

# HEALTH CARE

## AN EVOLVING BUT STILL UNCERTAIN ENVIRONMENT

### A FRAMEWORK FOR “REPEAL AND REPLACE”



Despite intense pressure to develop and pass legislation to repeal and replace the Affordable Care Act, congressional Republicans haven't yet found a politically viable solution. Their first attempt, the American Health Care Act, didn't muster enough support for a House vote. While

it's anyone's guess as to when the next attempt reaches critical mass, it's a good bet that AHCA will be its general framework.

As repeal-and-replace regroups, it's useful to review selected goals underlying AHCA and how they differ from ACA. According to [Christine Clements](#), a partner in Crowell & Moring's [Health Care Group](#), several of these goals are especially significant.

**Guaranteed availability and coverage of pre-existing conditions.** One of ACA's hallmarks is its guaranteed availability requirement that prohibits health insurance issuers from denying coverage to people with pre-existing conditions. The requirement allows individuals both to get health insurance when they need it and to discontinue coverage when they don't need it—a choice that contributes to adverse selection (i.e., when less-healthy individuals are the majority of a health insurance plan's members, the plan's premiums increase) and market instability. While AHCA also required guaranteed availability, it provided some relief to issuers. The idea was to help stabilize the insurance market by incentivizing individuals to apply for and maintain continuous coverage by allowing health issuers to charge higher premiums (up to 30 percent more) to individuals who did not maintain continuous coverage.

This provision did not go far enough for some Republicans

who want to reduce health insurance premiums. Following the withdrawal of AHCA from a vote, House Republicans proposed an amendment that would allocate \$15 billion from the Patient and State Stability Fund to a Federal Invisible Risk Sharing Program that would be administered by the Centers for Medicare & Medicaid Services. The program would provide payments to issuers with respect to claims for eligible individuals to reduce premiums in the individual market. Funding for the program would be available from January 1, 2018, through December 31, 2026. CMS would develop the parameters of the program after obtaining input from stakeholders, including a list of health conditions that would automatically qualify individuals for the program as well as a process for issuers to voluntarily qualify other individuals.

The program received mixed reactions from House Republicans. Some say the amendment doesn't go far enough, while others say that it doesn't provide enough funding to bring down premiums. “At some point,” Clements says, “Republicans will have to decide whether they can live with an imperfect repeal-and-replace bill or let ACA continue to be the law. By trying to get everything they want, no bill will make it to a vote.”

**Medicaid eligibility.** Medicaid is a joint federal- and state-funded health insurance program that is administered by the states. ACA expanded Medicaid eligibility to adults making less than 138 percent of the federal poverty level. Thirty-one states and the District of Columbia expanded their Medicaid programs under ACA. AHCA would have ended the enhanced funding for the expansion population effective January 1, 2020, except for individuals enrolled under the plan as of December 31, 2019, who did not experience a break in enrollment longer than one month. The expectation was that most Medicaid eligibles would experience a coverage break longer than one month, thereby quickly reducing the overall federal match for such individuals.



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A fundamental tenet of AHCA is that the federal government should simply give states per capita block grant funding and let them decide how to allocate the funding among Medicaid recipients. The goal is to reduce federal spending on Medicaid and allow states to design and implement a Medicaid program that meets their specific needs. Clements adds: “The new administration does not believe that one size fits all for Medicaid. States might also choose to apply for federal waivers to expand their Medicaid programs to cover low-income people who earn too much for Medicaid coverage. This would be consistent with AHCA’s objective of giving states more control over Medicaid.”

**Health savings accounts.** Republican proposals seek to encourage the purchase of high-deductible health plans by expanding the permissible uses of health savings accounts and increasing the annual allowable maximum contribution to an HSA for a person enrolled in a high-deductible health plan. HSAs have been around since 2003 and align well with the Republicans’ goal of reducing government’s role in the health care system. Clements notes, “Simply shifting some of the accountability for health care spending to individuals should make them smarter purchasers and, in the process, play a role in reducing overall spending on health care.”

All of this means continuing uncertainty and instability for consumers and issuers. President Trump recently threatened to stop funding ACA cost-sharing reduction subsidies—which are paid to issuers to help cover deductibles and out-of-pocket costs of low-income insureds—in an effort to get Democrats to the negotiating table. “It is unreasonable to expect issuers to commit to the marketplace for 2018,” Clements says, “without some assurance that the cost-sharing subsidies will be paid.”

## A STABILIZATION PLAN— FOR NOW

With no resolution of repeal-and-replace in sight, a recently finalized regulation may provide temporary stability for the nation’s health insurance marketplace.

The administration set the stage for the regulation when, just hours after the president’s inauguration on January 20, 2017, he signed Executive Order 13765. The order declared the administration’s intention to repeal the Affordable Care Act and got the process started by, among other things:

- Mandating that all federal agencies, including the Department of Health and Human Services, “shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of” any ACA provision that imposes a financial or regulatory burden on any stakeholder including patients, physicians, hospitals, and other providers, as well

## PRACTICAL STEPS IN AN UNCERTAIN ENVIRONMENT

Given the unsuccessful efforts thus far to repeal and replace the Affordable Care Act, here are a few suggestions that general counsel at health care-related companies should consider as they navigate the evolving health care landscape:

### Exit unprofitable markets

With low visibility in the marketplace, exiting from unprofitable ACA exchange markets could help health insurance issuers both to reduce potential liability and strengthen their bottom lines.

### Talk to your state regulator

Under the theory that it’s better to communicate than not, issuers—if they haven’t already done so—should establish a dialogue with their state regulator to assess their options for remaining in compliance with state law at least through 2018. The state regulator should be able to identify measures that would be most effective.

### Take advantage of actuarial flexibility

The new stabilization rule issued in April by HHS and its Centers for Medicare & Medicaid Services allows issuers additional actuarial flexibility in determining premium rates. Issuers should take advantage by offering insurance plans with lower premiums to attract new, presumably healthy, customers.

### Find new sources of funding

The expansion of Medicaid under ACA has allowed many safety-net and faith-based institutions to provide significantly more health care to those in need. If Medicaid funding declines or even dries up, these providers will need to find revenues elsewhere or be forced to provide less care.

### Stay vigilant and be prepared to zig and zag

Many physician and hospital organizations have come out against the proposals to curtail health care coverage included in the various iterations of repeal-and-replace. All providers should monitor these changes closely to determine how their businesses would need to adjust.



“As well intentioned as it originally was, the Stark Law [is] both out of step with current trends...and overly punitive of violations.” —Troy Barsky

as health insurance issuers, medical device manufacturers, and pharmaceutical companies.

- Requiring federal agencies to use their authority and discretion to provide greater flexibility to states.
- Instructing agencies to create a more free and open health care market consistent with ACA replacement proposals to permit the sale of health insurance products across state lines.

So, as Congress began to traverse the political minefield of repeal-and-replace, HHS and its Centers for Medicare & Medicaid Services released a final rule on April 13 “that will help stabilize the individual and small group markets and affirm the traditional role of State regulators.” In a press release announcing the final rule, CMS Administrator Seema Verna said, “While these steps will help stabilize the individual and small group markets, they are not a long-term cure for the problems that the Affordable Care Act has created in our health care system.”

The press release cites the following statistics related to ACA as problematic:

- Approximately one-third of U.S. counties have only one issuer participating in their health insurance exchange for 2017.
- Five states have only one issuer participating in their exchange for 2017.
- The premium for the benchmark second-lowest-cost “silver plan” on Healthcare.gov increased by an average of 25 percent from 2016 to 2017.
- Approximately 500,000 fewer Americans selected a plan during the exchange open enrollment period in 2017 than in 2016.
- Many states saw double-digit increases in their insurance premiums, notably:
  - Arizona: 116%
  - Oklahoma: 69%
  - Tennessee: 63%
  - Alabama: 58%
  - Pennsylvania: 53%

## KEY CHANGES

The final rule focuses on changes in six areas:

- **Open enrollment.** The rule shortens ACA’s insurance exchange open enrollment period to 45 days (i.e., November 1 through December 15, 2017) from 62 days (i.e., November 1, 2017, through January 31, 2018). This aligns open enrollment for exchanges with the open enrollment periods for employer insurance plans and the Medicare Advantage program. By modifying the enrollment period, CMS hopes to mitigate adverse selection by requiring individuals to enroll before the benefit year begins and pay premiums starting on the benefit year’s first day—rather than allowing individuals who learn they’ll need services in late December and January to enroll at that time.
- **Special enrollment period.** In response to perceived abuses of special enrollment periods—which allow individuals to enroll outside of the open enrollment period when there is a special circumstance (e.g., a new family member)—the rule requires verification of an individual’s SEP eligibility 100 percent of the time beginning in June 2017 (currently, SEP eligibility is verified only 50 percent of the time). The rule is limited to pre-enrollment verification of eligibility to individuals newly enrolled through SEPs in marketplaces using the Healthcare.gov platform. It also limits certain individuals’ ability to switch to different levels of coverage during a SEP. Christine Clements, a partner in Crowell & Moring’s Health Care Group, notes, “The SEP provisions may offer the most significant relief of all the rule’s changes.”
- **Network adequacy.** The rule reflects ACA opponents’ belief that the federal government should relinquish significant control of the health care system’s operation to the states and thereby reduce the waste of tax dollars on duplicative federal reviews of network adequacy. In an effort to make it easier for issuers to meet network adequacy requirements to participate in plan exchanges, the rule removes federal time and distance standards for health care provider networks in favor of state requirements. It also allows issuers to add essential community providers who weren’t identified on HHS’s website as available ECPs for 2018 and would reduce the ECP enrollment standard in a network to 20 percent from 30 percent.

- **Guaranteed availability.** Because ACA guarantees availability of health insurance coverage, issuers have long complained that enrollees could stop paying premiums and, instead, sign up for coverage again under a different product from the same issuer without any penalty. The rule attempts to remedy this by allowing issuers to require individuals to pay back past-due premiums before enrolling in a plan with the same issuer the following year. Issuers may exercise this new flexibility only to the extent permitted by state law. This change applies both inside and outside of the exchanges in the individual, small-group, and large-group markets and during applicable open enrollment or special enrollment periods.
- **Determining level of coverage.** The rule adjusts ACA's *de minimis* range used for determining the level of insurance coverage by giving issuers greater flexibility to provide patients with more coverage options.
- **Qualified Health Plan certification calendar.** In light of the need for issuers to make modifications to their products

and applications to accommodate the rule's changes, CMS concurrently issued separate guidance to update the QHP certification calendar and the rate review submission deadlines to give additional time to issuers to develop—and states to review—form and rate filings for the 2018 plan year that reflect the changes.

Clements isn't convinced that the rule will accomplish its goal of stabilizing the insurance marketplace while a revised repeal-and-replace bill takes shape. "While we think the rule has some helpful elements and features that health issuers have asked for," she says, "it's not going to change the overall uncertainty of where the marketplaces and health exchanges are going. We need a bill that a majority of Republicans support. Only then will it be realistic to talk about stability."

The rule's public comment period was unusually brief—a mere three weeks that ended March 7. Among the reasons CMS cited for the period's brevity was the necessity "to implement these changes in time to provide flexibility to issuers to help attract healthy consumers to enroll in health insurance coverage, improving the risk pool and bringing additional stability

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## THE STARK LAW: ON THE WAY OUT?

Unlike the Affordable Care Act, it appears that few lawmakers of any political stripe would mourn the demise of the Stark Law.

The Stark Law is a federal law prohibiting the referral of Medicare patients to an entity in which the referring health care professional has a financial interest. It originated as the Ethics in Patient Referrals Act introduced by former Rep. Pete Stark of California and was passed by Congress in 1989. Over the years, it has expanded through a series of legislative amendments and volumes of interpretive regulations.

"There's much about the Stark Law that should be changed," says [Troy Barsky](#), a partner in Crowell & Moring's Health Care Group and former director of the Division of Technical Payment Policy at CMS, who is actively engaged in efforts to revise the law. "As well intentioned as it originally was, it has grown into something that's both out of step with current trends in health care delivery and overly punitive of violations."

### OUT OF DATE

Perhaps the fundamental problem with the Stark Law is that it applies to the fee-for-service model of health care, in which doctors are paid by health insurers for services they perform rather than incentivized to produce better patient outcomes by collaborating with other health care providers. The medical world is decidedly moving toward outcome-based compensation models and away from fee-for-service.

Barsky points out that the Stark Law is a strict liability law, meaning that it can be legally violated even without proof of specific intent to violate. And violations are very costly. "Any provider organization that violates Stark," he explains, "must repay all Medicare funds paid under the arrangement deemed violative, which could amount to tens of millions of dollars. The organization could also face exclusion from the Medicare program and liability under the False Claims Act. The Department of Justice, in fact, uses the Stark Law to bring fraud claims, and in some cases has interpreted the statute inconsistently with the administrative agency designated to implement it."

As if this weren't enough, the Stark Law is so complex and contradictory that compliance with it can be a major challenge. "It rivals the tax code in this way," Barsky notes.

### FORECAST: QUIET IN THE NEAR TERM

At the moment, there's little congressional activity to address the Stark Law. This could change, however, once Congress has dealt with the Trump administration's more urgent legislative priorities. Activity could take the form of outright repeal or substantive revision.

"The current emphasis on reducing regulation could prove very positive for the Stark Law," says Barsky. "The law offers a great opportunity for simplification, and there's bipartisan support for doing something about it."



“There remain big gray areas as to what actually constitutes information blocking and what practices are ‘reasonable and necessary.’” —*Jodi Daniel*

and certainty to the individual and small group markets for the 2018 plan year.” Clements points out that “Fast action was also needed in light of the Republicans’ failure to get AHCA to a vote. The administration needed to send a signal to issuers.”

## TAKING THE SUBREGULATORY ROUTE

In addition to formal rules such as what HHS and CMS have issued, the government can take other avenues to propose and promulgate policies. The subregulatory route, which uses memos and other directives instead of rules and legislation, should be particularly popular, according to Clements.

HHS and CMS fired their opening subregulatory salvo in mid-March in a letter to state governors signed by HHS Secretary Tom Price and CMS Administrator Verma. The letter reaffirmed the administration’s commitment to giving more control of the health care system to the states, specifically with regard to Medicaid.

It named several areas as especially appropriate for greater state-level control: program management, ways to increase employment and community engagement, alignment of Medicaid and private insurance policies for non-disabled adults, “reasonable” timelines and processes for home- and community-based services transformation, and giving states more tools to address the nation’s opioid epidemic. “If Republicans are unable to agree on a repeal-and-replace bill, then we will see a lot of activity at the regulatory and subregulatory levels to limit the impact of ACA requirements,” Clements says.

## CURING MULTIPLE PROBLEMS IN A SINGLE ACT

While the battle to repeal and replace the Affordable Care Act is the focus of health care policy discussions, another important piece of health care legislation—the 21st Century Cures Act—has stayed under the radar.

The Cures Act, which was approved by Congress and signed into law in December 2016, was designed to “reform discovery, development, and delivery of new treatments and cures and maintain America’s global status as the leader in biomedical innovation.” It consists of three parts, each known as a division:

- Division A focuses on National Institutes of Health funding and administration of programs including precision

medicine, the cancer moonshot, reducing opioid abuse, and modernizing medical research and drug development. It also contains significant provisions to promote health information technology and the exchange of health information.

- Division B (originally a separate mental health bill) addresses, among other things, the prevention and treatment of mental illness and substance abuse and communication permitted by HIPAA.
- Division C concerns Medicare programs and federal tax laws related to health plans for small employers.

As a bipartisan bill that was passed in a divided Congress, the Cures Act sets a substantive agenda for 2017 for the Department of Health and Human Services. There is something for everyone, but we focus here on digital health provisions.

## BLOCKING COULD GET YOU TACKLED

Several of the Act’s health information technology-focused aspects are noteworthy across the health care sector, says [Jodi Daniel](#), a partner in Crowell & Moring’s Health Care Group and former director of the Office of the National Coordinator for Health Information Technology. One is a section of the new prohibition against information blocking, which is loosely defined as when a health care provider knowingly takes action likely to interfere with the access, exchange, or use of electronic health information and the practice is considered “unreasonable.”

“The law’s intention to promote the availability of information to support patient care is laudable; however, there remain big gray areas as to the scope of authority, what actually constitutes information blocking, and which practices are ‘reasonable and necessary,’” says Daniel. “Entities should be watching and participating in policy discussions because HHS can penalize you as much as \$1 million per information-blocking violation.”

HHS intends to publish regulations to provide greater clarity on information blocking, but this may take time in a new administration. “Health care parties should look for opportunities to educate HHS on the line between information blocking and important practices that protect patients and health care organizations,” Daniels notes.

She also recommends that health care providers and health care technology companies revisit their current policies

and practices concerning the exchange of electronic health information with an eye to aligning them more closely with the Act's objectives.

## ENCOURAGING PATIENTS' ACCESS TO HEALTH DATA

The Cures Act focuses on patients as well as health care-related entities. While patients have had a right of access to their health information for about 15 years, few ask for or succeed in getting copies of their records. The Act takes additional steps to address some of the challenges: It provides for business associates (including health information exchange organizations) of health care providers and health insurance plans to provide access to patients, encourages HHS to consider obligating health IT developers to meet certain requirements regarding electronic patient access when they certify their products, and requires additional education on the obligations to make patient records available to individuals.

Daniel says, "If you aren't making it easy to provide patients with access to their health information, you should look at your practices and consider making changes. If you are a health IT developer, you should anticipate these needs of your customers by considering patients as users of your systems or creating new products to meet the needs of individuals who can access their patient records." She expects new regulations or guidance to meet the new patient access provisions in the Act.

## NOT ENOUGH FOR TELEHEALTH

Another provision of the Cures Act that Daniel notes concerns telehealth services for Medicare beneficiaries. Existing law restricts the location of the patient at the time of the telehealth encounter to a certain type of health facility that must be located in a rural area.

"Telehealth allows health care providers and their patients to interact directly while being in different locations," she says. "It's a technology with great potential to widen access to health care while reducing costs."

But the Act doesn't change the existing telehealth rules. Instead, it authorizes the Centers for Medicare & Medicaid Services and the Medicare Payment Advisory Commission to study the matter and report on it to Congress within a year of the Act's passage.

"This is a disappointment to those who were hoping for expanded access to telehealth," notes Daniel. "But it at least shows that Congress wants to put its thumb on the scale now and intends to address the issue going forward. I anticipate additional interest in promoting telehealth in Congress this year."

## FDA LOSES AUTHORITY OVER HEALTH IT DEVICES

Congress limited the Food and Drug Administration's authority and oversight over the safety and effectiveness of health IT devices that previously were considered medical devices under

the Food, Drug and Cosmetic Act. The Cures Act provides that certain software functions, including those that are designed to create, store, transfer, or maintain electronic patient records, are no longer "medical devices" and thus not subject to FDA regulation.

"While this is consistent with FDA guidance, it significantly limits the potential for safety oversight of new health technology that doctors rely on every day," says Daniel.

However, Congress demonstrated some concern about the impact on safety and enabled HHS to regulate technology in this category if it is determined that the function would be reasonably likely to have serious adverse consequences and HHS provides notice. As Daniel notes, "Although the change in FDA oversight should provide health IT developers with greater certainty, HHS's ability to increase its scope of authority leaves ambiguity for these companies." HHS is expected to issue reports on medical software, risks and health benefits, and best practices in the next year or two.

## TARGETED RESEARCH FUNDING, LOWER ADMINISTRATIVE BURDENS

Two additional aspects of the Cures Act concern funding for specific medical research programs and the reduction of administrative burdens in several areas. Many of the areas of research focus will necessarily rely on health IT.

The Act provides NIH with a total of \$5.1 billion to be distributed over the next three to 10 years on four targeted medical research programs: the Precision Medicine Initiative to advance biomedical discoveries, the Cancer Moonshot Initiative, the Brain Research through Advancing Innovative Neurotechnologies Initiative, and regenerative medicines research using adult stem cells. Much of this research wouldn't have been possible without the growing amount of clinical data in electronic form and the exponential improvements in health care data analytics.

Daniel points out that the importance of this funding goes beyond the government's commitment of money and time. "It signals what NIH is thinking to the academic research community," she says. "This provides implicit direction as to what their research efforts should emphasize in the next few years."

As for steps to reduce administrative burdens, Daniel notes there are many, but highlights the goal of minimizing duplication of regulations and policies regarding financial conflict-of-interest disclosure for all research-funding agencies, and easing monitoring requirements for research grant subrecipients. Again, there should be regulatory activity to implement these changes.

Looking ahead, Daniel sees further benefits from the Cures Act. "We expect significant regulatory changes and guidance from across HHS in support of the Act over the next two years," she says. She adds that the limitations placed on agencies by the January 30, 2017, executive order that aims to reduce regulations will need to be worked through in order to bring about the modernization and promote the bipartisan changes adopted in the Act.