Health Care Reform and the ACA
—Katrina Pagonis and Stephanie Gross, Hooper Lundy & Bookman PC

A year after President Trump took office, the Affordable Care Act (ACA) remains the law of the land, but its future is uncertain. Although Republican efforts to fully “repeal and replace” the law have been unsuccessful so far, the Tax Cut and Jobs Act\(^1\) repeals a central pillar of the ACA—the individual mandate—in 2019, meaning that either we will discover how insurance markets fare without a penalty for failing to maintain coverage or Congress will intervene with additional health reform legislation. The administration has taken steps to provide consumers, insurers, and states with greater flexibility in satisfying the ACA’s other requirements and shortened the enrollment period for the ACA’s health insurance exchanges (Marketplaces). Despite this abbreviated open enrollment period, approximately 8.8 million signed up for coverage through HealthCare.gov.\(^2\)

Congress: Efforts to Repeal & Replace the ACA and Tax Reform. Much of the health policy news over the past year focused on Republicans’ efforts to make good on promises to repeal and replace the ACA. The House passed a bill that would have repealed much of the ACA by eliminating the individual and employer mandate penalties; giving individual and small group health plans greater flexibility in setting premiums, benefits, and cost-sharing; allowing states to waive certain ACA protections for individuals with preexisting conditions; repealing the ACA’s Medicaid expansion; and transforming Medicaid into a block-grant program.\(^3\) The Senate ultimately rejected its repeal-and-replace bill, with three Republicans—Senators Susan Collins (ME), John McCain (AZ), and Lisa Murkowski (AK)—voting against it.\(^4\)

After the Senate vote, Congress shifted its attention to tax reform legislation, which was enacted last month and signed into law on December 22, 2017. Along with a sweeping overhaul of the tax code, the new law repeals the individual mandate, a core component of the ACA. Some analysts caution that this will seriously threaten the stability of the individual and small group health insurance markets, including the Marketplaces. The Congressional Budget Office (CBO) estimated that between 4 and 13 million individuals would lose insurance coverage and that premiums in the individual and small group insurance markets would rise about 10% as a result of this provision.\(^5\) Others hold the view that the penalty for failure to have health
insurance was never large enough to significantly influence enrollment decisions, so its elimination will not dramatically alter insurance markets. There has been some discussion of Congress revisiting health reform as early as this year, but any repeal-and-replace effort may be even more challenging for Republicans after Alabama’s special election for Senate. Once Doug Jones (D-AL) is sworn in, the Republicans will hold a slim 51-49 majority in the Senate.

Executive Action & Legislative Efforts. While legislative action to repeal and replace much of the ACA remains elusive, the Trump administration has taken steps to limit the ACA’s reach. Leading up to the 2018 open enrollment period for the Marketplaces, the administration cut the outreach and marketing budget to $10 million (a 90% reduction), cut grants to enrollment assistance groups known as Navigators to $36.8 million (a 40% reduction), and adopted a six-week open enrollment period (a 50% reduction) for HealthCare.gov states. State-based Marketplaces like Covered California were insulated from these changes because they fund their own marketing, outreach, and enrollment efforts and can adopt a longer open enrollment period.

In addition, on October 12, the administration announced that it would no longer make payments to insurers for cost-sharing reductions (CSRs), taking the view that there is no permanent appropriation for these funds. These payments fund the offering of CSR-variant silver plans that have lower deductibles, copayments, and out-of-pocket spending limits for low-income Marketplace enrollees.

The House of Representatives successfully challenged these payments in the U.S. District Court for the District of Columbia, but Judge Collyer’s order enjoining the administration from making CSR payments remains stayed. Though the administration’s appeal continues to be held in abeyance, the parties recently reached a settlement agreement and submitted a joint motion to the district court seeking an “indicative ruling” that, on remand, the court would vacate its injunction. As the joint motion explains, the administration already decided not to make CSR payments, “obviat[ing] the need to resolve those issues in an appeal in this case.” The parties argued that an indicative ruling from the district court would allow the litigation to come to a close without the D.C. Circuit deciding whether the ACA creates a permanent appropriation for CSR payments.

Separately, 18 states and the District of Columbia sued to enjoin the federal government from cutting off these payments. The states were unsuccessful in obtaining injunctive relief in November, but a ruling on the merits is expected in 2018. The effect of the absence of CSR funding on 2018 premiums has varied by state. In 36 states, Marketplace insurers loaded the cost of lost CSR payments into the silver tier premiums, an approach that maximizes the other ACA subsidy—premium tax credits. As a result, most individuals shopping on the Marketplace in these states gained enhanced buying power. In a few states, however, insurers either did not account for the loss of CSRs or “broadly loaded” the cost of CSRs across all metal tiers, thereby diluting the buying power of premium tax credits.

To mitigate these potential sources of instability, Senators Patty Murray (D-WA) and Lamar Alexander (R-TN) announced a bipartisan effort to affirmatively appropriate funds for CSRs for two years. This legislative fix might render ongoing litigation over the CSRs moot. The proposed bill also would direct the administration to engage in outreach efforts to encourage enrollment through the Marketplaces, and would provide some flexibility to Marketplace plans. Though the CBO announced that the bipartisan legislation would reduce the deficit, the bill’s future remains uncertain at the time of writing.

From the standpoint of rulemaking, the Departments of Health and Human Services (HHS), Labor, and Treasury adopted market stabilization regulations in early 2017 that, among other things, imposed more stringent requirements for special enrollment periods, shortened the 2018 open enrollment period, and ended federal oversight of Marketplace plans’ network adequacy.

Additional ACA rulemaking is expected in 2018, starting with the 2019 Notice of Benefit and Payment Parameters. Each year, this rule sets forth parameters and provisions relating to the Marketplaces, including the risk adjustment program and user fees to fund Marketplace activities. The proposed 2019 Notice of Benefit and Payment Parameters is notable in that it would provide states with greater flexibility to define essential health benefits and enhance the state role with regard to plan management on the federal Marketplace.

Lastly, a proposed rule on association health plans (AHPs) was published on January 5, 2018. This was the first rule to come out of the White House’s October 12, 2017 executive order prioritizing the loosening of restrictions on AHPs, short-term, limited-duration insurance (STLDI), and health reimbursement arrangements. STLDIs and, to a lesser extent, AHPs, are not subject to many of the ACA’s health insurance market reforms.

Some analysts warn that more liberal rules for AHPs and STLDIs would draw younger and healthier individuals away from the Marketplaces, resulting in premium increases for a sicker Marketplace population.

Outlook for 2018

The day the Senate bill was rejected, President Trump announced on Twitter that he expected the ACA to “implode” on its own, even without legislative action. For now, though, it seems that ongoing uncertainty over the ACA’s fate has not proven too disruptive to health insurance markets. Though major national insurance companies have continued to withdraw their offerings from the Marketplaces, in 2018, there are no “bare counties” without health plans participating in the Marketplaces. Early enrollment was better than expected, but ultimately enrollment numbers fell below 2017 levels, likely due to an abbreviated enrollment period, consumer confusion, and significant marketing cuts.

In 2018, issuers will make projections about the effects of the repeal of the individual mandate on enrollment numbers and the risk profile of insureds and will continue tracking Marketplace enrollment numbers, the shifting regulatory landscape for the Marketplaces, and the likelihood of further legislative changes (whether stabilizing or destabilizing) in

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2018 TOP TEN

deciding on their 2019 Marketplace participation and premium rates. Individuals, particularly those without employer-sponsored coverage, will decide whether to take up or retain coverage without the individual mandate. Providers likewise will monitor the impact of the repeal of the individual mandate, other health reform initiatives, and issuer responses on the uninsured rate, Medicaid coverage and reimbursement, and patients’ cost-sharing obligations.

Fraud and Abuse: the More Things Change, the More They Stay the Same
—Kevin E. Raphael, Pietragallo Gordon Alfano Bosick & Raspanti LLP

The health care industry in 2018 will feature more horizontal consolidation of hospital systems and the testing of vertical integration between a pharmacy (CVS) and an insurance company (Aetna). Opioid litigation will remain in the spotlight, while commercial insurance carriers will increasingly enter the litigation fray to recover costs from various alleged abuses by providers, opioid manufacturers, compound pharmacies, and laboratories. Common across all these new or expanding areas of focus will be the typical fraud and abuse analyses under the Anti-Kickback Statute, Stark Law, and the False Claims Act. State laws likely will play a greater role in fraud and abuse litigation in 2018, although the challenged alleged conduct also will be familiar: kickbacks, improper financial relationships, and medically unnecessary services.

Opioid Enforcement and Litigation. Already a Department of Justice (DOJ) focus in 2017, opioids will remain a major focus of 2018 activities. Greater federal enforcement efforts against providers will be the norm, as will increased state law enforcement investigation and prosecution efforts. Expect more licensing board actions against health care professionals in conjunction with these criminal enforcement efforts.

Additional litigation against opioid manufacturers nationwide is likely, filed by local governments that have been hit hardest by the opioid crisis. This litigation will seek recovery for the expenses, health care and otherwise, incurred by these governmental units related to opioid addiction. Further, expect commercial health care insurance companies to experiment with related suits against prescribing providers to recover the costs related to the opioid prescriptions and the treatment provided to those subsequently addicted insureds.

Fraud and Abuse Litigation by Commercial Insurance Carriers. Similarly, commercial health insurance, automobile insurance, and workers’ compensation carriers likely will increase the use of fraud-based civil lawsuits against providers in state and federal courts. State insurance fraud laws, state whistleblower laws, and state laws governing workers’ compensation will feature prominently. These lawsuits will be premised on the following: allegations of kickbacks and other illegal financial relationships between providers and ancillary services, such as pharmacies and laboratories; violations of state and insurance fraud laws prohibiting financial inducements for referrals; and failure to comply with state licensing requirements.

Compounding Pharmacies. The federal government focused on compounding pharmacies and prescribing physicians in 2017, securing a number of convictions related to the use of kickbacks and the lack of medical necessity for the prescribed drugs. Compounding pharmacies increasingly will be scrutinized in 2018, given the increased costs of compound drugs compared to generic or brand named equivalents. The marketing relationships employed by compounding pharmacies will remain a focus and will be reviewed for the existence of kickbacks or other improper financial inducements for referrals.

Laboratories. Laboratory fraud, including that related to toxicology screenings affiliated with drug treatment programs, likely will become a hot topic in 2018, particularly as the opioid litigation delves deeper into the course of practice in prescribing opioids and uncovers the details of these relationships between providers and laboratories. Anti-Kickback concerns will feature prominently in investigations and litigation surrounding the referral and provision of toxicology screening services by laboratories.

Post-Escobar Application of Materiality Standard. The application of Escobar’s materiality standard to a variety of Medicare regulations in implied certification False Claims Act cases likely will be an issue to watch in 2018. False Claims Act litigation may be significantly impacted, as defendants assert that the Medicare regulations they are alleged to have violated are not material to the government’s decision to pay the relevant claims.

Fraud and Abuse Challenges to Integration. Both the vertical and horizontal integrations in the health care market will highlight typical fraud and abuse concerns of Anti-Kickback Statute and Stark Law compliance. Will the new structures created by these integrated entities, and the newly formed relationships between physicians and the consolidated entities, fully address these compliance concerns?

Meet the New Boss, Same as the Old Boss: Ransomware Will Continue to Vex Health Care in 2018
—Leonardo Tamburello, Willis Towers Watson

2018 likely will see ransomware’s continued exploitation of known vulnerabilities that will be multiplied by the ever-increasing attack surface thanks to “smart” products, including medical devices, that make up the “Internet of Things” (IoT).

Until underlyng vulnerabilities such as running unpatched or outdated and unsupported operating systems are significantly reduced or eliminated, ransomware will continue to proliferate. In 2017, one-fifth of health care organizations in the United States and United Kingdom responding to a poll reported still having Windows XP machines on their network. Slightly less (18%) reported that they still have connected medical devices running Windows XP on their networks. Companies that continue to rely on Windows XP do so at their
own considerable risk considering Microsoft ended support for Windows XP in April 2014, and no longer provides security updates or technical support for it.21

Coming into 2017, individual consumers were the most common victims of ransomware. WannaCry and Petya/NotPetya, which were designed to spread laterally inside a network, conclusively reversed this trend as business networks were crippled by these forms of malware.22 Both of these ransomware variants used the same known exploit for which a patch was available as a propagation mechanism, though Petya and its variants were more advanced in their ability to detect and evade anti-virus defenses.23 The Petya family also added another fiendish twist: although they presented as typical ransomware demanding a payment in exchange for a decryption key, in reality there was no capability to restore the encrypted files. Consequently, if a payment was made, nothing would be recovered. In effect, it was disk-wiping malware masquerading as ransomware.24

The ransomware attacks led by the WannaCry and the Petya families affected numerous health care entities including a health system spanning parts of Pennsylvania, Ohio, and West Virginia; a prominent U.S. pharmaceutical manufacturer; a multinational law firm; and at least one major health care vendor.25 Fueled by existing and newly discovered exploits, the flood of new ransomware variants continues. In the first half of 2017, researchers identified at least 71 new families of ransomware.26

This type of destructive malware could find new fertile ground among medical devices and the estimated 22.5 billion other devices comprising the IoT expected by 2021. In the general consumer marketplace, these “things” include devices such as toys, thermostats, door locks, and cars.27 While the hacking of consumer devices can have serious consequences, the stakes are considerably higher in the health care space where “smart” devices such as insulin delivery systems, inhalers, and ingestible sensors are being developed.28

In August 2017, the Food and Drug Administration (FDA) and Department of Homeland Security warned that medical devices that contain configurable computer systems, including pacemakers, could be vulnerable to intrusions and exploits.29 The vulnerabilities identified by these warnings included improper authentication that could be bypassed or compromised, potentially allowing a nearby attacker to issue unauthorized commands to the device; improper controls on power consumption, which could permit an attacker to repeatedly send commands to reduce battery life; and missing encryption between the device and programmers and home monitoring units.30 Although these exploits would require an attacker with a high degree of skill, the manufacturer took them seriously enough to develop firmware updates for affected devices but stopped short of requiring them to be implemented for all patients. Instead, it recommended that providers and patients “discuss the risk and benefits of cybersecurity vulnerabilities and associated firmware update at the next regularly scheduled visit.”31 It is not yet clear if a physician consultation regarding “cybersecurity vulnerabilities and associated firmware update” will be widely reimbursable by payers anytime soon, but presumably we can at least expect an applicable ICD-10 code in the near future.

More recently, microprocessor manufacturer Intel announced the discovery of four firmware vulnerabilities affecting several lines of its processors. This means that potentially millions of PCs, servers, and IoT devices are at risk. Although it remains unclear how swiftly these flaws might be leveraged into actionable exploits, vendors such as HP, Dell, and others have already completed patches addressing them.32 It remains up to individual consumers and system administrators to ensure that patches like these are actually implemented.

Until underlying vulnerabilities are significantly reduced or eliminated through retirement of outdated and unsupported applications like Windows XP, and patching becomes the rule rather than the exception, ransomware will continue to proliferate in 2018 and beyond.

Payment Reform Model Trends in 2018

While payment reform has been a hot topic in health care for the past several years with the prior administration famously promising to tie 90% of all Medicare fee-for-service payments to quality or value by 2018, the goals of the new administration are far less clear in this regard, particularly since virtually all of the major payment reforms were inherited from the previous administration.

2018 promises to be the year in which the new administration’s full vision of payment reform comes into focus. That vision is likely to be marked by clear shifts in emphasis but not wholesale refutations. This prediction is bolstered by HHS Secretary nominee Alex Azar’s testimony during his confirmation hearing in which he called the “launching [of] so many of the alternative payment models” “one of the great legacies of Secretary Burwell’s tenure.” The specific trends in each of the payment reform programs are discussed below.

Bundled Payment Programs. Perhaps the greatest uncertainty surrounded the fate of the mandatory bundled payment programs for hip and knee replacements (commonly referred to as the Comprehensive Joint Replacement, or CJR program), heart attacks, and cardiac bypass surgery. The dissolution of all such mandatory payment programs was a distinct possibility, especially since the then-HHS Secretary Tom Price, as a congressman, sent a letter to the Centers for Medicare & Medicaid Services (CMS) calling the CJR program a “high-risk government-dictated reform[] with unknown impacts.” In the last weeks of 2017, however, CMS issued a final rule leaving the mandatory CJR program intact in 33 of the original 67 geographic areas while rescinding the cardiac bundled payment programs entirely. In that same rulemaking, CMS promised to develop more optional “bundled payment model(s) during CY 2018 that would be designed to meet the criteria to be an Advanced APM [alternative payment model].” This promise is particularly important to physicians since currently there are limited options for participation in Advanced Alternative Payment Models (APMs).
An early sign of the administration’s focus in 2018 is CMS’ rollout on January 9, 2018 of the next-generation Bundled Payments for Care Improvement (BPCI) program that will take effect after the original BPCI program expires in September of 2018. The BPCI Advanced program remains optional and includes a new iteration of 32 clinical episodes. CMS will set target prices in May of 2018. The program also qualifies as an Advanced APM, making it the first developed by this administration.

Medicare Access & CHIP Reauthorization Act of 2015 (MACRA). On November 2, 2017, CMS released its final rule updating for 2018 the Quality Payment Program required by MACRA. Under that rule, 2018 will be “a second year to ramp-up the program . . . in preparation for a robust program in year 3 [i.e., 2019].” While CMS made several minor changes in an attempt to make the program more user-friendly, one key change for 2018 is that the Merit-based Incentive Payment System (MIPS) for the first time will factor costs in a participant’s performance, weighting it at 10%. Participants should take advantage of 2018 as a phase-in period since costs will account for 30% of a participant’s score in 2019. As mentioned above, CMS will continue to push for expanded participation in risk-based APMs, which will continue to require at least 8% down-side risk. CMS also plans to add Advanced APMs, such as the Medicare Accountable Care Organization (ACO) Track 1 Plus (1+) Model, and reopen the CPC+ and Next Generation ACO in 2018.

A New Focus for Innovation at the Center for Medicare and Medicaid Innovation (CMMI). CMS has been outspoken regarding the big-picture shift it intends to undertake for CMMI in 2018, heralded by the departure of the director of CMMI, Dr. Patrick Conway. The details of that shift, however, are uncertain. According to CMS, in the coming years CMMI will focus on testing models in various areas, including increased participation in APMs; consumer-directed care and market-based innovation models; physician specialty models; prescription drug models; Medicare Advantage (MA) innovation models; state-based and local innovation, including Medicaid-focused models; and mental and behavioral health models.

In September 2017, CMS Administrator Seema Verma penned an op-ed discussing CMMI’s initiative to crowd-source ideas for improving Medicare and Medicaid through a public request for information. In the article, Verma stated that improvement “will require health-care providers to compete for patients in a free and dynamic market, creating incentives to increase quality and reduce costs.”

As 2018 progresses, we will see to what extent future payment reform models will reflect a downsized role for the government and a trend toward more market-driven, outcome-based, and patient-centered models.

Medicaid Outlook for 2018
—Charles Luband, Dentons US LLP

After a year where legislative proposals in large part focused on potential dramatic changes to the structure of the Medicaid program—including elimination of open-ended federal funding and of the enhanced federal match for expansion populations—changes to the Medicaid program in 2018 are likely to be more incremental (unless major entitlement reform efforts ensue). In fact, even if 2018 brings renewed efforts to repeal and replace the ACA, it seems unlikely that Medicaid reform will be the centerpiece it was in the 2017 legislative efforts. Additionally, Medicaid was in some ways buoyed by electoral activity in 2017: Maine voters supported Medicaid expansion, notwithstanding opposition of the state governor. The following Medicaid issues are likely to be critical in 2018.

Medicaid Expansion. At present, 32 states and the District of Columbia have expanded their Medicaid programs to cover individuals with incomes up to 138% of the federal poverty level—the expansion made “voluntary” by National Federation of Independent Business v. Sebelius. Federal matching for costs of “newly eligible” beneficiaries is 94% for federal fiscal year 2018; this reduces to 93% in 2019, and 90% thereafter. HHS estimated in March 2016 that 20 million people had gained health insurance coverage since 2010, including over 14.5 million in the Children’s Health Insurance Program (CHIP) and Medicaid, reducing bad debt for hospitals and shoring up state finances.

Now that repeal of the Medicaid expansion provisions in the ACA appears to be off the table, an important question for 2018 is whether additional states will opt in to the Medicaid expansion. As noted above, over 58% of Maine voters in 2017 voted to require the state to adopt the Medicaid expansion. It seems possible that other states in 2018, particularly Idaho and Utah, could follow Maine’s lead and put Medicaid expansion on the ballot. Change in the composition of the Virginia legislature also could result in expansion. One question at the federal level is whether CMS will make it easier or more difficult for states to expand.

Medicaid Waivers. In March 2017, HHS and CMS issued a letter to states indicating a willingness to use Section 1115 demonstration authority to “support innovative approaches to increase employment and community engagement” and “align Medicaid and private insurance policies for non-disabled adults.” That letter and CMS’ actions since have confirmed that additional change in the Medicaid program in 2018 is likely to occur in the context of Section 1115 demonstration waivers. A number of states have waiver requests pending that include provisions not previously approved by CMS, including work requirements, drug screening and testing, time limits on eligibility, and premiums and disenrollment for non-payment of premiums for non-expansion populations. Some of the requests are part of expansion waivers, while others would apply to non-expansion populations. It is quite possible that Medicaid advocates will litigate if CMS approves some of the waiver requests.

Medicaid Disproportionate Share Hospital (DSH). Medicaid DSH payments, which states can use to reimburse hospitals for Medicaid shortfalls and uninsured costs, were scheduled for substantial cuts in the ACA. These DSH cuts presently are scheduled for federal fiscal year 2018 (i.e., beginning October 1, 2017), although it is possible these reductions will be postponed along with the CHIP extension leftover from 2017. CMS
Payment Advisory Commission (MedPAC) issued a report that health insurance marketplace.

emerging value-based payment initiatives, and instability in the operating costs, and increasing market share continue to reason to believe the trend will continue in 2018.

Traditional factors like improving access to capital, reducing and continuing uncertainty regarding the health insurance reimbursement pressure, changing payment methodologies, likely will continue in 2018.

establish programs under the new framework. This activity on these issues. CMS issued a final rule providers. In 2017 there was substantial CMS and state activity require that managed care plans make payments to certain and an informational bulletin, on June 30, 2017, which told states that it would not enforce many of the provisions of the 2016 rule. In 2018, CMS likely will indicate whether it intends to allow implementation of the 2016 rule to move forward or whether it intends to rewrite the rules.

One provision of the 2016 rule that CMS allowed to move forward concerned restrictions on the ability of states to require that managed care plans make payments to certain providers. In 2017 there was substantial CMS and state activity on these issues. CMS issued a final rule and an informational bulletin, and many states submitted proposals to states to establish programs under the new framework. This activity likely will continue in 2018.

Medicaid Managed Care. Managed care is the predominant delivery system in Medicaid. In May 2016, CMS published a comprehensive Medicaid managed care final rule that substantially changed state discretion in implementing and operationalizing managed care. The Trump administration published an informational bulletin on June 30, 2017, which told states that it would not implement the provisions of the rule. In 2018, CMS likely will indicate whether it intends to allow implementation of the 2016 rule to move forward or whether it intends to rewrite the rules.

Hospitals also face continued pressure to move patients to less expensive settings. Beginning January 1, 2018, off-campus hospital outpatient departments that are not grandfathered or excepted from the Bipartisan Budget Act of 2015 will be paid 40% of current Outpatient Prospective Payment System rates, representing a 20% decrease from the previous year. Lower rates and strict limits on the relocation of grandfathered facilities create real obstacles for hospitals that seek to grow their community presence.

Commercial insurers also are increasingly pursuing site-neutral payment policies. For example, in 2017, Anthem announced that it will no longer pay for certain advanced imaging services provided at hospital-based facilities located in nine states. Anthem also indicated that, in certain markets, it would no longer cover non-urgent visits to hospital emergency departments for minor conditions that could be safely treated in lower-acuity settings.

In addition, value-based payment and population health initiatives are prompting many hospitals to consider affiliations and partnerships as a means of acquiring the expertise and support necessary to thrive in the future. Take, for example, the potential impact of MACRA, under which a portion of Medicare payments to physicians will be tied to goals such as quality and cost. MACRA may drive more physicians to join hospitals, as hospi-
Drugs may be better situated to provide the administrative support necessary to make the most of the new physician payment models. Hospitals that are behind the curve when it comes to building the necessary infrastructure may seek to partner with other hospitals that are further along. Similarly, population health and care coordination initiatives may drive consolidation as hospitals seek to develop and extend service offerings.

With that said, the current administration has not clearly staked out its position on value-based purchasing initiatives, and it has acted to limit the effect of certain bundled payment programs. In 2016, CMS imposed mandatory bundled payment programs for several of the most common procedures for Medicare beneficiaries. With the change in administration, however, CMS reversed course, scaling back the mandatory nature of participation in the Comprehensive Care for Joint Replacement model and canceling altogether several other bundled payment models. CMS also issued a request for industry comments on the future direction of the CMMI, the organization created by the ACA to test innovative payment and service delivery models.

Lastly, uncertainty in the health insurance marketplace likely will add to the pressure felt by many hospitals. In late December, Congress passed a sweeping tax reform bill that repealed the individual mandate at the center of the ACA. As a result, many expect healthy people to leave plans, resulting in a sicker, more expensive group of covered lives, which may cause some insurers to exit the exchanges. According to a November 2017 estimate, repealing the individual mandate would increase the number of uninsured people by 4 million in 2019 and by 13 million in 2027.45 For many hospitals, such an increase would likely lead to an increase in bad debts, uninsured discounts, and charity care.

In this environment, hospital consolidation likely will be a major theme in the year ahead. While many industry analysts expect traditional merger and acquisition activity to remain robust, alternative structures likely will constitute an increasingly large portion of the hospital consolidation landscape. In particular, hospitals may pursue clinical affiliations, management agreements, or the development of regional networks in an effort to brace for expected changes in payment policy while retaining a degree of independence.

**Drug Cost/Pricing**

—Lindsay P. Holmes and Lee H. Rosebush, BakerHostetler

For yet another year the cost of prescription drugs tops the list of concerns in the health care industry. Why? Drug costs continue to rise and players in the drug industry continue to be unable to explain exactly why drug costs continue to rise. For this reason, the pharmaceutical industry and those in the supply chain remain in the spotlight.

In 2017, Congress continued to struggle to understand and combat rising drug costs. As in previous years, Congress introduced a numbers of bills focused on pricing and transparency in the pharmaceutical industry. A few examples include S. 414 requiring HHS to negotiate lower drug prices with pharmaceutical manufacturers via the Medicare Part D program and report to Congress on those negotiations. H.R. 1038 would prohibit prescription drug sponsors who participate in the Medicare program from retroactively reducing payment on certain claims submitted by pharmacies. H.R. 1316 called for requirements to be placed on pharmacy benefit managers (PBMs) that contract with prescription drug plan (PDP) sponsors, including prohibiting a PBM from requiring “that a plan enrollee use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM.” H.R. 1776 required, among other things, manufacturer reporting of research and development expenditures, marketing and advertising costs, etc. S. 637 allowed “patients and employers to compare PBMs’ ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions that are passed through to plan sponsors.” S. 637 also required that a PBM, who has contracted with a PDP sponsor or Medicare Advantage organization, pass a minimum percentage of aggregate rebates and discounts to the plan sponsor. While not all of these bills made it far in the legislative process, their existence in rapid succession demonstrates Congress’ keen interest in this topic.

Interestingly, introducing new laws was not the only way Congress made the public and the industry aware of its concerns about the cost of drugs in 2017. Based on a bipartisan request by a number of Senators, the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP) held multiple hearings on drug costs, first in June 2017 and then in October 2017. At the second hearing, the Senate HELP Committee brought together members of the pharmaceutical industry including representatives from drug manufacturers, drug wholesalers, PBMs, and pharmacies to discuss how the prescription drug delivery system impacts how much patients pay for those drugs.

Notably, Congress is not the only branch of the federal government taking notice of the drug pricing problem. Early in his term, President Trump emphasized the need to curb drug prices. In March 2017, President Trump tweeted that he was “working on a new system where there will be competition in the Drug Industry. Pricing for the American people will come way down!” In the summer of 2017, a draft Executive Order related to drug pricing circulated among the media and was intended to “[r]educe burdens caused by regulatory and administrative actions that inflate or distort prices for beneficiaries of Federal health programs” and “[r]escind, revise or simplify regulations and other administrative actions that inappropriately or unfairly contribute to higher prices or cost-sharing for medical products for American patients.” The draft Executive Order would require certain action from multiple departments within agencies, including FDA, CMS, the Internal Revenue Service, and the Health Resources and Services Administration. The draft Executive Order took a similar tone to the Executive Order issued in January of 2017 requiring that every new regulation be matched with the identification for elimination of two old regulations. Although the draft Executive Order has yet to
make it to a final version, President Trump has indicated, at least publically, that he has no intention of letting the industry off the hook. For example, more recently President Trump took to the twitterverse again to rail against soaring drug prices, including taking a shot at Merck’s Chief Executive Officer for “ripoff drug prices.” In addition, both President Trump, and his HHS Secretary nominee Alex Azar, have identified the need to lower drug prices as a “top priority.”

With respect to specific drugs, there have been several federal and state governmental probes into raising prices of epinephrine and diabetes supplies, including insulin and test strips. For example, there is an ongoing price-fixing lawsuit accusing several companies (both PBMs and manufacturers) of violating both federal and state law when setting prices for diabetic testing supplies. In addition, a number of drug manufacturers and a PBM have been the target of questions related to the increase in price of certain critical allergy and diabetes drugs. Several insulin manufacturers also face class actions related to recent pricing. Although the scrutiny and calls for transparency continue, it is unclear what impact it will have on the actual price of drugs in the coming year.

The Opioid Epidemic—Legal Issues
—Ellie Bane, Catholic Health Initiatives

“[A] disease that touches too many of our communities—big and small, urban and rural—and devastates families, all while straining the capacity of law enforcement and the health care system.”53 The United States is in the midst of a devastating opioid misuse epidemic that kills at least 90 people per day44 and has been deemed a “public health emergency” by the Trump administration. As America attempts to address this very real public health crisis, the effects of opioid misuse have created a number of legal issues. This piece provides a general overview of the most common health care related legal issues that have arisen from the opioid epidemic.55

Hospitals will face increasing legal challenges in dealing with the opioid epidemic in 2018. Notably, these challenges include dealing with admissions and discharges related to opioid users and also reporting opioid users while remaining compliant with state and federal patient privacy laws. Hospitals must deliver care to opioid users in the same manner as they deliver care to all patients seeking treatment. However, in the case of opioid users, this can create legal challenges regarding what information can be shared with family members, what community outreach can occur, and what social services can be offered to patients.

A significant issue for hospitals is the pain scale implemented in most facilities. Pain scales were used, among other things, as a metric of patient satisfaction and recovery process in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). However, an unintended consequence of the pain scales was a focus on pain levels, painkillers, and an atmosphere that may have contributed to the current pain medication/opioid epidemic. Hospitals also can expect to be faced with labor and employment shortages as the need for substance abuse treatment and related services increases. Hospitals, already under pressure with staffing shortages, may find themselves needing to increase qualified staff.

Facilities may face financial pressure by virtue of the Institutions for Mental Disease (IMD) Exclusion, which prohibits federal reimbursement for Medicaid patients in residential facilities treating mental diseases, including substance use disorders, that have 16 beds or more in the facility. The result of the IMD exclusion has been that many patients delay seeking treatment and end up using hospital emergency rooms for treatment as a last resort. Various federal proposals have been considered to relax, remove, or modify the IMD prohibition for opioid addiction/treatment.

Physician practices also are experiencing a myriad of legal issues as the front line in dealing with pain medication usage and a source of perpetuating the opioid epidemic with invalid, or unnecessary, pain prescriptions. The government continues its investigation into pill mills with the help of the DOJ’s newly established Opioid Fraud and Abuse Detection Unit that is using data analytics to identify over-prescribers.56

The large number of deaths from opioid abuse and related causes has created problems for morgues and medical examiner offices. Laboratories and morgues have increased demands while experiencing staffing shortages and a potential lack of compliance with state and local morgue and laboratory requirements.57

Pharmaceutical companies and pharmacies may have the most uncertain legal issues stemming from the opioid epidemic. A majority of states are investigating opioid pharmaceutical manufacturers, with a multitude of cities and counties either in pre-litigation or active litigation against the same defendants.58 Government actors are employing a similar litigation strategy to the initial steps used in fighting tobacco companies. Additionally, pharmacies are now in a similar position to hospitals and physician offices in that they need to monitor pain medication seekers, as well as over-prescribers. Insurers also have started to respond by refusing to cover certain highly addictive pain medication or limiting the number of opioids prescribers can administer to first time users. Such coverage actions may be grounds for future legal issues among pharmaceutical companies, pharmacy benefit managers, and payers.

The FDA also has taken steps to curb the opioid epidemic by demanding that an opioid be pulled from the market due to public health consequences and increasing access to medication-assisted treatment options by approving new drug formulations and devices.

In fiscal year 2017, HHS invested almost $900 million in opioid-specific funding, including to support state and local governments and civil society groups, to support treatment and recovery services, to target availability of overdose-reversing drugs, and to train first responders.59 HHS announced in September 2017 that it was awarding an additional $144.1 million in federal grants to prevent and treat opioid addiction that was authorized by the Comprehensive Addiction & Recovery Act. In the fall of 2017, the Trump administration declared the opioid crisis a “public health emergency” and the White House’s Opioid Commission released their final report making recommendations to help
combat this crisis. Declaring the opioid crisis a public health emergency allows HHS to accelerate temporary appointments of specialized personnel to address the emergency (pending any funding needed); work with the Drug Enforcement Administration (DEA) to expand access for certain groups of patients to telemedicine for treating addiction; and provide new flexibilities within HIV/AIDS programs. However, declaring a public health emergency did not provide the immediate additional funding to combat opioid abuse that declaring a national emergency would have allowed. The administration unveiled a five-point opioid strategy to: improve access to prevention, treatment, and recovery support services; target the availability and distribution of overdose-reversing drugs; strengthen public health data reporting and collection; support cutting-edge research on addiction and pain; and advance the practice of pain management.

States are using various legislative and administrative efforts to fight the opioid epidemic. Some states have enacted legislation allowing naloxone access without a prescription. Ohio has enacted a community-based overdose education and naloxone distribution program called Project DAWN. Community efforts like Project DAWN represent opportunities for health care providers to work with their communities to combat opioid abuse. West Virginia, hit particularly hard by the opioid crisis, has applied for a Medicaid waiver to address substance abuse and is using $24 million from a settlement with opioid distributors to expand the availability of addiction treatment. State responses also include legislative efforts to limit the type of prescriptions that can lead to opioid abuse, requiring reporting by pharmacies, and potentially requiring additional steps (including checking the prescription drug monitoring program) before allowing prescriptions of opioids and related drugs.

*The author thanks Ashley Thomas, Baker Donelson, for her input on this piece.*

### Telemedicine and Digital Health

—Nathaniel Lacktman, Foley & Lardner LLP

The most activity and progress for coverage of telehealth services in 2017 has been at the state level, with approximately 36 states and the District of Columbia having telehealth commercial insurance coverage laws. Under these laws, a health plan must cover services provided via telehealth to the same extent the plan already covers the services if provided through an in-person visit. The laws do not mandate the health plan provide entirely new service lines or specialties, and the scope of services in the enrollee’s member benefit package remains unchanged. A subset of states includes payment parity language in their telehealth commercial insurance coverage laws. Telehealth payment parity is different from coverage in that it enables providers for telehealth services to be reimbursed at the same or equivalent rate the health plan pays the provider when the service is provided in-person.

On the Medicare side, telemedicine providers celebrated another successful year of growth, as CMS reported a 28% increase over total payments for telehealth services under the Medicare program compared to last year. In addition, effective January 1, 2018, CMS added seven new codes as covered telehealth services, including psychotherapy, care planning for chronic care management, and health risk assessment. CMS also eliminated the use of the –GT modifier to designate the service was delivered via telehealth, instead replacing it with the simpler “02” Place of Service code. Perhaps the most interesting Medicare coverage change for 2018 is that CMS will reimburse for remote patient monitoring (RPM) services (via its decision to unbundle CPT code 99091), so providers should look to that as another revenue opportunity in the coming year. At least a half-dozen bills remain pending in Congress, any one of which would significantly expand Medicare coverage of telehealth services if signed into law.

On the Medicaid side, 48 states and the District of Columbia provide reimbursement for some form of telemedicine services, most commonly real-time audio-video. Among those states, 15 reimburse for store and forward services and 21 states reimburse for remote patient monitoring. Yet, nearly half of the state Medicaid programs still limit coverage to when the patient is located in a facility or practitioner’s office, and do not reimburse when the patient is at his home.

### Licensing and Interstate Medical Practice

Last summer, Texas finally enacted a new law to eliminate its notable barriers to practicing via telemedicine, effectively ending a multi-year antitrust lawsuit between Teladoc and the Texas Medical Board. As we enter 2018, physicians can now create a valid doctor-patient relationship via telemedicine in all 50 states (although states continue to maintain variances and nuances on required technology, consent, and practice standards for telemedicine). On the licensure front, nine medical boards offer telemedicine special limited licenses, a decrease from 11 last year. In addition, the Federation of State Medical Boards’ Physician Licensure Compact is now live and underway, with 22 states currently participating. The Compact is essentially a clearinghouse for single-point licensure applications in multiple states, and participating state medical boards each retain their licensing and disciplinary authority. It is a step in the right direction, but most telemedicine advocates would have preferred a more streamlined reciprocal arrangement. Finally, Congress is using its federal supremacy powers in a bill that would allow doctors in the Veterans Administration (VA) to deliver telemedicine services to VA patients, without regard for state licensure or the patient’s location. The bill passed the House in November and is expected to pass the Senate as well.

### Telemedicine Prescribing and Controlled Substances

After creating a valid doctor-patient relationship, telemedicine-based prescribing is widely permitted among the states, although a number of states require the use of real-time audio-video before issuing a prescription. This is changing, and states are beginning to embrace store and forward telemedicine prescribing, which is distinguishable from the problematic and unpermitted
power restoration to elder care facilities during natural disas-

ters. As of mid-November 2017, more than a dozen different
bills addressing power sources, access during emergencies, and
related safeguards had been proposed to the Florida legislature.
The Florida Health Care Association (FHCA) issued a news
release noting that it recommended some of the proposals, but
opposed other changes for the practical effect they may have
on facilities’ responsibility to acquire liability insurance. In
a similar push for legislation in response to natural disasters,
California lawmakers are proposing bills to prevent public
utilities from passing on uninsured damage costs to consumers.
The legislation is prompted by utilities’ ongoing efforts to
recover costs in wildfires not covered by insurance by passing
them along to ratepayers.

Natural disasters and emergencies similar to the recent
hurricanes and fires led CMS to establish a new emergency
preparedness rule for facilities that participate in Medicare and
Medicaid. The rule attempts to establish consistent emergency
preparedness requirements for health care providers participat-
ing in Medicare and Medicaid. The new rule, which took
effect November 16, 2017, requires health care providers across
17 settings to develop and maintain policies and procedures,
communication plans, and training and testing. Under the
rule, nursing homes, such as the one in Florida where resi-
dents perished during Hurricane Irma, must have alternative
sources of energy capable of maintaining safe temperatures.
In response to the final rule on emergency preparedness, The
Joint Commission also updated its guidelines for emergency
management across several health care settings. The updates
include 21 new or revised elements of performance for hospitals
and critical access hospitals, 29 for ambulatory surgery centers,
and 39 for home health agencies.

Other public health concerns followed the recent hurri-
canes’ path and are sure to continue into 2018. In Texas and
Louisiana, officials have concerns that the heavy flood waters
may lead to water contamination from oil, gas, and chemi-
cal operations in the area as well as increased incidences of
mosquito-carried illness such as chikungunya, dengue, West
Nile virus, and Zika virus. In addition to creating new health
problems and injuries, many people with existing conditions
are facing issues with access to medications that may have been
damaged or lost, and treatment at hospitals and dialysis centers
that may have been temporarily closed following the storms.
Longer-term public health problems include exposures to
molds and mildews triggering illness, similar to the increases
seen following Hurricane Katrina.

During the hurricanes, many hospitals and treatment
centers were forced to temporarily close or prioritize available
services. Now, hospitals may be feeling the financial strain
of caring for patients who could not afford treatment and
postponing more lucrative surgeries and procedures. On an
individual level, many may be facing unexpected medical bills
as well as increased insurance premiums in the next year that
may take a backseat to paying for home and car repairs and
replacements. These issues are sure to be focal points for states
struggling to assure their health care facilities are ready to
address emergency conditions in 2018.
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70 See www.imlcc.org.


63 Texas HB 2561, effective Sept. 1, 2017.

64 Center for Connected Health Policy, State Telehealth Laws and Reimbursement Policies (Fall 2017).


67 See supra note 64.

68 Texas SB 1107.

69 See supra note 64.

70 See www.imlcc.org.


58 States include West Virginia, Ohio, and Washington; a coalition of 41 state Attorneys General served subpoenas on the major five opioid manufacturers in September 2017; Cities include Chicago, Dayton, Seattle, Indianapolis, and Cincinnati.


55 The article was drafted as of November 30, 2017, it is expected that certain legislative efforts and plans may arise before publication that will not be addressed. Due to the constantly growing opioid epidemic and wide range of legal issues it presents, AHLA is working on a number of resources for its members. Notably, an upcoming issue of AHLA Connections will include articles describing specific legal issues hospitals, physician offices, and pharmacies face in response to the opioid crisis. Additionally, a work group is collaborating on a Toolkit designed to address many aspects of the opioid epidemic.


