template for administering Medicaid through block grants. There's pent-up demand for a workable strategy."

But Flynn cautions against unbridled optimism about the plan's future. "To approve the plan," he notes, "CMS must conclude that it meets Medicaid's fundamental objectives, which boil down to providing health care services to those unable to afford them. Courts have already shot down two states' efforts to place work requirements on Medicaid recipients, on the grounds that CMS's conclusion was arbitrary and capricious under the Administrative Procedure Act. Potential plaintiffs are aware of this and will likely seize on it as a line of attack."



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Crackdown on Subregulatory Guidance

Government agencies have long relied on guidance documents to state policies or interpret existing statutes or regulations. Such guidance doesn't have the force of law but, historically, has often been treated as such.

Not anymore. In two October 2019 executive orders, the Trump administration mandated that guidance documents be used only to explain existing regulations and not as legally binding determinations themselves, and that enforcement actions must be based on a violation of law and not on noncompliance with guidance.

According to Crowell & Moring's Xavier Baker, the impact on health care could be chaotic. "The health care regulatory landscape has been thrown into uncertainty," he says.

"Huge questions arise, such as how will the Department of Health and Human Services and the Centers for Medicare and Medicaid Services handle the orders' burdensome administrative requirements? Will any of their guidance somehow change? How can providers and payors be sure they're fully compliant? This will take time to sort out, and the ride could be bumpy," he says.

Baker urges health care entities to discuss with counsel whether their regulators may be relying on guidance to make their cases. Entities should also thoroughly review the executive orders to determine whether they qualify for any of the numerous and complex exceptions specified.

Potential Game-Changer for the Stark Law

If there's a poster child for the law of unintended consequences, it's the Stark Law. The law was originally passed in 1989 to combat physician conflicts of interest and other fraudulent business practices under the traditional fee-for-service health care system. Yet over the years it's grown overly complex and contradictory, and has become a compliance headache due to its numerous revisions, exceptions, and interpretations.

The Stark Law stands as a real barrier to modernizing the U.S. health care system—but perhaps not for much longer. Last October, CMS proposed new rules to modernize the law, and the Office of Inspector General of the Department of Health and Human Services did the same for the related Anti-Kickback Statute and the Civil Monetary Penalties Law.

The proposed rules could be game-changing for the Stark Law, says Troy Barsky, a Crowell & Moring partner and former CMS senior official. "CMS's proposal is a badly needed effort to align the law with today's value-based health care model that emphasizes quality of care, innovation, and collaboration among parties to benefit patients," he says. "It compels providers to assume real financial risk if they want to benefit from the rule's stronger protections."

Barsky points out that the CMS/OIG proposals asked many questions in an effort to get wide industry comment. This suggests both that the agencies were looking for more ideas and that the final rules, which he expects around midyear, could be quite different from the original proposals.

Regardless, he believes providers are likely to gain key benefits that were previously difficult, if not impossible, to obtain under the Stark Law. "The new rules should provide clear pathways to compliance, present new business opportunities, and give providers more flexibility to engage in value-based care," he says.



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