REGULATORY FORECAST 2017
Special Report: What Trump Means for Business

OPPORTUNITIES AND RISKS IN THE NEW ERA

HEALTH CARE, ENVIRONMENT, AND MORE

HOW REGULATORY REFORM WORKS
NEW OPPORTUNITIES AND CHALLENGES FOR BUSINESS

This is Crowell & Moring’s third annual Regulatory Forecast. Along with our Litigation Forecast, this volume has previously been published in January, to help readers plan for the year ahead. But this is no ordinary year, and we realized this Forecast would benefit from an assessment of President Trump’s first 100 days, rather than trying to imagine in January how this administration would effectuate its many promises and bold ambitions.

One hundred days in, the transition continues. Some plans have gone smoothly; with others, it’s too soon to tell. This puts more responsibility on our readers to figure out how to make what some see as the opportunity of a lifetime work for them—advocating for the repeal of regulations they find onerous, participating in key government affairs processes, and making friends with agencies to bring about change that is good for business.

In putting this book together, our guiding principle, as both the co-editors of this book and the co-chairs of Crowell & Moring’s Administrative Law & Regulatory Practice, was to provide information that will help you better understand what’s on the horizon and what you can—and should—do about it.

This first year of a presidency is critical. By next year, the congressional elections will be underway; the following year, a new Congress could redefine priorities. Then it’s back to campaigning for the presidency. For businesses, there is work to do. Crowell & Moring is ready to help.

—Dan Wolff and Richard Lehfeldt

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The reality of the first 100 days of the Trump presidency may not be playing out exactly as outlined during the campaign, but the bottom line is that Trump’s approach to regulation presents a fresh opportunity for businesses to reexamine their objectives in Washington.

HOW WASHINGTON IMPACTS BUSINESS

With great change comes great opportunity. And there’s no denying that Washington has entered a time of great change. A new pro-business administration has made it its business to rethink, roll back, and repeal a raft of regulations that industry has been rallying against for most of the past decade.

Just how this will play out, which regulations will survive, which will die, and which will be freshly born remains to be decided. As we’ve seen in the battles raging around health care reform, change is more easily desired than done. Regulations are complicated and feature equally complicated politics. As you’ll see on page 18, while the road to reform is well-defined, the steps can be anything but easy to navigate.

But navigation is critical. Engaged participation can make a difference; it can shape law and policy. Businesses owe it to themselves and their stakeholders to leverage the opportunities inherent in this dynamic environment.

Helping you navigate the new regulatory landscape is why we’re here. This volume is filled with actionable insights that our government-facing attorneys and professionals have gleaned from their years of government service and their daily interactions with government officials around the world, across a range of regulated industries. Feel free to connect with them to probe further. We also hope you will stay connected and monitor developments through our new series on regulatory change: Trump: The First Year at www.crowell.com/TrumpFirstYear.

—SCOTT L. WINKELMAN
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TRUMP’S REGULATORY TAPESTRY

BROAD BRUSHSTROKES, WIDE-OPEN SPACES, AND MAJOR OPPORTUNITIES

Two-term presidencies have a way of inducing collective amnesia when a new chief executive comes to town. So it’s worth remembering: a new administration always has different (and often dramatically different) objectives than its predecessor. At the same time, some things remain the same: the rulemaking process, the very similar process of “unmaking” a rule, and the unchanged role of the federal courts in this process. For corporations, a change in administration usually means both new opportunities and regulatory uncertainty. This same tension presents itself under the Trump administration, but seemingly to a greater degree at the extremes—with the president’s personal emphasis on deal-making, the opportunities appear to be enormously tantalizing, but the prognosis for his aggressive de-regulatory agenda remain very difficult to predict.

Industry shouldn’t wait. It should act. The reality is that the regulatory tableau is evolving but needs the input of the business community that Candidate Trump pledged to help. First-to-move companies have a potentially historic opportunity to make a difference in the regulatory arena, not just for this administration but for years to come.

“The fact of the matter is that the Trump administration has extended an open invitation to industry to come to Washington and share its ideas,” says Angela Styles, chair of Crowell & Moring and the former administrator for federal procurement policy within the Office of Management and Budget at the White House. “While with every new administration there are usually vast differences between campaign rhetoric and executive action once the new president takes office, what we’ve seen in the first 100 days of the Trump administration is that he really wants to make good on his campaign pledges. He’s clearly not content to cast aside as ‘rhetoric’ everything he promised in the campaign.”

So while Donald Trump’s presidency may not represent revolutionary change, neither does
it represent business as usual in the regulatory world—it’s more a reset against the backdrop of all the “inside-the-Beltway” constants. The bottom line is that President Trump’s approach to regulation presents a new opportunity for corporations to reexamine their objectives in Washington and to probe opportunities for achieving those goals.

TRUMP’S CAMPAIGN AGAINST THE “ADMINISTRATIVE STATE”

Trump launched his bold regulatory agenda in both general and specific ways. He gave early definition to his philosophy of scaling back the regulatory state through an executive order calling for the federal government to rescind two regulations for every new one it promulgates. And he took quick action on specific pledges made on the campaign trail by, for example, approving completion of the Keystone XL and Dakota Access pipelines, thus reversing two very controversial determinations of the Obama administration.

Indeed, literally from Day 1, Trump has shown a desire both to pull back on specific actions of his predecessor and to create the blueprint for longer-term shrinking of federal regulation. And in addition to his own direct actions, he moved quickly and successfully to fill the vacancy on the Supreme Court with a judge famously skeptical of agency authority (see sidebar, page 7). Moreover, his election has single-handedly emboldened Congress to utilize the Congressional Review Act to kill 13 regulations to date after having done so only once since its enactment 20 years ago (with still more CRA actions anticipated).

As the contours of the game board take shape, there are a lot of ways for businesses to move within it. Executive branch agencies are expressly asking the business community—in-deed, the public generally—for their input on which rules impose outsized economic burdens or no longer make sense.

“In a certain sense, it’s a jump ball,” Styles explains. “The Trump administration has made clear, and even acted on, its intentions in a number of regulatory areas, and that creates some tremendous opportunities. This president prides himself on being a dealmaker, and so far he has not presented agencies with ideological mandates. He wants to shake things up and get things done, and this approach provides a huge opening for businesses that may have felt they’ve been waiting eight years or even longer for just this moment.”

To be sure, every administration undergoes shifts in regulatory priorities, particularly when control changes from one party to the other. And Styles notes that while Trump may represent a bigger shift than usual, it’s not as though we’re without historical comparisons. President Ronald Reagan, for example, also took a big swing at the regulatory apparatus, deregulating airlines and savings and loans with tremendous consequences for each industry and for America. Business should recognize the similar opportunities presented by Trump.

Despite moving quickly to effectuate some of his campaign promises with regard to regulation, much uncertainty remains. For example, Candidate Trump repeatedly promised to revive the U.S. coal industry, and President Trump moved quickly to begin rescinding the prior administration’s Clean Power Plan, a comprehensive greenhouse gas reduction rule. But what now? How this and other similar incomplete puzzles will be filled in is where the business opportunity exists. To help shape the regulatory agenda, as opposed to merely waiting to do business in it, the time to act is now.

“Time is of the essence,” Styles says. “The senior leader-

“President Trump wants to shake things up and get things done, and this approach provides a huge opening for businesses.”

—Angela Styles

“Gorsuch believes the duty to interpret the law—even ambiguous law—rests properly with the courts and not with the executive.”

—Tom Lorenzen
ship teams have landed in all the agencies and White House components, and now is the time to develop your policy goals and help shape the administration’s.”

Opportunities for businesses to effect regulatory change will come in four main buckets, Styles suggests:

- **Executive orders**: Out with the old, in with the new. President Trump has already used his unilateral authority to reverse previous executive orders by President Obama on several occasions. Executive orders, unlike regulations, are the classic “low-hanging fruit” in that they can be done and undone by a new administration with the stroke of a pen. And although executive orders are not regulations, “they have huge, practical, day-in, day-out effects in terms of executive agenda-setting,” Styles says.

  “Executive orders give definition to a president’s priorities,” Styles explains. “Through an executive order, the president is saying ‘this is what’s important to me and this is how we’re going to operate around here with respect to this or that subject matter.’”

- **Congressional Review Act rescission**: Another opportunity for swift reversal of burdensome regulations is the Congressional Review Act, under which agency rules promulgated during the last 60 legislative working days of the prior Congress may be rescinded by Congress, by a simple majority vote. The CRA window dates back to June of last year, and therefore covers a period during which the Obama administration finalized a flurry of final regulations that are currently up for grabs.

  The CRA was rarely used after Congress passed it in 1996, but the new Congress is making up for lost time. For example, Congress abolished a rule passed late in the Obama administration that required the Social Security Administration to identify individuals whose rights to gun ownership should be restricted. And it reversed the SEC’s “resource extraction” rule, a Dodd-Frank regulation...
requiring publicly traded mining, oil, and gas companies to disclose payments they make to foreign governments—a rule that many corporations viewed as federal overreach.

• “Two-For-One” regulatory relief: Trump’s “two-for-one” executive order poses a challenge and opportunity for every executive branch agency (but not the independent agencies), as well as an opening for the business community to focus on redundant or burdensome regulations that could be packaged with new proposed regulations.

“Two-for-one but also on businesses’ other concerns,” Styles says. “Businesses can help get the wheels in motion.”

• Enforcement discretion: In most cases, agencies have broad discretion to choose which areas of their enforcement authority they choose to prioritize. “Although agencies are charged with, and have an obligation to do, whatever Congress says needs doing by statute, they have a lot of discretion in execution as well as prosecutorial discretion in enforcement,” Styles says. This discretion can have important ramifications in areas such as environmental policies, workplace safety and health, financial regulation, and consumer protection.

Republican administrations typically approach administrative enforcement through more public-private cooperative models of regulation rather than measuring success through citations and civil penalties, and that is virtually certain to be the case in this administration. So, for example, the IRS is in the process of redesigning its model for auditing large businesses with the goal of making the process more collaborative. The IRS is looking to work more with taxpayers to identify and resolve issues earlier in the process and thereby avoid contentious, costly litigation.

SETTLING IN FOR THE LONG HAUL

Much political and media attention has been paid to the four swifter forms of intervention described above. But after the initial blitz of executive orders and CRA rescissions, the new administration is now staffing up and settling in for the time-honored and arduous process of rulemaking and legislating that will determine the arc of this presidency. Business leaders have the opportunity to influence actions in a variety of regulatory areas. While “repeal and replace” will no doubt be a popular refrain in the halls of many agencies, savvy companies will also be looking to this administration to shape regulation through entirely new, albeit more business friendly, regulatory programs that will provide for certainty and consistency—and that will outlive this administration.

Be that as it may, while businesses should be gearing up to engage in what is clearly a new era in federal regulation, they shouldn’t necessarily expect easy, quick, or always favorable results. Both rescinding regulations and promulgating new ones will take time and will invite lengthy, complex litigation. Congress will continue to have a huge role, and legislating—even with Republican majorities in both houses—does not guarantee easy success, as shown by Congress’s recent attempt to “repeal and replace” the Affordable Care Act.

In addition, as the federal government moves to push authority increasingly to the states in areas such as health care and environmental regulation, a new brand of federalism may emerge that the business community will have to grapple with. If regulatory authority recedes in Washington

“President Trump has made one thing clear: He wants to do regulatory reform in the interest of unleashing more economic growth.” —Jim Flood

“Americans are looking for Washington to take action on the issues that keep them up at night. The issue that matters the most is the economy.” —Scott Douglas
and devolves outward to the states, businesses operating across state lines will need to bone up on their state programs, especially in areas where compliance is no longer being dictated from Washington.

“The best advice we can give to our clients is neither to overreact to some of the more sweeping remarks that have characterized the first 100 days of this new administration, nor to sit back and wait for things to happen,” Styles advises. “The opportunity to engage with Washington is now.”

CONGRESS’S ROLE IN SHAPING REGULATORY STRATEGY

Regulatory reform isn’t just a hot topic at the White House. Congressional Republicans also want to notch wins for business.

“There is near unanimity across the Republican party on the need for regulatory reform,” says James Flood, chair of Crowell & Moring’s Government Affairs Group and former counsel to Senate Minority Leader Charles Schumer (D-N.Y.). “And President Trump has made one thing clear: he wants to do regulatory reform in the interest of unleashing more economic growth.”

Congress is likely to find Democrats working with Republicans on requiring more transparency and public disclosure from federal agencies in proposing new regulations. “These are basic reforms that Republicans and Democrats can agree upon, as well as modernizations that can get bipartisan support,” says Scott Douglas, a senior policy director in Crowell & Moring’s Government Affairs and Health Care groups who served as finance director for Senate Majority Leader Mitch McConnell.

“While in some circles compromise has become a dirty word, Americans are looking for Washington to take action on the issues that keep them up at night,” says Douglas. “The issue that matters most is the economy. Under a jobs-first agenda, there will be new discussions about tax reform, infrastructure investments, removing regulatory barriers for business expansion, and the need for access to quality education to train the workers of the future.”

However, Flood and Douglas note, Congress will have a far tougher time enacting tort reform, an initiative that has deadlocked legislators for decades, despite its popularity in the business community.

To be most effective in making arguments in any area of regulatory reform, business leaders should be prepared to explain how their priorities are consistent with the administration’s goals. “In addition to putting your best foot forward,” Douglas explains, “you must use the language they use and marry your agenda with the Trump administration’s agenda.”

MAKING AN IMPACT IS UP TO YOU

When you’re ready for your voice to be heard, here are some practical tips for how business leaders can engage with Washington:

Count the Cost
Track new proposals and calculate the economic impact on you. Devote resources in D.C. to the legislation and regulation that most hurts you. Tell lawmakers and regulators how the new bill or regulation will impact jobs, investment, and your ability to compete.

Go Through the “In” Doors
The Trump administration established a new Office of American Innovation to work with business leaders on making government more effective. Call it. And if you know any CEOs who now are on various White House advisory panels, contact them.

Don’t Wait
President Trump will continue to use executive orders and other “fast action” authority to cut regulation and spur the U.S. economy. Speak early and often. The opportunity will not be there forever.

Be Ready for Tax Reform
Tax reform affects every corporation in America. This administration’s efforts present the greatest opportunity for a major reset since the Reagan administration. Engage on the details of tax reform that impact your business.

Watch for Unexpected Openings
Rulemaking takes time, and the administration prefers not to regulate unless it has to—but be prepared to engage in the process, either proactively or defensively, when these opportunities arise.
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.

“Simply shifting some of the accountability for health care spending to individuals should make them smarter purchasers.”
—Christine Clements
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

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.

**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 for ensuring that they aren’t taking actions that could be considered information blocking.
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.
ANTITRUST

NEW WIND BLOWS IN AN OLD WIND

It appears increasingly likely that the Trump administration will take a traditional Republican approach to antitrust issues: tough on crime, friendly on mergers. But a de-emphasis on federal enforcement could create openings for states and international jurisdictions to become more aggressive.

A shift to a merger-friendly stance would be a significant change versus the immediate past. “The Obama years could be considered the high-water mark in terms of antitrust enforcement,” says Ryan Tisch, a partner in Crowell & Moring’s Antitrust Group.

“This was true as represented by several metrics, beginning with staffing,” Tisch elaborates. “Both the DOJ and the FTC added significant resources, notably trial lawyers, who were much more willing to litigate—and possibly lose—tough cases. As a result, enforcement was especially aggressive: the DOJ and the FTC blocked more than 40 mergers during Obama’s time in office. And they weren’t shy about using cutting-edge legal theories to make their cases.”

A KINDER, GENTLER ANTITRUST REGIME

But it’s a new day, with a new sheriff in town who is decidedly pro-business and strongly believes that the marketplace should be the final arbiter of whether companies succeed or fail. The nomination in March of Makan Delrahim as assistant attorney general of antitrust underscores that these tenets will likely form the foundation of antitrust policy going forward. [Note: At press time, Delrahim’s confirmation by the Senate was widely expected, but hadn’t yet occurred.]

Joe Miller, a partner in Crowell & Moring’s Antitrust and Health Care groups and former assistant chief of the DOJ’s Antitrust Division’s Litigation 1 Section, says, “Delrahim would set the tone for antitrust enforcement. He’s been a high-level antitrust lawyer in the George W. Bush administration as well as an M&A lawyer and understands how Washington works. Given his background, it’s reasonable to expect him to approach the job with a traditional enforcement perspective.”

That perspective rests on two fundamental presumptions: Mergers typically are beneficial to society because they create efficiencies in areas like pricing and distribution that work in favor of consumers. And classic laissez-faire: businesses should be allowed to duke it out in competition via mergers and other strategies because, ultimately, the marketplace will sort out who the winners and losers are.

For the DOJ and the FTC, this signals a return to merger analysis that rigorously focuses on economics and efficiencies. If a deal looks like it makes economic sense and will generate efficiencies, then it’s more likely to be approved.

As demonstrated by the markets, the financial community appears to expect a more merger-friendly approach. Merger arbitrage spreads—the difference between the actual stock price of a company involved in a pending merger and the presumably higher stock price at which the deal should take place—have narrowed. This indicates that investors are confident not only that deals will stand up to regulatory scrutiny, but also that deals will close at their announced prices.

THINGS TO THINK ABOUT

What should companies be thinking about if they’re considering merging or acquiring? Tisch has several suggestions:

- Expect economic analysis to figure prominently in regulators’ analyses.
- Think hard about the economic and competitive implications of your deal before setting plans in motion.
- Prepare to advocate for your deal under the assump-

“If we give other jurisdictions reason to believe that [the United States] is loosening up, they may feel compelled to become tougher on deals than they already are.” —Ryan Tisch

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tion that the new regime will listen to pro-competition deal stories—and that those stories will best be told via sophisticated economic analysis, customer reactions, and contemporaneous company documents.

WILD CARDS

Even if Delrahim is approved as the new DOJ antitrust head and the Republican view becomes standard policy, there are a couple of wild-card scenarios that could potentially reduce enforcement visibility into at least mid-2017.

One is the simple fact that the FTC doesn’t have its full set of commissioners. Currently, there’s only a Republican acting chairman and one Democratic commissioner, meaning that three seats—two Republican and one Democrat—are unfilled. “This could end up being a regulatory black hole,” says Miller. “The administration isn’t hurrying to fill these openings, and its plans aren’t clear. Proposed deals could languish as businesses decide whether to move forward in light of the regulatory uncertainty. If your deal is a close call, you want to know who fills those seats before you sign a definitive agreement.”

Another wild card is the possibility that the administration’s agenda on issues such as trade and jobs could somehow find its way into the antitrust review process. While the influence of politics to this extent would be unprecedented, Tisch cautions that it shouldn’t be ruled out. “Given the uncertainty surrounding so many policy areas, it’s important to remember that there are multiple scenarios that could play out,” he says. “But it’s too soon to tell. We’re eager to see what new leadership does and how it could affect antitrust decision making.”

POWER VACUUM?

Federal regulation isn’t the only game in town when it comes to antitrust. Depending on the nature of the transaction, there often are state-level hurdles to cross, and, in the case of big multinationals, non-U.S. jurisdictions come into play as well.

If the DOJ and the FTC end up taking an unequivocal hands-off approach, one consequence could be that the United States would cede some enforcement power to these other players. The question then becomes whether the other players would step up and try to fill the vacuum.

“There could easily be an uptick in state-level activity if federal enforcement recedes. This is something that companies should take very seriously,” Miller says. “While many states don’t allocate much in the way of resources to antitrust, some states do, and they can be quite aggressive. New York and California are good examples. Also, some deals can be very locally focused, such as hospital mergers. States definitely want to have a bigger say in what happens in their own backyards.”

Miller adds that Crowell & Moring is monitoring state enforcement agencies more closely and keeping clients informed of potential changes in their degree and range of oversight. As for deals with an international element, regulators outside the U.S. have become a greater presence in the past few years and continue to flex their muscles. They’ve also been coordinating their activities more closely than in the past.

Tisch warns that any perceived laxity in federal regulation could have adverse consequences for the United States. “The U.S. has long been the global leader when it comes to antitrust enforcement, and until now, many other countries have taken their cues from what we do or don’t do,” he says. “If we give other jurisdictions reason to believe that we’re loosening up, they may feel compelled to become tougher on deals than they already are. Companies should place greater importance on addressing the concerns of non-U.S. regulators, as well as to develop a unified deal narrative that could resonate with regulators in multiple nations.”

KEY POINTS

Back to the future
Antitrust enforcement policy will likely return to a traditional pro-competition stance.

Economics and efficiencies will be key
Regulatory analysis—and any deal’s chances of approval—will focus on economics and efficiencies.

Seize the day
Less federal enforcement could mean more from states and other countries.

“Delrahim would set the tone for antitrust enforcement. Given his background, it’s reasonable to expect him to approach the job with a traditional enforcement perspective.” —Joe Miller
PATHWAYS FOR REGULATORY REFORM

1. DEVELOPING THE POLICY
After you determine your regulatory agenda, work with both the relevant agency and the White House to help them formulate an acceptable policy. Even a simple rescission can take weeks to formulate, as the agency must have a sound basis for its action. Administering a buy-in for a proposed new regulation can take considerably longer. Expect other stakeholders to push their own competing views at the same time!

2. DRAFTING THE PROPOSED RULE
Work with the appropriate agency to formulate the proposed rule or rule rescission. This can be complicated, because the rule may be required by statute, a judicial decision, or a settlement. It can result from the agency's own initiative, or you can formally petition the agency to initiate a rulemaking. Bear in mind that in many instances, there are no hard deadlines for action.

3. COMMENTING ON THE PROPOSAL
Once a rule or rule rescission has been proposed, it's open for public comment—from anyone in the world—through public hearings and written comments directed to the agency through www.regulations.gov.

4. FINALIZING THE AGENCY ACTION
After considering public comments, the agency prepares a final action. Problems with the draft final rule can be addressed through OIRA, which, after a review process involving all interested federal agencies, may bounce it back to the proposing agency for further review and change. OIRA will meet with stakeholders during this process to hear their views, but will not express its own.

5. PUBLISHING THE FINAL ACTION
After the public and interagency comments have been considered, the agency publishes its final action (either a rule, a rule rescission, or a decision not to issue a final rule), together with a response to all public comments and all required technical support documents. Notice of the agency's final action is published in the Federal Register. Supporting documents are available at www.regulations.gov.

6. JUDICIAL REVIEW
New regulations, decisions not to regulate, and rescission actions all can spawn litigation. Those affected by agency final action can seek the court's review of whether the agency's action is authorized by statute and whether its conclusions are supported by the record it developed. There is generally no discovery; the agency's record serves as the evidence. Regulations may also be stayed under special circumstances pending judicial review. If the Supreme Court grants review, that can add another full year of litigation.

6A. CONGRESSIONAL REVIEW ACT AND APPROPRIATIONS
"Major" regulations (those with $100M or greater effect on the economy) are generally subject to review by Congress for a period of 60 legislative days under the CRA. Regulations subject to the CRA may be voided by a simple majority vote of both houses, subject to presidential veto. If a rule is voided through the CRA, the agency cannot adopt a "substantially similar" rule without express congressional authorization. Older regulations can be rescinded through the appropriations process, by cutting off funds for implementing the rule.

7. IMPLEMENT, REVISE, RESCIND
Once congressional and judicial reviews are completed, the action returns to the agency. If that action is a regulation, it's either implemented—if it has been upheld—or rewritten or abandoned, if it was invalidated or remanded. If the action is a rule rescission and the courts or Congress have not invalidated it, the agency strikes it from the books.

As the business community, encouraged by the Trump administration’s pro-business policies, anticipates the review and possible repeal or revision of regulations that have hampered their ability to operate and grow, it’s important to understand the complex process by which regulations both come into being and cease to be. The process—which is virtually the same whether you’re proposing the development or the dismantling of a regulation—is as straightforward as anything you learned in middle school civics. Yet, at the same time, there’s nothing straightforward about it. The seemingly simple path shown in the diagram is actually rife with pitfalls, potholes, and detours. A proposal or rescission can be changed or derailed at many points: during policy formulation or the public comment period, during interagency review (run by the Office of Information and Regulatory Analysis, a little-known yet very powerful arm of the White House’s Office of Management and Budget), in ensuing litigation, or through congressional review. Above all, the process takes time. Lots of time, including a 30- to 60-day waiting period before implementation, even after the final rule is issued. “Anyone who believes a new rule can be put in place, or an old one rescinded, in days or weeks is in for a surprise,” says Crowell & Moring partner Dan Wolff. “Stakeholders should be prepared for a lengthy process involving development and presentation of positions on favorable outcomes, submission of comments once a rule or rule rescission is proposed, and likely litigation over any final agency action.”
The Trump administration has made energy and environmental policy a top priority and has outlined some of the regulatory reforms it intends to pursue, including easing major regulatory burdens on industry, promoting coal production and consumption, and shifting authority from the federal government to the states. While these initiatives would represent a departure from many of the Obama administration’s priorities, they would not necessarily reverse other objectives that the prior administration held near and dear, such as improving the nation’s power grid and loosening regulatory burdens on infrastructure development. President Trump’s promotion of coal as an energy source, for example, doesn’t necessarily equate to a rejection of renewables.

WHAT WE KNOW:
R.I.P. THE CLEAN POWER PLAN AND THE WATERS OF THE UNITED STATES RULE

As a candidate, Trump promised to rein in the Environmental Protection Agency, which he alleged was making it too difficult for energy companies to develop and operate their facilities. He also criticized the Obama administration for legislating by executive order, sidestepping both Congress and the courts. The installation of Scott Pruitt—who as Oklahoma attorney general sued the EPA at least 14 times—to lead the EPA underscored the president’s commitment to making the agency more business friendly.

Within its first 100 days, the administration has made a significant down payment on its promises with regard to two recent and controversial EPA rulemakings: the Waters of the United States rule and the Clean Power Plan, both of which are on appeal in the federal courts. On February 28, 2017, the president signed an executive order directing the EPA to review and reconsider the WOTUS rule, and on March 28, the president ordered the EPA to “take all steps necessary” to review, suspend, revise, or rescind the Clean Power Plan, including all legal guidance developed in support of that rule. On April 28, 2017, the D.C. Circuit granted a 60-day abeyance of the case and ordered supplemental briefing on important procedural matters.

These EOs, while very significant, are only the beginning of a lengthy regulatory process that is certain to result in protracted litigation. “The administration’s swift action on the WOTUS rule is no surprise,” says David Chung, a partner in Crowell & Moring’s Environment & Natural Resources Group. “But undoing a final regulation itself entails a rule-making process, whether the administration simply rescinds the rule or whether it rescinds and replaces it. Whether the forthcoming rulemaking actions stick is an entirely different question. So there is significant uncertainty.”

The WOTUS rule asserts EPA power over every creek, pond, or other wet spot with a “significant nexus” to a “navigable waterway.” President Obama said its purpose was to “provide the clarity and certainty business and industry need about which waters are protected by the Clean Water Act” and hold polluters accountable. But interests in homebuilding, agriculture, and other industries rallied against the rule because of the power it could give the EPA to penalize them if, for instance, a farmer uses fertilizer in or near a ditch.

Because of President Trump’s and Administrator Pruitt’s opposition to the WOTUS rule, as well as its uncertain status on appeal, “we don’t expect any aspect of the WOTUS rule to go into effect this year, if ever,” Chung says. “The questions are, how will it be pulled back, and what will replace it. Nothing is locked in yet.” Interestingly, the U.S. Supreme Court recently decided not to stay proceedings on the narrow issue of whether facial challenges to the WOTUS

“Simply counting on the states to perform federal statutory mandates doesn’t make those mandates go away.”
—Larry Eisenstat
rule belong in a federal district court or a court of appeals in the first instance. But those proceedings have no bearing on the merits of the rule.

The March 28 EO on the Clean Power Plan, one of Obama’s signature regulatory achievements, has broad implications for the nation’s environmental and energy policy. The final rule, promulgated in 2015, was the first national regulation to address carbon emissions from new and existing power plants and was announced as a historic and important step in reducing national greenhouse gas emissions and curbing climate change. The Obama EPA characterized the Clean Power Plan as offering the utility sector “the ability to optimize pollution reductions while maintaining a reliable and affordable supply of electricity for ratepayers and businesses.”

Opponents of the plan (including Pruitt, then attorney general of Oklahoma) have fought the Clean Power Plan on a number of grounds, including allegations that the EPA exceeded its legal authority and impinged on core state prerogatives with regard to resource planning and the development of electric power infrastructure, and the concern that the Clean Power Plan represents an economically destructive, “job-killing” approach to curbing carbon dioxide emissions. Many of the rule’s opponents, including the president, have also challenged the science that supports greenhouse gas reduction policy.

Today, the rule remains stayed by the Supreme Court while pending before the D.C. Circuit, and has been publicly disavowed by the new administration. The EO does not moot the pending D.C. Circuit appeal of the Clean Power Plan, but it essentially ensures that the Clean Power Plan will not become the law of the land. What replaces it, however, will be litigated for many years to come, and may ultimately be addressed by Congress.

If the Trump administration simply scraps the Clean Power Plan, the rule’s opponents—many of whom have already turned to state-level opposition to new federal regulations—will continue to challenge the EPA’s authority and the science that underpins its efforts to address climate change. The EO brings into sharp focus the administration’s determination to roll back the costly regulation pushed under Obama, but leaves the future of climate change policy in limbo.

THE SOCIAL COST OF CARBON

Some of the later Obama administration regulations justified their promulgation in part on cost-benefit analyses that assumed a “social cost of carbon.” Implicit in this recognition was the idea that carbon dioxide and other greenhouse gases are causing global climate change and, therefore, that decreasing the output of such gases could help roll back man-made climate change. For example, the previous administration cited the “avoided carbon” and its social costs as factors to be considered when weighing alternative power resources that would emit less greenhouse gases than, say, a new coal-fired plant, or that might replace an existing coal-fired place—ipso facto, putting such a “cleaner” facility online would yield the “benefit” of reducing the emissions of greenhouse gases from the older or differently sourced power plant it replaced and therefore produce a significant environmental benefit.

President Trump’s March 28 EO tackled this issue head-on, directing the elimination in all federal agencies of the “social cost of carbon” metrics used by the prior administration and disbanding the interagency working group established by Obama to assess those costs. In an administration that has already announced that it will lessen regulatory costs imposed on the business community, the burden of justifying new regulation will go up by definition if agencies are either directed not to consider a social cost of carbon or are directed to heavily discount that cost.

“The extent to which the administration even recognizes carbon consumption as having a cost associated with it remains to be seen,” Crowell & Moring’s Larry Eisenstat says. “And it isn’t clear how it will treat any externality, any potential pollutant.”

“Those pipelines will probably get built. President Trump has made it clear that shale and fracking are things he wants to support.” —Elliott Laws

“Trade partners...each implementing aggressive, market-based climate policies, could retaliate...in a way that could have serious negative consequences.” —Tom Lorenzen
“Nuclear power is one of the cheapest energy resources, but it’s not recovering its fixed costs in the wholesale competitive power markets.” —Richard Lehfeldt

THE PRICE OF BACKING AWAY FROM PARIS CLIMATE COMMITMENTS

The Trump administration has questioned the scientific consensus underlying the landmark 2015 multilateral climate accord (the Paris Agreement) that was executed by President Obama in the spring of 2016. The goal of the Paris Agreement is to collectively limit the increase in global temperatures to no more than two degrees Celsius.

The new administration has already begun the process to rescind or substantially revise the Clean Power Plan, a cornerstone of Obama’s effort to achieve the Paris goals. But exiting the Paris Agreement could be risky, says Crowell & Moring’s Tom Lorenzen. Withdrawal could have broad economic policy implications, he says, that range from ceding competitive advantage in trade and technology innovation to China, to hampering job growth in clean energy and infrastructure development, and could also lead to trade wars. “Trade partners, including China and the EU, each implementing aggressive, market-based climate policies, could retaliate for our backing away in a way that could have serious negative consequences for the U.S. economy,” he says.

Plan and the WOTUS rule and shifts authority over air and water pollution to the states, an additional concern is whether the states are up to the task, notes Larry Eisenstat, a partner at Crowell & Moring and chair of the firm’s Energy Group. “Simply counting on the states to perform federal statutory mandates doesn’t make those mandates go away—it just shifts costs to state budgets, potentially invites diverse and conflicting interpretations of the law, and is certain to spur litigation for years to come,” he says.

The Clean Air Act and the Clean Water Act already encourage delegating authority to state environmental regulators, with the EPA acting as a federal backstop to support the states, foster uniformity, and ensure compliance, adds Elliott Laws, a Crowell & Moring partner, chair of the firm’s Environment & Natural Resources Group, and a member of the Government Affairs Group. When coupled with Trump’s proposed 31 percent EPA budget cuts, however, the states will be called on to shoulder statutory responsibilities they may not be able to afford and that are certain to invite citizen suits that will sap scarce resources further.

WHAT WE DON’T KNOW: THE ROAD BACK TO “TRADITIONAL” ENERGY RESOURCES

The Trump administration has already announced that it will review another milestone of Obama’s environmental legacy: a stiff ramp-up in requirements for improved automotive fuel economy and reduced emissions. Automakers requested this review, claiming that they are unable to meet the higher standards in time, and that there is insufficient consumer demand for the types of smaller or electric-powered vehicles on which the companies are depending to meet the standards. The Trump administration could seek to rescind or delay the fuel economy standards and could also move to strip some of the federal tax credits that were put in place to promote the commercialization of all-electric and plug-in hybrid vehicles.

The Trump administration has already weighed in forcefully on energy production and the development of energy-related infrastructure. Among the first EOs signed by Trump authorized completion of the Keystone XL and Dakota Access natural gas pipelines—both projects the Obama administration held in abeyance after environmentalists objected. “I think those pipelines will probably get built,” says Laws. “President Trump has made it clear that shale and fracking are things he wants to support.”

Trump also has put a major emphasis on reviving the coal industry, which has been stymied both by historically low natural gas prices and by Obama-era environmental regulations. “It will be interesting to see how the president and his agencies balance their goal of wanting to preserve coal and coal-fired plants against their preference for free markets and competition, because right now coal-fired generation is above market,” says Eisenstat. “The president may not want to pick winners and losers or subsidize various technologies for cleaning up coal. But in today’s market, various coal plants would have to be subsidized in order to stay in operation or be built.”

“Elections have consequences,” said President Obama in 2010, and the new administration could appropriately seek to put its thumb on the scale for the coal industry much as the prior administration did for renewables and demand response—through direct subsidies, tax reform, research and de-
development, and procurement policy (the federal government being the largest electricity consumer in the country). But all of these come at substantial literal and political cost. Undoing regulations is more difficult than Candidate Trump made it out to be, and it is not likely to revive the coal industry on its own; the next steps in that initiative are largely unwritten.

THE ROLE OF REGULATION

“The good news for the utility industry is that the president has singled out the power grid as something that must be significantly augmented for reliability and security purposes,” Eisenstat says, “and that he wants to plow $1 trillion into rebuilding the nation’s infrastructure.” Electric power infrastructure has traditionally been financed through ratepayer charges, rather than through the federal authorization and appropriations process, and that makes such development potentially easier politically.

The administration could help support electric infrastructure development in at least two ways. It could throw its weight behind efforts to liberalize and speed up the approval process for new transmission lines and upgrades to existing lines. Interstate transmission lines now require regulatory approvals from all states through which the line passes, giving effective veto power to any state on the line. Congress last tried to give the Department of Energy and the Federal Energy Regulatory Commission limited federal backstop authority to override a state’s refusal to approve a transmission line in the 2005 Energy Policy Act, but successful challenges to that provision all but neutered its effectiveness. The underlying problem still needs to be addressed: if the nation’s transmission system is to be strengthened and modernized, the century-old regulatory structure supporting its development has to be reexamined, streamlined, and rationalized.

A different issue has emerged with regard to power plant development and plant life extension. Last year, in the Talen v. Hughes case, the Supreme Court held that supplemental payments to the developer of a new natural gas power plant, authorized by the state of Maryland and effectuated through contracts that compensated the developer for the difference between the PJM cost of power and the competitively bid cost of actually building the plant, were preempted under the Federal Power Act.

The Court made clear that its decision was limited to the particular facts, but the Talen case has spawned numerous disputes before FERC and several state regulatory commissions, in federal district court cases, and in an ongoing technical conference at FERC, all asking the same question: under what circumstances may a state within a wholesale competitive market provide additional payments to a developer to build or (in the case of existing plants) continue to operate plants it wants to include in its resource mix? Some market participants have taken the position that any payment that exceeds the market price may be an unconstitutional subsidy, and FERC and DOE are looking for middle ground in what will be a long dispute.

This evolving battle has significant ramifications for nuclear power and coal-fired generation—each of them a significant part of the national portfolio, but neither currently competitive with natural gas. “Nuclear power is one of the cheapest energy resources out there, but it’s simply not recovering its fixed costs in the wholesale competitive power markets,” says Richard Lehfeldt, a Crowell & Moring partner, a member of its Energy Group, and former counsel to the House Energy & Commerce Committee. “Many states have enacted or are considering legislation that compensates these plants for their environmental attributes, but those payments have been challenged by numerous stakeholders as either anti-competitive or unconstitutional,” following the rationale of the Talen decision.

Similar challenges may arise, at least in the organized markets, should the administration throw its support behind attempts to extend the plant life of the existing coal fleet. FERC’s and the states’ efforts to balance and accommodate these sometimes competing interests, and Trump’s appointments to FERC, will play a large role in how that balance is achieved.

In addition, one shouldn’t necessarily equate Trump’s desire to help the coal industry with hostility toward wind, solar, and other renewable power, so long as the role of these resources is market-oriented and not interventionist, as it was in the Obama administration. The rapidly expanding solar and wind industries also support tens of thousands of jobs across the United States, a factor that is likely to mitigate against “anti-renewable” initiatives.

“Trump clearly has not shown any sympathy or support for renewables,” says Eisenstat, “but he also hasn’t indicated he’s hostile to renewables either, and those resources are increasingly competitive in today’s market. I think we’ll see a continued increase in diversity in the energy infrastructure regardless of what other power sources the Trump administration wants to support.”

“Undoing a final regulation itself entails a rulemaking process, whether the administration simply rescinds the rule or whether it rescinds and replaces it.” —David Chung
GOVERNMENT CONTRACTS

CLASH OF AGENDAS MEANS MORE UNCERTAINTY

With a new negotiator-in-chief at the table, will there be more or less regulation of government contractors? It depends.

Donald Trump expressed his view on government contractors even before he officially became president. In a six-day period in December 2016, he said that the costs of both the new Air Force One presidential aircraft and the F-35 next-generation fighter jet were “out of control.”

The message was clear: contractors were taking advantage of the government and their prices (presumably attributable to waste, fraud, and abuse) had to come down.

One of President Trump’s policy imperatives, meanwhile, is that government regulations are strangling businesses and economic growth and must be dramatically reduced. His executive order of January 31, 2017, stipulated that for every new regulation issued, at least two existing regulations must be eliminated.

The most natural way to accomplish the first objective would be to create new checks and balances—i.e., regulations. But doing so clashes head-on with the call for regulatory rollbacks.

UNCERTAIN NEW WORLD

Welcome to the uncertain new world of government contractors.

“The administration has put forth two mandates that are very difficult to reconcile,” says David Ginsberg, a partner in Crowell & Moring’s Government Contracts Group. “It’s impossible to predict which, if any, will prevail, which means that government contractors will have to be prepared for both.”

Given the strength of the administration’s conviction about both goals, it’s not unreasonable to think that a third scenario—call it “convenient coexistence”—could emerge.

According to Gail Zirkelbach, a partner in Crowell & Moring’s Government Contracts Group, the implementation of cost controls doesn’t necessarily have to take the form of new regulations. “There are other ways to reduce spending on contractors,” she says. “The budget proposal for fiscal 2018, which directs non-national security federal agencies to cut spending by $54 billion, is the most obvious. The administration could take the executive order route as well, which it clearly won’t hesitate to do. Agencies could also simply take a tougher nego-

NEW LIFE FOR COMMERCIAL ITEMS?

In the world of government contracting, commercial items are non-defense goods sold to the government that also are sold to the private sector. Think coffee makers and office supplies rather than weapons and radar systems.

The primary law governing the sale of commercial items to the government is the Federal Acquisition Streamlining Act of 1994, which was originally intended to make the procurement process easier both for contractors and the government. Over the years, though, many clauses have been added to FASA, making the procurement of commercial items more burdensome for both parties—and more expensive for the government.

“FASA is a natural candidate for regulatory rollbacks,” says Crowell & Moring’s Gail Zirkelbach. “Contractors and the government would both be very pleased to have less red tape to deal with, and the government could conceivably save billions as contractors cut prices to reflect their savings from reduced compliance requirements.”

“It’s impossible to predict which of [two mandates], if any, will prevail, which means that government contractors will have to be prepared for both.” —David Ginsberg
tiating stance and encourage their personnel to try harder.”
At the same time, there’s no shortage of candidates for contractor regulations or prior executive orders that could be eliminated, watered down, or enforced less aggressively.

WHAT SHOULD CONTRACTORS DO?

Alan Gourley, a Crowell & Moring partner in the firm’s Government Contracts Group, recommends several measures that contractors should take to adjust to the new regulatory environment:

- **Don’t forget about current regulations.** It’s prudent to stay focused on compliance with existing regulations—especially regarding costs—until things change.

- **Prepare to change course.** Even as contractors comply with current regulations, they must be ready to do things differently, which appears inevitable.

- **Be ready for terminations for convenience.** Government contracts give the government the right to terminate the contract at any time without giving a reason, a provision known as termination for convenience. In the current environment, such terminations could become more frequent. Contractors should expect more of them to happen and be sure that they have the ability to terminate their own subcontractors for convenience if necessary.

Since government contractors are generally entitled to a negotiated settlement for an equitable recovery of costs and losses incurred in the event of termination for convenience, they should keep ample documentation to submit potential recovery claims and to have those claims certified (which is required for claims to proceed).

“Contractors and the government would both be very pleased to have less red tape to deal with.”
—Gail Zirkelbach

INFRASTRUCTURE: GOOD NEWS AND BAD NEWS

In President Trump’s initial address to Congress in February, he called for $1 trillion in new infrastructure spending. The goal would be to repair and upgrade the nation’s aging highways, bridges, airports, dams, railways, mass transit systems, and more.

If the president’s intentions become reality, government contractors could see a bonanza of new projects and revenue streams. But the picture might not be entirely rosy, says Crowell & Moring’s David Ginsberg.

“If infrastructure projects materialize on the grand scale that’s expected,” Ginsberg says, “they’ll be administered and at least partially funded not just by the federal government but by states and local governments too. Having more parties to deal with would likely compel contractors to hire additional counsel with deep experience in local laws and policies.”

Two other issues raise potential red flags that could persuade contractors to enlarge their legal teams even further. The first of these is labor. Up to 1.1 million U.S. construction workers reportedly are undocumented immigrants—meaning not only that the supply of skilled workers could be materially reduced by the administration’s tough stance on immigration, but also that contractors would need to be extra vigilant about compliance with immigration laws.

The second issue relates to financing. The administration says that its plan should be funded through a combination of public and private capital, rather than direct appropriations. Contract provisions accordingly could become more complicated.
UNTANGLING RHETORIC FROM SUBSTANTIVE CHANGES

Trade relations and foreign policy in general are likely to be a major focus—of both rhetoric and substance—under President Trump. In its first months, the new administration has escalated tensions with Iran, withdrawn from the Trans-Pacific Partnership, begun the process of renegotiating the North American Free Trade Agreement, increased focus on North Korea, and generally applied an “America First” lens to every aspect of global relations.

Untangling the rhetoric from the substantive changes will be one of the major challenges for companies. During the run-up to the November election, the Trump campaign staked out a number of positions that would have overturned long-standing policy, but its substantive actions in the first few months in office have been more understated. Companies that can accurately predict how the administration will implement its stated objectives will have a competitive advantage.

“No one is questioning America First, *per se*, or that we should be looking to prioritize support of American businesses,” says Jini Koh, counsel in Crowell & Moring’s International Trade Group. “But by the same token, the economy is so globally interconnected now that most companies appreciate the full impact of internationalization, even if the average American consumer may not. We have not seen proposed changes this fundamental from a new administration in years. The effects can be stunning.”

RETHINKING TRADE AGREEMENTS

Trump’s first act in this regard was to abandon TPP, a deal among 12 countries on either side of the Pacific Ocean that represent about 40 percent of the world’s economic output. The president alleged that the TPP would have reduced U.S. sovereignty and played favorites among American industries. But Koh says TPP represented “a much larger strategic policy play, a geopolitical play, to ensure that China does not take over all of Asia.” Trump has said his administration will seek to even the playing field on trade with China on a bilateral basis.

The biggest trade uncertainty looming now is how Trump is ratcheting up pressure on Mexico and on U.S. companies that manufacture there. From his continued insistence that the nation will build a wall between the United States and Mexico, to his threat of new tariffs, to congressional Republicans’ talk of a “border tax” that would essentially accomplish the same thing, to saber-rattling for changes in NAFTA, Trump has bet so much political capital on upending this particular relationship that Koh expects some major changes.

“NAFTA could be a better deal for the U.S.,” she says. “It was one of the first major free-trade agreements that the U.S. signed, and the rules are tricky and hard, so there is definitely room to streamline the rules. But the United States cannot dictate terms as it could in the ’90s, since Canada and Mexico are closer to parity with the U.S. now than they were then. This is primarily the result of years of investment that American companies have made south of the border, through setting up manufacturing operations in Mexico and importing the products for distribution in the U.S. If there are increased duties, do we expect American companies to simply absorb them? Very unlikely—they’ll be passed down to consumers.” Companies should be making sure they understand their own supply chains and be ready to advocate for their interests at the table when the opportunity, suddenly and probably abruptly, arises.

“The economy is so globally interconnected now that most companies appreciate the full impact of internationalization, even if the average American consumer does not.” —Jini Koh
GETTING TOUGHER WITH SANCTIONS

During the campaign, Trump also threatened a dramatic series of changes to U.S. economic sanctions, but his actions in office have been more understated on three of the highest-profile U.S. sanctions programs. With respect to Iran, Candidate Trump made political hay in highlighting what an “awful deal” President Obama had struck with Iran in the Joint Comprehensive Plan of Action, threatening to withdraw from the agreement on his first day in office.

However, several months into the new administration, “all signs are that Trump is not going to pull the U.S. out of that agreement, but instead will ramp up enforcement of sanctions against Iran for conduct not covered by the agreement, such as new designations related to Iran’s missile program and with respect to its support for terrorism,” says Carlton Greene, a partner at Crowell & Moring, a member of the firm’s International Trade and White Collar & Regulatory Enforcement groups, and former chief counsel at the Financial Crimes Enforcement Network. Additionally, “he’s more likely than a Clinton administration would have been to broadly construe the agreement and really hold Iran to account for it.”

On Cuba, the approach Trump will take is murkier, Greene says. “The opening to Cuba has led a lot of U.S. companies to start looking at Cuba as a market, so now he’s getting significant lobbying by industries such as aviation and hospitality,” Greene explains, that may limit the actions Trump might take to unwind the Obama administration’s relaxations of the Cuba sanctions, which he opposed during the last few months of the campaign.

“Another factor is how long Raul Castro will stay in office,” Greene adds. “It’s possible they could do some kind of face-saving deal for both sides that would allow the Trump administration to realize minor, additional concessions from Cuba about elections or opening the market to U.S. business interests and cultural exchanges. On the Cuba side, the countervailing gain would be that the existing relaxation of sanctions is kept in place and ways are found to strengthen it at the margins.” President Castro has stated publicly that he will not run again in 2018, notes Greene, “potentially providing a mutually convenient legal predicate for further relaxation of sanctions that are contingent on a change in regime in Cuba.” Russia, obviously, is the trickiest of the “big three” sanction priorities. While Trump has publicly criticized U.S. sanctions on Russia, the likelihood of any immediate relaxation has declined precipitously since the beginning of the administration in the face of hostile reactions from some members of Congress to any relaxation and in light of pending investigations relating to Russian interference in the U.S. election. Adding to this is the fact that the European Union recently reaffirmed its sanctions with respect to Russia. Greene says that in this political environment, U.S. economic sanctions against Russia “will largely stay in place” for the time being.

THE FUTURE OF ANTI-MONEY LAUNDERING

Anti-Money Laundering and Suspicious Activity Report requirements are areas where President Trump’s ideology and campaign promises could play out in unpredictable ways. While a number of banks and financial institutions have petitioned the government to streamline SAR reporting obligations to focus on higher-risk activity, SAR reporting “is going to continue just the way it is now because it’s tremendously useful to law enforcement, and they will press very hard to keep it functioning as it has,” says Crowell & Moring’s Carlton Greene.

As for AML more generally, Trump has positioned himself as a pro-business president and has promised to roll back financial regulations across the government. On the other hand, he has positioned himself as a “tough on terrorism” leader, Greene notes. “Those things create a dynamic tension when you talk about AML,” he says. Greene does not, therefore, expect substantial AML regulatory change during the first year of the administration, while the administration deliberates ways to ease the regulatory burden on banks and other financial institutions without being seen to weaken the ability to “follow the money” for terrorist actors by FinCEN, an agency that has substantial support in Congress and with law enforcement.
A new program to prevent insider cyber threats has the right idea—but has government contractors scratching their heads about how to comply.

In May 2016, the Defense Department’s Defense Security Service amended the National Industrial Security Operating Manual, creating a new requirement that contractors with DOD facility security clearances have a written plan for implementing an insider threat program aimed at preventing cyber attacks. DSS further mandated that the plan be in place by November 30, 2016.

This requirement for cleared contractors is a natural extension of Executive Order 13587 and the National Insider Threat Policy—both signed by President Obama in 2012—which called for the creation of an insider threat task force to develop a government-wide program for deterring, detecting, and mitigating insider threats. Given that cleared contractors have access to and safeguard significant amounts of classified information in performing work for and on behalf of government agencies, it makes sense to require similar programs for them.

So why formalize a program now? According to Adelicia Cliffe, a partner in Crowell & Moring’s Government Contracts and International Trade groups, “The glare of the 2013 document leaks by Edward Snowden and the arrest in 2016 of another National Security Agency contractor for long-term document theft highlight that insider threat risks are not limited to agency employees, and that contractors are also in a position to exploit and compromise classified information. When security breaches of this magnitude happen, the government has to step up its efforts and make prevention a bigger priority.”

The DSS program has five minimum requirements for affected contractors:

- Designation of an insider threat program senior official to establish and execute the program
- Development of a written implementation plan
- Reporting of “relevant and credible information” regarding potential insider threats
- Training programs for managers and all cleared employees, plus annual refreshers
- Information security controls to monitor activity on classified information systems

But DSS’s guidance falls short on specifics—in fact, it expressly states that the plans must be tailored to each organization’s business—leaving contractors with unanswered questions about the plan’s logistics, content, and training, among many areas. For now, they’ve had to figure things out as they go.

As with the federal agency insider threat program requirements, contractors must implement the insider threat program consistent with legal, civil liberties, and privacy policies. Cliffe emphasizes the significance of this intersection as a particularly thorny area for cleared contractors, in light of the sensitivity of insider threat information and the potential consequences of reporting an individual under the program.

She strongly recommends that contractors include privacy experts in the planning and implementation of their insider threat programs. These experts should be key advisors to be consulted early and often, she says.

“Contractors should proactively engage with DSS to get ahead of the curve to avoid compliance issues and help shape DSS’s expectations going forward.” —Adelicia Cliffe
WHAT ELSE SHOULD CONTRACTORS DO?

Contractors should take additional steps to make their insider threat programs practical, feasible, and flexible, Cliffe says. The result should be something that works both for the contractor’s business and its existing industrial security program, and that satisfies the DSS requirements.

First, interdisciplinary teams should be set up to foster collaboration across management, legal, and technical groups. An example would be a work group or task force that includes representatives from human resources, the legal department, and operational and technical departments.

Second, contractors’ obligations under their programs are numerous and substantial, meaning that they’ll need significant resources both to comply and monitor compliance. They should plan ahead to make sure that such resources are in place.

Third, recent experience shows that contractor employees aren’t the only potential source of insider threats—subcontractors, vendors, and other business partners with access to sensitive information pose major threats as well. Contractors should therefore consider extending their training programs beyond their own personnel to include third parties with access to classified information.

Finally, contractors should use the program as an opportunity to review and upgrade their current information systems, security policies, and security procedures to ensure compliance with the DSS requirements.

Cliffe takes this idea a step further: “Even better,” she says, “contractors should proactively engage with DSS to get ahead of the curve to avoid compliance issues and help shape DSS’s expectations going forward.”

FIVE TRENDS IN INFORMATION SECURITY AND PRIVACY

What’s the latest in information security and privacy law? Evan Wolff, a Crowell & Moring partner, co-chair of the firm’s Privacy & Cybersecurity Group, and former advisor to the DHS, notes these emerging trends:

CYBER AS A TEAM SPORT
As cybersecurity escalates in importance for many businesses, responsibility is shifting from IT professionals to corporate risk managers, lawyers, and CEOs.

DEVELOPMENT OF REGULATIONS AND STANDARDS
Increasingly, governments are imposing regulatory requirements and standards on companies that handle sensitive government, business, and personal information. Cybersecurity requirements for federal contractors are contained in the Defense Federal Acquisition Regulations and NISPOM. The European Union, Russia, and China have cybersecurity requirements that can also affect U.S. businesses.

ISSUES THROUGHOUT THE CORPORATE LIFE CYCLE
Privacy and cyber concerns must be dealt with from corporate inception and are becoming more significant factors in mergers and acquisitions, to the point where they can be the primary deal drivers. As a result, cyber-focused due diligence is becoming standard.

FEAR OF LITIGATION COSTS
Cyber breaches not only have a negative impact on corporate reputation, but they also can trigger litigation. A massive 2014 cyber attack against The Home Depot has cost the company upwards of $200 million to defend and settle subsequent litigation. Efforts to anticipate and mitigate cyber-related litigation risk are multiplying accordingly.

MORE SOPHISTICATED RISK MANAGEMENT
Cyber threats to the nation, businesses, and individuals are getting stronger and more complex. Risk management will have to get more sophisticated to keep pace, including by investing in technical controls and human resources, often through the creation of new positions, notably chief information security officers.
Look for the Trump administration to significantly relax the pro-consumer stance of the Obama administration, particularly when regulating businesses that collect and use consumer data and provide the backbone of the rapidly evolving digital economy.

Nowhere is this changed approach more apparent than at the Federal Communications Commission. Because former telecommunications industry attorney Ajit Pai has been an FCC commissioner since 2012, the Trump administration didn’t need Senate confirmation to elevate Pai to chair of the politically bipartisan, five-member FCC.

Under Chairman Pai, the FCC has already canceled, suspended, or stayed a long list of Obama-era regulations affecting broadband services, telecommunications, video content, and customer privacy rights. And in an act with both immediate business impact and potentially far-reaching ramifications, Pai announced in February that the agency would take a hands-off approach to the proposed $85 billion merger between AT&T and Time Warner, a megadeal between a content distributor and a content producer that could reshape both industries. Thus far, the Trump administration has not indicated it will oppose the merger.

All of this is just a preamble, however, to anticipated corrective action by the new FCC leadership in the arena of “net neutrality.” President Obama counted as one of his administration’s signature tech achievements the FCC’s 2015 net neutrality rules that, among other things, prevented internet service providers from blocking or discriminating against otherwise lawful internet use, and from assessing mandatory fees for “fast lane” access to consumer devices for businesses that provide data-driven content and services such as streaming video, music, and interactive online games.

“It’s not clear whether Pai will reverse the FCC’s jurisdiction over ISPs or rescind net neutrality, but it’s certainly not going to be implemented or enforced in the same way,” says Chris Cole, co-chair of Crowell & Moring’s Advertising & Product Risk Management Group. “It’ll be interesting to see if the Trump administration believes, for instance, that it can just withdraw parts of the rules.”

Pai’s rationale is that the FCC’s tide of regulations under previous Chairman Tom Wheeler has suppressed broadband investment in the U.S.—leading with the net neutrality rule that reclassified broadband service as a utility—and thereby created concerns about equity, fairness, and access to internet usage similar to those for phones and electricity.

On March 1, the new FCC chair also suspended part of the agency’s broadband-privacy rules that required companies to take “reasonable measures” to secure consumer information such as financial data and web browsing histories. Additional rules, scheduled to take effect later this year but whose future is now uncertain, would prevent ISPs from sharing sensitive customer data with third parties without permission—information ranging from financial data to browsing history and app usage, says Kristin Madigan, counsel in Crowell & Moring’s Commercial Litigation and Privacy & Cybersecurity groups and a former attorney at the Federal Trade Commission.

Among other things, this change raises questions about “earlier settlements in terms of what obligations remain—and what will be the legacy of the short life” of the privacy rules, Madigan says. “This move could swing power back to the FTC as the primary regulator in this space.”

Peter B. Miller, senior counsel in Crowell & Moring’s Advertising & Product Risk Management and Privacy & Cybersecurity groups and former chief privacy officer at the FTC, adds that “Pai has sent strong signals that the FCC will

“[The FTC] will be more likely to act only where there’s real evidence of injury, [rather than addressing] conduct [where] there was no concrete evidence of harm.” —Chris Cole
be shifting from its prior, more draconian approach to privacy and data security regulation to a practical one that more closely aligns with that of the FTC.”

**A MORE BUSINESS-FRIENDLY FTC?**

The FTC, currently led by Acting Chairman Maureen Ohlhausen, is expected to be more circumspect and accommodating of business concerns than was true in the Obama administration. Ohlhausen, a Republican, has served as an FTC commissioner since 2012 and has advocated for “regulatory humility” in the agency’s exercise of its policy and enforcement authority.

“She’ll look not only at evidence of harm to consumers, but also at the impact on business and on innovation,” predicts Miller. “You’ll be seeing much more of a focus on very traditional areas of fraud and deception.”

Cole says that in practice, the Republican-led FTC “will be more likely to act only where there’s real evidence of injury such as monetary loss, versus the previous standard in which the agency reached out to address conduct that could have caused harm even though there was no concrete evidence of harm.”

**CFPB IN TRUMP’S CROSSHAIRS**

President Obama and the Democrat-controlled Congress created the Consumer Financial Protection Bureau in the wake of 2008’s financial collapse as a safeguard against financial defrauding of American consumers. Since its inception, the agency has grown to more than 1,500 employees and recovered nearly $12 billion for consumers.

Under the Trump administration, however, a double whammy could cripple or even wipe out the CFPB: a court case (currently on en banc appeal at the D.C. Circuit) that could put the highly independent agency and its single director under the control of the president rather than the indirect control of the Federal Reserve, and vocal criticism by Republicans on the Hill and elsewhere who say that the CFPB needs at least a drastic structural overhaul, if not outright elimination.

Crowell & Moring’s Chris Cole believes that, one way or another, the CFPB “is likely to undergo substantial change” under the Trump administration. The Department of Justice entered an appearance in the D.C. Circuit and, contrary to the position of the CFPB and the DOJ under Obama, supported the prior panel’s ruling that the CFPB director structure is unconstitutional and advocated for either direct presidential power to hire and fire the CFPB director at will or a finding that the agency itself is unconstitutional.

In addition to the court case and the Trump administration’s skepticism about federal regulation generally and CFPB enforcement actions in particular, pending bills on the Hill would reform or eliminate the CFPB. “One would do away with CFPB entirely and allocate all of its enforcement authority to the FTC and other agencies,” Cole says. “Others would create a commission structure giving the president the right to appoint or nominate all of the CFPB commissioners. Somewhere in between is likely where all this will land.”

“[FTC Acting Chairman Maureen Ohlhausen] will look not only at evidence of harm to consumers, but also at the impact on business and on innovation.” —Peter Miller
NEW PARTNERSHIP AUDIT REGULATIONS: PREPARE FOR CHANGE

Regulations governing audits of large partnerships were already burdensome, but a law set to take effect soon should make partners wince even more.

The story starts with a bit of legislative history. Since 1982, the Tax Equity and Fiscal Responsibility Act and its subsequent amendments have provided audit and litigation procedures for large partnerships. TEFRA remains in force today but in 2018 it will be replaced by the Bipartisan Budget Act of 2015. Although the IRS announced proposed regulations in January 2017, they have not been published in the Federal Register, likely as a result of the Trump administration’s freeze on regulatory guidance.

“Under TEFRA, the Internal Revenue Service could determine which partner actually paid taxes on income from partnership operations, and people have gotten used to those rules over the past 35 years,” says Jennifer Ray, a partner in Crowell & Moring’s Tax Group. “But BBA will push more of the work onto the partnership’s owners. The IRS supports this change at a time when it is being asked to do more with less.”

Among the many differences between the large-partnership audit regimes for TEFRA and BBA, perhaps the most prominent relate to the collection of taxes and the person designated to represent the partnership with regard to tax matters.

**Tax collection.** TEFRA audits occur at the partnership level, but tax is ultimately collected from individual partners—a process that can be especially difficult for the IRS to navigate due to the complex ownership structures of many large partnerships.

BBA audits will also occur at the partnership level, but, in a crucial difference, the default rule will be that the partnership pays the taxes. A partnership can elect to push the tax liability out to the partners only by agreeing to a higher interest charge. [Note: Partnerships can opt out of BBA partnership audit rules if they meet specific criteria.]

**Designated representative.** Under TEFRA, the partnership must designate a partner (called the “tax matters partner”) to represent it on tax matters. TEFRA contains requirements to notify partners of certain events, and partnership agreements typically require the tax matters partner to keep the other partners informed about proceedings and discussions with tax authorities as well as to obtain the other partners’ consent to take material actions.

BBA calls the designated person—which BBA doesn’t

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**KEY POINTS**

**New audit regime**

The audit regime for large partnerships is changing.

**Partnership pays taxes**

The partnership—not its individual partners—will pay taxes owed after audit.

**Review partnership agreements**

Make sure that agreements address issues raised by the new audit regime.

“The two-for-one concept makes sense in many areas, but not in tax law. Numerous tax regulations exist to provide necessary guidance to taxpayers.” —Jennifer Ray
require to be a partner—the “partnership representative” and gives him or her the exclusive right to take audit-related actions. Other partners have no rights under the BBA to receive information or to participate. As with tax collection under BBA, this simplifies the audit process for the IRS but makes it more onerous for partners.

Ray has little doubt that many of the proposed BBA regulations will become finalized eventually.

What about the Trump administration’s mandate that two regulations be eliminated for every new one adopted? Which existing regulations would have to be cut so that the BBA regulations could become official? “The two-for-one concept makes sense in many areas,” notes Ray, “but not in tax law. Numerous tax regulations exist to provide necessary guidance to taxpayers.”

**ACTION STEPS**

There are a number of steps that existing and potential LLCs (and other entities treated as partnerships for tax purposes) should consider in anticipation of the BBA audit regime, if they haven’t already done so, Ray says.

- **Restructure current partnership agreements.** It’s critical to review LLC and partnership agreements that were originally written to comply with TEFRA.
  
  “Agreements will have to spell out some things with particular clarity,” says Ray. “The issues that are most important in this regard include how the partnership representative should be selected, what the partnership representative can and cannot do during the audit, and how to decide whether the partnership itself pays taxes or passes taxes on to individual partners.”

- **Clarify tax obligations of buyers and sellers of partnership interests.** The parties should agree on whether the seller has to indemnify the buyer for the seller’s share of any of the partnership’s pre-closing tax liabilities. Failure to specify who pays (and what they pay) is virtually an invitation to disputes.

- **Decide whether eligible partnerships should opt out of BBA rules.** This decision will be made on an annual basis, with the partnership’s tax return and before the partnership knows whether it will be audited.

—David Fischer

“[The Altera decision] is a good thing for parties in litigation with the IRS because it creates a significant procedural burden that the IRS must meet.”

**LAYING THE GROUNDWORK FOR CHALLENGES TO REGULATIONS**

The comment period for the proposed regulations relating to the Bipartisan Budget Act of 2015’s large-partnership audit provisions, which began in January, could well be uneventful. The importance of comments, however, could be significantly affected by an unrelated tax case making its way through the federal courts.

In *Altera Corp. v. Commissioner*, the U.S. Tax Court unanimously held invalid a 2003 Treasury Department regulation mandating that controlled entities entering into qualified cost-sharing arrangements share stock-based compensation costs.

In February 2016, the IRS appealed the decision to the Ninth Circuit Court of Appeals, which hasn’t yet issued its decision.

Altera’s relevance to BBA lies in a portion of the Tax Court’s decision related to the Administrative Procedure Act. The Tax Court held that the Treasury Department (of which the IRS is a bureau) is subject to APA’s notice and comment requirements.

One of these requirements is that government agencies must not only give the public an opportunity to comment on proposed regulation, but also must respond to the comments received. Under APA, failure to respond could render the proposed regulations invalid.

“The Altera decision means, among other things, that tax lawyers must be experts in the Administrative Procedure Act,” says David Fischer, a partner in Crowell & Moring’s Tax Group. “This is a good thing for parties in litigation with the IRS because it creates a significant procedural burden that the IRS must meet. If they want their proposed regulations to become law, they’d better respond to comments.”

For opponents of the proposed BBA regulations, the message is clear: submitting comments could create an additional right to challenge.
Although much of the Trump administration’s labor and employment agenda has yet to crystalize, the agenda will likely include repealing or rolling back pro-employee regulations and executive orders implemented by the Obama administration. There is much evidence that the new administration will chart a more business-friendly course.

“We are likely to see efforts to repeal and replace many of these laws. But even if some of these laws and regulations remain on the books, a big unanswered question is whether we’ll see active enforcement under the administration,” says Trina Fairley Barlow, a partner in Crowell & Moring’s Labor & Employment and Government Contracts groups.

**RETREAT FROM THE OBAMA ERA**

President Obama’s Fair Pay and Safe Workplaces Executive Order was the first on the chopping block. On March 27, President Trump signed a joint resolution under the Congressional Review Act disapproving the FPSW Final Rule. Though most of the rule’s requirements had been put on hold in October 2016 when a U.S. District Court judge in Texas granted a preliminary injunction, the rule’s paycheck transparency requirements became effective on January 1, 2017. The president’s signature eliminated the entire rule and negated the need for further court action. Contractors are relieved they will not be subjected to what many viewed as unnecessary, overly burdensome compliance obligations, says Rebecca L. Springer, counsel in the Labor & Employment Group at Crowell & Moring.

Other Obama-era laws have also faced judicial roadblocks. On November 22, 2016, a federal judge temporarily enjoined implementation of Obama’s revised Fair Labor Standards Act overtime rule, which raised the minimum salary an employee must earn to be exempt from overtime pay. The revised rule included automatic upward adjustments to the requisite salary level every three years. These revised rules would require employers to either pay overtime to larger segments of their workforces or increase the salaries of white collar workers above the salary level threshold. Critics argued that these requirements would undermine the growth of small and mid-sized businesses.

“It is very unlikely that the revisions to the FLSA issued by the Obama administration will be implemented in their current form regardless of how the court rules. We are likely to see more employer-friendly FLSA amendments or the dispensing of efforts to amend the FLSA altogether,” Barlow says. “Employers who already spent time and resources preparing for implementation are asking what they should do now. Legally, employers have no obligation to implement the changes to the FLSA while they are temporarily enjoined. Yet employers may face morale and operational problems if workers were notified of wage increases in anticipation of the new rules.”

**CONTRACTOR SICK LEAVE UNCERTAIN**

The Trump administration is also likely to take a fresh look at another regulatory imposition enacted by its predecessor: the requirement of up to seven days of paid sick leave each year for covered employees performing work on or in connection with covered government contracts.

The paid sick-leave obligations apply to certain types of federal contracts entered into after January 1, 2017, and the Trump administration has not yet moved to negate the rule. Ivanka Trump, the president’s daughter and a leading advisor, expressed her support for parental leave during the campaign, and President Trump highlighted it during his first address to Congress. It is possible we will see some “tweaking, rollback, or reversal of the federal contractor requirements, with the federal government (or states) then implementing new paid sick-leave rules,” Barlow says. In any event, any new labor direc-

“A big unanswered question is whether we will see active enforcement of the laws [that remain on the books] under the Trump administration.” —Trina Fairley Barlow
tives are likely to be aimed broadly at the business community, Springer adds, rather than just at federal contractors.

**PAY EQUITY REMAINS A KEY CONCERN**

Pay equity, a key focus of the Obama administration, will likely remain a significant issue for employers. Companies have experienced pressure not only from the federal government, but also from state legislatures, corporate shareholders, and the general public to provide more pay transparency and address the perceived gender gap in wages. This drumbeat is likely to continue, though it is unclear what role the federal government will play in enforcement efforts given Trump’s stated intentions to reduce the Department of Labor’s budget. “We’re going to see the fight on pay equity issues continue,” Springer says, “but we suspect much of that activity may be in the state legislatures and through private litigation.”

Though pay equity concerns will remain at the forefront, the fate of the recent revisions to the EEO-1 report remains unclear. The requirement that all employers with 100 or more employees provide aggregate annual compensation data on their EEO-1 reports was introduced by the Obama administration last year to further its pay equity enforcement efforts. Numerous employer groups expressed concerns that this was an overly burdensome obligation and worthless for enforcement purposes. The revised EEO-1 reports are not due until March 2018, so the administration has time to decide if it will take any action to roll back these changes.

**JOINT EMPLOYER DOCTRINE UNLIKELY TO EXPAND**

Trump’s appointments to fill vacancies at the National Labor Relations Board are likely to have a huge impact on another high-profile matter left over from the Obama years: the joint-employer standard. The NLRB currently is deciding whether McDonald’s should be considered a joint employer in labor and wage complaints brought against its franchises. Among other things, a board decision that the fast-food giant indeed exercises determinative control over franchisees’ employment practices could make it easier for labor unions to organize quick-heve workers.

**ERISA GETS TIED UP WITH HEALTH CARE**

One area that will gain more attention is the impact of ERISA on health and welfare plans. Regardless of the fate of the Affordable Care Act, expect heightened litigation against employers and their boards of directors and officers as both corporate and individual fiduciaries of health and welfare plans under ERISA.

“Historically, plan sponsors, the courts, and the DOL have been focused on ERISA’s application to retirement plans, but there are equal protections for health and welfare plans. With the passage of the ACA seven years ago there’s been greater focus on compliance, governance, and ERISA’s fiduciary requirements for health and welfare plans,” says David McFarlane, a partner in Crowell & Moring’s ERISA & Employee Benefits Group.

Whatever health care plan emerges from Congress, McFarlane explains, “it will be subject to the fiduciary and other requirements of ERISA, and health and welfare plan sponsors will be increasingly exposed” to litigation, with significant personal exposure to the plan sponsor’s board of directors and officers.

“[Any health care plan] will be subject to requirements of ERISA, and plan sponsors will be increasingly exposed [to litigation].”

—David McFarlane
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