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For the health and life sciences law community



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OFFICIAL MAGAZINE OF AMERICAN HEALTH LAWYERS ASSOCIATION



1. Health Care Reform and the ACA

—Katrina Pagonis, Hooper Lundy & Bookman PC,
and Amy Sanders Morgan, Bass Berry & Sims PLC

The outlook for the Affordable Care Act (ACA) under the new Trump administration is hazy at best. Since the ACA's enactment nearly seven years ago, Republican leadership has called for its repeal, criticizing its key pillars—the individual mandate, the Medicaid expansion, and federal regulation of the insurance market. With a Republican administration and Congress, it seems likely that this rhetoric will be transformed into actual policy, upending a health reform effort under which an estimated 20 million adults have gained coverage.¹ There is very little precedent for unwinding a government program of this magnitude.

Repeal-and-Replace Efforts

Despite extensive discussion about “repealing and replacing” the ACA, the content of any final Republican health reform package is uncertain. There are, however, some common themes among Republican proposals, many of which are included in the Republican House leadership’s “A Better Way” agenda for health care reform.² The deregulation of health insurance is frequently emphasized, which arguably would allow individuals to shop for lower premium plans (perhaps across state lines) with leaner benefits and higher cost-sharing obligations. Certain popular ACA protections, however, are likely to be retained, namely the ban on preexisting condition exclusions, the availability of dependent coverage to age 26,

and the prohibition of lifetime limits on benefits. Instead of an individual mandate, a continuous coverage requirement has been proposed to incentivize coverage: individuals with a gap in coverage could face higher premiums based on health status. Other proposals include high risk pools, premium tax credits tied to age rather than income, and limiting Medicaid growth through block grants or per capita spending limits.

At present, the central constraint on health reform legislation is the absence of a filibuster-proof (60-vote) Republican majority in the Senate. Republican congressional leaders demonstrated in 2016 that significant portions of the ACA could be repealed by a simple majority through reconciliation,³ an expedited process for considering budget bills. Work is already underway to prepare reconciliation legislation that will eliminate or neutralize subsidies for insurance purchased through the health insurance exchanges (Marketplaces), the Medicaid expansion, and the individual and employer mandates, and reconciliation also could be used to enact some elements of an ACA replacement package. However, other landmark provisions of the ACA (e.g., annual limits, out-of-pocket maximums, essential health benefits) likely lack the budgetary impact needed to be part of reconciliation.⁴

Congress is currently preparing to pursue a two-phase repeal-and-replace strategy, first passing a delayed repeal of certain ACA provisions through reconciliation. Under this strategy, Congress would then undertake more comprehensive health reform legislation (requiring 60 Senate votes). With the current makeup of the Senate, this would necessitate some level of bipartisan support, allowing swing votes in the Senate to influence the final reform package.



Executive Action on Reform

Despite the emphasis on repeal-and-replace efforts, the next phase of health reform need not begin or end with Congress. Instead, the executive branch could shift the federal regulatory framework for public and private health coverage. The Trump administration could use the discretion afforded by the ACA itself to significantly change how the law is implemented and interpreted—without legislative action—using notice-and-comment rulemaking, subregulatory guidance, waivers, non-enforcement, and litigation positions.

New leadership at the Department of Health and Human Services (HHS) could transform the ACA through notice-and-comment rulemaking (e.g., redefining “essential health benefits”). Further, a significant body of subregulatory ACA guidance (e.g., requirements for hardship exemptions to the individual mandate and for contraceptive coverage⁵) could be altered without a lengthy rulemaking process. Other informal administrative strategies may include limiting HealthCare.gov enrollment efforts or adopting non-enforcement policies for specific ACA requirements, citing the Obama administration’s previous non-enforcement of certain ACA rules as precedent.⁶ Without a supportive administration, healthier individuals may choose not to pay into the individual market risk pool and insurers still bound by the ban on preexisting condition exclusions might be more likely to withdraw and/or raise premiums.

The administration also may halt some or all Center for Medicare & Medicaid Innovation demonstration projects or work with states to shape health reform through Medicaid and ACA State Innovation waivers. Waivers that impose financial burdens on Medicaid beneficiaries could become more common, such as those in the Healthy Indiana Plan 2.0, which requires beneficiaries to pay into health savings accounts.⁷ Moreover, states might also propose waivers adding work mandates or other restrictions to their Medicaid programs.

Lastly, litigation priorities of the new administration could have far-reaching effects, particularly its litigation position in *House v. Burwell*, which threatens to eliminate cost-sharing reduction payments to insurers.⁸ The U.S. District Court for the District of Columbia held that these payments are improper without an appropriation,⁹ but the ruling was stayed on appeal.¹⁰ If the Trump administration withdraws or loses the appeal, reimbursement for insurers would cease, but further litigation may follow as insurers seek payment from the Court of Federal Claims. Further, insurers may exit the Marketplaces to avoid any requirement to offer cost-sharing reductions without federal payment.

State-Level Health Reform

As we enter a new era of health reform, it is possible that we will see expanded innovation by states beyond the Medicaid waivers discussed above. In the years leading up to the enactment of the ACA, states and municipalities experimented with pay-or-play mandates that sought to expand employer-sponsored coverage and public coverage options within the confines of Employee Retirement Income Security Act (ERISA) preemption. In addition, some states have fully incorporated the ACA’s insurance market reforms into state law and have established state-run insurance exchanges that could continue operating even if federal support for the Marketplaces is with-

drawn. The likely elimination of federal funding for Medicaid expansion and Marketplace subsidies, ERISA preemption, and any new preemption provisions facilitating the interstate sale of insurance, however, might limit these efforts.

Conclusion

The coming transitions in political power created startling uncertainty. Clarity will emerge as the Trump administration sets and pursues its agenda over the coming years. The primary metrics of success under the ACA—affordability, access, and quality—will undoubtedly remain significant, but perhaps with a new emphasis on personal responsibility. Shifting priorities (affordable for whom? access to what?) will reveal differences in our understanding of the fundamental goals of health reform.



2. MACRA Implementation—Medicare Physician Payment Reform Continues in 2017

—Ben Durie, Hooper Lundy & Bookman PC

On October 14, 2016, the Centers for Medicare & Medicaid Services (CMS) released the long-awaited Final Rule implementing the Medicare Access and CHIP Reauthorization (MACRA) Act of 2015, which went into effect on January 1, 2017.¹¹ MACRA repealed the beleaguered sustainable growth rate methodology and replaced it with the new Medicare Quality Payment Program, which offers Medicare providers a choice between two reimbursement tracks—the first requires reporting under the Merit-based Incentive Payment System (MIPS) and the second requires participating in an Advanced Alternative Payment Model (Advanced APM). Depending on which track providers choose, and how well providers perform on a range of quality, cost, and outcome-based measures, providers will see positive or negative adjustments in their Medicare reimbursement starting in 2019.

Key Feature of 2017 Is “Pick Your Pace”

The key change in the Final Rule is the softening of several central program elements and the introduction of a transition year in 2017, which CMS refers to as “pick your pace.” In response to feedback from the provider community—CMS received over 4,000 comments on the Proposed Rule—CMS created four different possible pathways for clinicians in 2017:¹²

- » **Option 1: Test the Quality Payment Program.**¹³ This option allows providers to familiarize themselves with the program by submitting at least one measure each in the quality and improvement activity categories or reporting the measures in the advancing care information category. Providers using this option will not qualify for any positive payment adjustments but will avoid negative payment adjustment in 2019.
- » **Option 2: Partially Report.** If providers report at least one measure in each MIPS performance category, they can avoid the negative payment adjustment in 2019 and may be eligible for a small positive payment adjustment.

» **Option 3: Fully Report.** The third option is to fully report under all of the MIPS performance categories for at least 90 consecutive days. Under this option clinicians can earn moderate positive payment adjustments and may be eligible for even more if they qualify as exceptional performers based on the data reported.

» **Option 4: Participate in an Advanced APM.** The fourth option is to participate in an Advanced APM. Those providers who qualify will be eligible for a 5% payment incentive in 2019.

Loosening of MIPS Requirements

MIPS is a combination of the existing Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier or Value Modifier, and the Electronic Health Record Meaningful Use Program, with the addition of a new performance category assessing resource use. The four performance categories under MIPS are called: (1) Quality; (2) Advancing Care Information; (3) Clinical Improvement Activities; and (4) Resource Use.

In another attempt to ease the transition for clinicians, in the Final Rule CMS lowered the reporting requirements for each of the performance measures and delayed the rollout of the Resource Use category until 2018. For the 2017 performance year, the weighting of the performance categories is: Quality (60%), Advancing Care Information (25%), and Improvement Activities (15%).¹⁴

Push Towards Alternative Payment Models Continues

MACRA retains a traditional fee-for-service (FFS) pathway for clinicians, albeit tied to quality and other outcome-based measures, but APMs likely remain the direction Medicare reimbursement is headed and Advanced APMs offer the largest incentives for participating providers. The MACRA Final Rule loosened the downside risk requirements for qualifying as an Advanced APM, although the thresholds are still higher than many in the provider community would have liked.¹⁵ In addition, the Final Rule outlined plans to expand the number of APMs that could qualify by amending the current Maryland All-Payor Model and the mandatory episode payment models being rolled out for certain participating hospitals (such as the Comprehensive Care for Joint Replacement Model and the proposed cardiac bundle models). CMS also hinted at the creation of a new Accountable Care Organization Track 1 + model for 2018.¹⁶

Open Questions for 2017 and Beyond

It remains to be seen how CMS will approach the continued implementation of MACRA and other value-based payment initiatives under the new administration. It is worth noting that Representative Tom Price, who has been nominated to lead HHS, has been critical of CMS' handling of MACRA implementation and the mandatory episode payment models established by CMS and the Center for Medicare & Medicaid Innovation.¹⁷ It is likely that the movement towards value-based reimbursement will continue in 2017 and beyond, but providers will need to keep a close eye on how MACRA implementation unfolds.



3. Medicaid Outlook

—Mark Gallant, Cozen O'Connor, and
Charles Luband, Dentons US LLP

Much of the activity in Medicaid in 2017 will be dictated by new leadership, particularly in the incoming Trump administration. Representative Tom Price, who has been nominated to head HHS, has long fought for repealing the ACA and for cutting Medicaid funding. Seema Verma, who has been named to serve as CMS Administrator, has a strong Medicaid background and is best known for formulating Indiana's expansion waiver as well as for expanding state control over Medicaid eligibility and payment policy.

Medicaid Expansion and ACA Repeal

The largest Medicaid development for the coming year is the fate of "Medicaid expansion" under the ACA. At present 31 states and the District of Columbia have expanded their Medicaid programs to cover individuals with incomes up to 138% of the federal poverty level—which was made "voluntary" under *National Federation of Independent Business v. Sebelius*.¹⁸ Federal matching for 2016 is 100% of the costs of "newly eligible" beneficiaries, and reduces to 95% in 2017. HHS estimated in March 2016 that 20 million people 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. The new Congress, at least at this moment, appears poised to "repeal" the ACA swiftly without debate (to be effective after the midterm election) through the budget reconciliation process, while having reached no consensus on a "replacement" for the ACA. The fate of Medicaid expansion is unclear. New York and California alone stand to lose \$21 billion in 2017 if the enhanced federal matching funds are eliminated. State financial solutions to an expansion repeal could include reduction of coverage or optional services, and cuts to provider reimbursement.

Budget reconciliation proposals also include defunding Planned Parenthood. Access for family planning services (which include contraception, cancer screenings, and treatment of sexually transmitted diseases) is guaranteed to Medicaid enrollees under current law.

Medicaid Block Grants or Per Capita Caps

Medicaid block grants or Medicaid per capita caps also could be a significant topic of discussion for the new Congress, having been encouraged by the President-elect, Senate Majority Leader, and House Speaker. Both a block grant (fixed annual per state federal grant) and per capita cap (fixed dollar per beneficiary limit) structure would provide states with greater flexibility in exchange for limits on federal funding, while many questions remain unanswered. For example:

- » What requirements will be imposed on states in the context of coverage, benefits, or accountability?
 - Will states need to maintain current coverage or benefit levels?
 - What must states do to draw down federal funds?





» How will block grant or per capita amounts be set? Will initial amounts reward or penalize certain states (e.g., those where medical costs are more/less expensive or states that did/did not expand Medicaid?)

Medicaid block grants and/or per capita caps will likely be strongly opposed by Democrats and many current Medicaid stakeholders. Details regarding any proposal may expose new fault lines that may or may not track party lines.

Medicaid Waivers

With or without an expansion repeal, the new administration may take a more liberal view than CMS has to date in approving “premium support” or “private option” expansion coverage through Section 1115 Medicaid waivers, including the approval of beneficiary work requirements and premiums. Republican Governors in Michigan and Arizona have been highly supportive of continuing waiver-based expansion programs. Thus far, CMS has declined to approve mandatory job or work training program components of such waivers, rejecting such proposals from Pennsylvania, Arizona, and Michigan. CMS also has rejected waiver requests to require partial premiums for enrollees with incomes falling at or below 100% of the federal poverty level. The next Secretary would have broad discretion to allow for such requirements under new or renewed expansion waivers, an area in which the CMS Administrator designee is well versed.

Medicaid Supplemental Payment Issues and Managed Care
Medicaid supplemental payments—i.e. payments above Medicaid base rates—comprise a significant portion of Medicaid expenditures. They include Medicaid disproportionate share hospital (DSH) payments, Upper Payment Limit (UPL) payments, and payments made through Section 1115 waivers through a Safety Net Care Pool (SNCP), Low Income Pool (LIP), Uncompensated Care (UC) pool, or Delivery Systems Reform Incentive Payment (DSRIP) pool. Per the Medicaid and CHIP Payment and Access Commission 2015 Chart Book, supplemental payments were over \$47 billion in federal fiscal year (FFY) 2014. There are many open questions regarding Medicaid supplemental payments for 2017:

DSH

Medicaid DSH payments, that reimburse hospitals for Medicaid shortfalls and uninsured costs, were scheduled for substantial cuts in the ACA. These DSH cuts, which Congress justified based on projected reductions of uninsured patients, presently are now scheduled for FFY 2018, and would be a significant issue for 2017 if implemented. If the ACA is repealed and/or amended, the impact on DSH cuts is a significant question.

Waiver Pools

Although CMS has permitted supplemental payment pools under waivers, CMS wrote to all states with uncompensated care pools in November 2015, emphasizing that coverage is the best way to secure access to health care and that UC pools are not an alternative to Medicaid expansion. Many states—including Florida and Texas—have waivers that include payment pools and are up for renewal in 2017. How the new CMS will treat these payment pools is an open question.

Medicaid Managed Care Pass-Throughs and Payment Reform

Medicaid managed care—under which benefits are administered by private Medicaid Managed Care Organizations (MCOs) that receive per member per month capitation fees and deliver services through a contracted provider network—already has eclipsed Medicaid FFS programs. Over 60% of all beneficiaries were enrolled in comprehensive Medicaid managed care programs as of 2013, and this trend is increasing. Many states have taken steps to adjust supplemental payments—previously the province of Medicaid FFS—to this new environment by channeling these funds to providers through MCOs. The comprehensive Medicaid Managed Care Final Rule published on May 6, 2016, provided explicit authority to states to require MCOs to make payments to certain providers to encourage value-based purchasing, delivery system reform, or to establish provider payment initiatives within the compass of “actuarially sound” rates. CMS also included a new transitional authority, temporarily permitting “pass-through payments” to hospitals, physicians, and nursing facilities. Under an Informational Bulletin issued on July 29, 2016, and a proposed regulation published on November 22, 2016, transitional MCO pass-throughs—which CMS permitted to avoid service disruptions and economic harm to safety-net providers, despite generally prohibiting such payments—would be limited by the aggregate amount of annual pass-throughs already in place as of July 5, 2016. CMS’ action on managed care supplemental payment issues could be a significant issue in 2017.



4. The Rise of Ransomware

—Jon Neiditz, Kilpatrick Townsend & Stockton LLP

Ransomware is the business model that has risen to dominance of the cybercriminal market. Among the reasons for its success are quick introduction and deployment without the development costs and need for sustained stealth of data exfiltration, and quick and direct payments not requiring complex internet networks for the purchase and sale of personal information. Ransomware attacks have quadrupled this year, averaging 4,000 per day, according to the Justice Department.¹⁹ The Federal Bureau of Investigation (FBI) noted ransomware costs organizations have been willing to disclose totaled \$209 million in the first three months of 2016, compared to a total \$24 million for all of 2015.²⁰ A report released in August found that about 80 new ransomware “families”—an increase of 172%—were discovered in the first half of 2016.²¹

Beneath the numbers lies a sea change in the way the law will come to see information security incidents, because ransomware is a visible portent of other major threats to cybersecurity that involve controlling, damaging, and interrupting systems, denying access to data and destroying or otherwise harming the integrity of data without acquiring the data, rather than what we have come to know as “breach.”

The popular notion of a data breach today was forged by the California legislature in 2002, when the state became the only jurisdiction in the world to require notification to individuals about breaches of some types of their personal information.²² This innovative law attracted little national attention until

February 2005, when ChoicePoint announced that it suffered a breach affecting 30,000 Californians, and the world soon learned that the only reason Californians were so unlucky was that no other state required notification. Statutes modifying but fundamentally following the California model spread like wildfire across the country. Through their similarity and the similarity of the breaches they forced companies to disclose, those statutes reified—constructed and then petrified—what we think of today as a data breach. Generally, we think of a breach as unauthorized access to or acquisition of unencrypted personal information that compromises the security or privacy of that information. The Health Information Technology for Economic and Clinical Health (HITECH) Act incorporated that concept into the Health Insurance Portability and Accountability Act (HIPAA), and construing “compromise” led HHS over a long and winding road to its simple and elegant four-factor risk assessment.²³

The information security world, on the other hand, has always been more focused on a wider variety of incidents. Moreover, both security frameworks and standards such as National Institute of Standards and Technology and corporate security processes have evolved more rapidly than law; they have become adaptive programs responding to ever-changing risks and focused on detection and response as well as prevention.

Even though ransomware is the dominant current information security threat to health care providers,²⁴ notification laws still focus on breach. In other words, until recently, state and federal breach notice requirements did not appear to apply to ransomware because the protected data is encrypted rather than accessed or taken, even though choosing a facility under a ransomware attack may entail much greater risks than the identity harms associated with a facility suffering data breach. For the unprepared health care provider not able to prevent ransomware or quickly contain it to prevent more harm, ransomware may interrupt cancer treatment, render the patient record unavailable,²⁵ or result in other greater and immediate threats than identity theft.

Recognizing the threat, HHS put out an innovative and comprehensive “Fact Sheet” on “Ransomware and HIPAA,” which treats ransomware as a notice-triggering data breach by default, unless it is determined via the familiar four-part HIPAA breach risk assessment not to constitute or involve such a breach.²⁶ Like other guidance on ransomware available from the United States Computer Emergency Readiness Team (U.S.-CERT),²⁷ the FBI,²⁸ and the Federal Trade Commission (FTC),²⁹ the Fact Sheet emphasizes key protections such as safe, segregated, and reliable backups and patching, monitoring, and training to avoid phishing, putting them in the context of HIPAA risk analysis. The Fact Sheet then shoehorns ransomware into HIPAA’s Breach Rule “because ePHI encrypted by the ransomware was acquired” in the absence of a determination through the usual four factors of a “low probability that the PHI has been compromised.”

Where the Fact Sheet most reveals that the old legal framework of breach notification is a Procrustean bed for emerging cybersecurity threats is in its response to how a ransomware attack on encrypted PHI triggers breach notification.³⁰ Since the regulatory paradigm is breach, the Fact Sheet must make such an event notice-triggering only when the underlying data loses its encryption. From the standpoint of harm, of course,

that is beside the point; the ransomware harms primarily by interfering with the availability of the information, not with its confidentiality, and the continued encryption of the information to HIPAA standards does not protect its availability.

The biggest emerging cybersecurity threats, like ransomware, are principally about the control of systems rather than breaches of personal information. The threats posed to cyber-physical systems in the Internet of Things—connected cars caused to crash, connected medical devices caused to malfunction, attacks by connected buildings—are a major area of risk of harm, and we now have an IoT botnet threatening the Internet through the Mirai DDOS attack.³¹ And beyond the IoT, of course, looms the specter of cyberwar. A robust regulatory regime focused on the diversity of harms that may be caused by security incidents would escape the paradigm of breach and view security harms more broadly. As talk of a uniform federal security breach response law bubbles up again with a new administration and Republican-controlled Congress, the question becomes whether an incident response law can be crafted based on the emerging risks of 2017 rather than those known in 2002.



5. Fraud and Abuse: Defying Gravity

—Tony Maida, McDermott Will & Emery LLP

From the industry perspective, the fraud and abuse environment can seem controlled by a mysterious wizard ensconced in the Emerald City, far removed from the challenges of operating a health care business. This year was no exception. Let’s peek behind the curtain for 2017.

Post-Escobar Implied Certification. Much of the Supreme Court’s analysis in *Universal Health Services, Inc. v. United States ex rel. Escobar* emphasized the “demanding” nature of the implied certification’s materiality standard, which will be the subject of considerable litigation in the coming years. Scienter is another important implied certification issue, including whether the defendant knew compliance with the standard at issue was material to the government. Also, several courts have held that ambiguous regulations cannot state an implied certification claim if the defendant’s interpretation of the regulation was reasonable.³² Given the abundance of ambiguous regulations in the health care arena, this is a topic to watch.

60-Day Rule. It’s been almost a year since the birth of the Medicare Parts A and B overpayment rule (and over two years for Parts C and D³³) interpreting the ACA’s requirement to report and return overpayments within 60 days of identification.³⁴ What triggers the rule’s requirement to conduct reasonable diligence and when the clock starts ticking are just two of a host of questions lawyers and their clients will continue to contend with in 2017. Perhaps the most important question—is there an overpayment—moves beyond a 60-Day Rule analysis to determining whether the Medicare requirement at issue is a condition of payment, participation, or something else. Despite the absence of clear answers, the government has been investigating allegations of 60-Day Rule violations under the reverse false claims principle.





Statistical Sampling and Medical Necessity. The debate swirling around these two controversial topics will continue to wage. From the government's perspective, relying on statistical sampling to prove falsity and damages has understandable appeal. And if one believes in statistical sampling, then it is a short jump to believe that medical necessity issues can be addressed by it. Providers will contend that medical necessity is, at its core, a clinical judgment made by the treating physician based on many factors, including the information available at the time, the physician's clinical knowledge experience, and the patient's clinical history. Defense counsel will note that patients and physicians are not fungible, especially when the allegation is the defendant committed fraud by providing the service to that patient.

Yates Memo Implementation. In a June 2016 speech by Acting Associate Attorney General Bill Baer, the Department of Justice (DOJ) explained its view that "full cooperation" in civil matters includes disclosing "all facts relating to the individuals involved in the wrongdoing" and "proactive cooperation." Some argue that this view seems to undermine the ability of a corporation to properly defend itself. If the company does not believe there was "wrongdoing" in the first place, then it has no "individuals involved in the wrongdoing" to throw under the bus. Further, it's not clear whether defendants who cooperate more will benefit from a better monetary deal than defendants whose cooperation is viewed by DOJ as less robust.

More Data-Driven Government Actions. DOJ, the HHS Office of Inspector General (OIG), and CMS appear to be taking an increasing number of actions based on apparent patterns or trends found through data analytics. Of course, the data often only tells part of the story. As a result, data results typically start an initial inquiry or, at times, a more formal investigation by DOJ, OIG, or a CMS contractor. In contrast, under CMS' newly enhanced revocation authority,³⁵ the first contact with CMS about a specific matter or concern may be the revocation notice, which goes into effect in 30 days after the date of the letter. A hectic and costly scramble ensues for the provider to review the issue and try to submit an effective and complete reconsideration request in time.

Stark Reform? The government and relators continue to pursue Stark Law claims against hospitals based on a "practice loss" theory that questions whether employed physician salaries are fair market value, commercially reasonable, or take into account the volume or value of referrals if the physicians' professional collections are less than the salary. The long-standing debates about how to judge these three critical, yet ambiguous, concepts have not been resolved, providing little clarity to hospitals that are trying to do the right thing. At the same time, payment reform is pushing hospitals and physicians toward greater financial integration. Absent judicial relief, additional legislation may be needed to reform Stark to take into account the practical realities of running a hospital and competitively paying physician employees. Congress showed interest in legislative changes last year and may again. The new administration may also become interested in taking aim at reducing the burden of the law's byzantine regulatory scheme.



6. Federal Antitrust Enforcement: Another Busy Year in Store

—Michael Greer, Hall Render Killian
Heath & Lyman PC

After a year of robust federal antitrust enforcement activity in health care featuring many important cases and rulings, antitrust will continue to be an issue to watch in 2017. Notably, the beginning of 2017 will be important as payers and providers wait for rulings on the DOJ's antitrust challenges of both the Anthem acquisition of Cigna and the Aetna acquisition of Humana. Separately, providers will be digesting Third Circuit and Seventh Circuit opinions preserving the FTC's winning streak against hospital mergers and contemplating whether a provider will ever again beat an FTC merger challenge in court. Meanwhile, looming in the background will be the unanswered question of how federal antitrust enforcement will look during the Trump administration.

Payer Consolidation

In July 2016, the DOJ and a number of states challenged Anthem's acquisition of Cigna³⁶ and Aetna's acquisition of Humana,³⁷ claiming the mergers would fundamentally reshape the health insurance industry and restrict competition by consolidating the industry into three mammoth insurance companies. After a request for an expedited trial was granted, both cases were heard before the U.S. District Court for the District of Columbia at the end of 2016, and both judges promised to deliver decisions in early 2017. The importance of these rulings cannot be overstated, as these mergers have the ability to reshape the landscape for both payers and providers for years to come.

Provider Consolidation

Throughout 2016, providers watched as three FTC hospital merger challenges—one in Huntington, WV,³⁸ one in Harrisburg, PA,³⁹ and one in the North Shore area of Chicago⁴⁰—wound their way through the judicial process. In both the Harrisburg and Chicago cases, the FTC faced at least temporary setbacks for the first time in more than a decade when the respective federal district courts⁴¹ handed favorable rulings to the hospitals. But, after successfully appealing both cases to the Third Circuit⁴² and Seventh Circuit,⁴³ respectively, the FTC's winning streak against hospital mergers remains intact, foreshadowing a continued aggressive enforcement environment against hospital mergers in 2017. In the Huntington hospital merger, the FTC was forced to withdraw its challenge after the state of West Virginia passed a certificate of public advantage, or COPA, law, granting antitrust immunity under the state action doctrine to the proposed hospital merger. While these three cases initially seemed to signal a changing antitrust landscape for hospital mergers, in the end the provider victories proved to be temporary and unlikely to alter the FTC's hospital merger enforcement focus or methodology. In 2017, the FTC will likely remain vigilant in challenging hospital mergers that it finds to be problematic from a competition standpoint.

Health Care Antitrust During the Trump Administration
Although reading the tea leaves to divine what a Trump

administration means for the future is a new national pastime, it remains unclear how federal antitrust enforcement will be affected. Often, it is claimed a Republican administration will be more business friendly and less enforcement oriented, while a Democratic administration will be the opposite. But, in reality, the DOJ Antitrust Division and the FTC tend to be insulated from the political leanings of new administrations because both agencies have career staff who play a significant role in managing antitrust investigations and pride themselves on their independence. That being said, Trump will appoint a new Assistant Attorney General to run the DOJ Antitrust Division and will fill empty FTC Commissioner positions. Currently, of the five positions on the FTC Commission, two are open, plus FTC Chairwoman Edith Ramirez's term is set to expire on April 5, 2017, meaning Trump will have the ability to appoint three of the five FTC Commissioner positions. In theory, the Trump administration could result in a more business-friendly agenda from the top down via these appointments. But, of note, Trump named former Republican FTC Commissioner Josh Wright to lead his transition team for antitrust. Josh Wright, both a JD and PhD economist, is known for his staunch support in using economics and empirical evidence to make antitrust decisions. Based on this, the best prediction might be that antitrust enforcement during the Trump administration will focus more on empirical evidence and less on judgments about economically irrelevant matters (which can cut both ways and may or may not be business friendly depending on the specific facts and circumstances).



7. Drug Pricing

—Lindsay Holmes, Lee Rosebush, and
Allison Rochford, BakerHostetler

Following in 2015's footsteps, the pharmaceutical industry experienced another year of focus on drug pricing by lawmakers, the media, advocacy groups, and consumers. Interestingly, unlike in previous years, this topic for both regulators and the public alike concerned branded and generic drugs. In 2016, actions involving drug pricing were hot and heavy, ranging from allegations of, and congressional hearing involving, a nearly 500% increase of a life-saving injectable drug to a settlement involving DOJ and generic drug rebates to allegations of potential collusion in the diabetic drug space.

Congressional Involvement

The Senate Special Committee on Aging led the effort in 2016 to address the rapid price increase of older, off patent, drugs by branded drug companies. In reaction to "egregious price spikes for certain drugs," Senators Susan Collins and Claire McCaskill, Chairwoman and Ranking Member of the Committee, continued their bipartisan investigation into certain pharmaceutical companies' business models and pricing practices.⁴⁴ Stemming from the Committee's investigation, Senators Collins and McCaskill introduced legislation that would allow for Food and Drug Administration (FDA) fast-tracking of certain generic drug applications.

In addition to the hearing, Senators Collins and McCaskill sent a joint letter to a chief executive officer of a drug manufacturer highlighting that a particular injectable drug had

seen an increase in price of nearly 500%.⁴⁵ According to the Senators, this same drug was a "relatively old product" and they, therefore, requested the company provide information and a briefing about the drug's pricing and marketing dating back to 2007. Senator Bernie Sanders, and House Committee on Oversight & Government Reform Ranking Member Elijah Cummings, requested DOJ and FTC explore possible colluding of diabetes products manufacturers involving the allegation that the manufacturers had tripled the cost of insulin medication in the last decade.⁴⁶

DOJ Involvement

Recently, following an investigation of a drug manufacturer's drug classification as a generic drug in the Medicaid rebate program, DOJ reportedly settled with the manufacturer for \$465 million to resolve scrutiny over the misclassification.⁴⁷ Specifically, the settlement involved whether the drug in question was a "brand" or "generic" drug under the Medicaid Drug Rebate Program. The manufacturer was paying the CMS a 13% rebate, as the drug was listed under the generic classification, whereas the government argued the product should have been classified as a branded drug with a rebate of 23.1%.

Related Actions

Interestingly, the FTC also is starting to take serious notice of the drug pricing world. For example, in 2016 the FTC sued, and then later voluntarily dismissed a suit, against a branded drug company for alleged anticompetitive pay-for-delay settlements involving two different drugs.⁴⁸ In the complaints, the FTC alleged the manufacturer paid hundreds of millions of dollars to generic competitors to extend the companies' market exclusivity at a cost of \$3.5 billion to consumers and taxpayers.⁴⁹ By paying to extend the exclusivity, the FTC was alleging that the brand manufacturer could continue to charge a higher price for the drugs in question.

Looking Forward

Drug pricing issues are likely to remain a hot topic as we move into 2017. President-elect Trump campaigned on a populist message that included promises to permit the importation of prescription drugs from Canada and negotiations of drug prices by the Medicare program. Both proposals, often popular in Democratic circles, may not gain much traction in the Republican-controlled Congress. It is unclear how these proposals or other drug pricing policies will fit into the larger debate surrounding current health care policies and programs. With that said, drug pricing will likely remain a topic to watch throughout 2017.



8. Developments in Telemedicine Legal Issues

—Tara Kepler, Law Office of Tara Kepler, and
Stacey Murphy, Norton Rose Fulbright

The array of legal issues affecting telemedicine use in the health care industry is growing faster than the government (and even attorneys) can manage. In addition to the common telemedicine legal issues that have been addressed over the years, several new legal issues and challenges for the utilization and reimbursement of telemedicine have surfaced in 2016 and



will likely continue to have a significant impact on telemedicine use in 2017.

FTC and FDA Involvement

The FTC and the FDA have recently become surprisingly active in the telemedicine niche of the health care industry. For example, the FTC filed a lawsuit against Lumos Labs, Inc., and reached a \$2 million settlement agreement in early 2016, based on Lumos Labs' advertising claims about its mobile application the "Lumosity Program." Lumos Labs allegedly advertised that use of its "brain training" software could delay and protect against medical conditions such as dementia and Alzheimer's disease. The FTC successfully argued that the advertising was impermissible because Lumos Labs could not substantiate these claims with competent and reliable scientific evidence.⁵⁰

The FTC and FDA also published informational websites in 2016 to assist health care software developers in assessing the range of federal laws that may apply to their technology platforms.⁵¹

In September 2016, the FTC filed an amicus brief in support of Teladoc (a publicly traded telemedicine company) in Teladoc's federal lawsuit against the Texas Medical Board.⁵² In its brief, the FTC asserted that state medical boards may not have the authority to regulate telemedicine in the event that such regulation could be motivated by the anticompetitive and personal self-preservation motives of physician medical board members.

Minimum Standards for Establishing a Patient-Physician Relationship Through Technology

Another hot legal issue for telemedicine practice is whether a physician is permitted to prescribe a medication for a patient with whom the physician has only interacted through an Internet questionnaire and a telephone conversation, in lieu of a live video encounter or traditional in-person examination.⁵³

States like Texas have expressly prohibited this type of "telephone-only" prescribing relationship by regulation,⁵⁴ and the Texas Medical Board's position on this is not an anomaly.⁵⁵ A survey of state laws on this question shows that numerous states (12 states and the District of Columbia) have new or existing laws that expressly prohibit a physician from prescribing medications for a new patient based solely on a telephone conversation.⁵⁶

Another difficulty with this evolving legal issue is that some states have prohibited the telephone-based practice of medicine in administrative decisions when the relevant statutes and regulations have otherwise not expressly addressed the issue. For example, California has what appears to be one of the broadest and most permissive statutory frameworks for the use of telemedicine, but the following excerpt from an administrative decision by the California Medical Board makes California look more like Texas as it relates to telephone-only relationships with patients: "A physician cannot do a good faith prior examination based on a history, a review of medical records, responses to a questionnaire and a telephone consultation with the patient, without a physical examination of the patient."⁵⁷

Telehealth Left out of MACRA; What Now?

CMS finalized the rule implementing MACRA, which replaced the traditional Medicare physician FFS reimbursement system with a value-based reimbursement system, on October 14, 2016.⁵⁸ Under the MACRA proposed rule, tele-

health visits were to count as in-person encounters for MIPS scoring purposes.⁵⁹ Surprisingly, this provision was largely left out of the MACRA final rule.⁶⁰ Advocates, however, are pushing Congress to expand Medicare's new payment policy to telehealth with the CONNECT for Health Act.⁶¹ This act would waive several limitations on telehealth and remote monitoring, and would specifically allow for such technology to be reimbursable under Medicare in more circumstances than is currently the case—possibly bridging the gap left by the MACRA final rule.⁶²

In all, government involvement in telemedicine use is rapidly evolving, and it will be interesting to see how the laws eventually settle over the coming decade.



9. Nondiscrimination and the Affordable Care Act

—Dorothy Cornwell and Susan Fradenburg,
Smith Moore Leatherwood LLP

Section 1557 of the Affordable Care Act (ACA), entitled "Nondiscrimination," garnered new attention in 2016 after the Department of Health and Human Services Office for Civil Rights (OCR) issued its final rule on May 18, 2016. Despite the detailed regulations and OCR's extensive commentary, the rule leaves significant room for interpretation. However, the coming year may answer some lingering questions about the new requirements as OCR and private litigants continue to pursue test cases and establish precedent for discriminatory conduct.

One major question is whether Section 1557—or the ACA—will survive under the Trump administration. Section 1557 could be saved from a plan to "repeal and replace" the ACA, since it is relatively detached from the web of ACA provisions aimed at neutralizing the costs of guaranteed coverage. On the other hand, the final rule creates additional risks and compliance costs for the overburdened health care and health insurance industries. Thus, Section 1557 may be incompatible with a "replacement" act emphasizing cost containment over access to care. Nevertheless, the regulations as written reflect the current law and impose several new requirements on covered entities, including most health care providers and health plans.

Discrimination on the Basis of Sex

Because Section 1557 incorporates preexisting federal anti-discrimination laws, the rule does not impose significant new requirements for most covered entities—except for the prohibition against sex discrimination. Discrimination "on the basis of sex" includes discrimination related to pregnancy, childbirth, and sex and gender stereotyping. Covered entities must respect an individual's gender identity, which may be different from the sex assigned at birth and could be male, female, neither, or a combination of both.

Covered entities may still provide separate male and female facilities, but they must provide comparable facilities to individuals regardless of sex. Health plans may not restrict coverage for sex-specific health services based on gender identity or sex assigned at birth. Coverage for gender transition care is not mandatory, but coverage denials can no longer claim that the care is cosmetic, experimental, or not medically necessary. Coverage determinations must be based on criteria applicable

to any other medical condition. On December 31, 2016, a federal district court issued a nationwide injunction blocking just the portion of the OCR Rule that prohibits discrimination on the basis of “gender identity” and “termination of pregnancy.”⁶³ As of this writing it was unclear how HHS would respond to the ruling.

Notices and Accessibility

Another significant aspect of the rule relates to the requirements for meaningful access for individuals with disabilities or limited English proficiency. The posting requirements, which publicize the provider’s obligations pertaining to protection from discrimination and provision of language services, went into effect October 17, 2016. The requirements are detailed, and include the following:

- » Notices of nondiscrimination must convey:
 - That the covered entity does not discriminate on prohibited bases;
 - That auxiliary aids and language assistance services are available, and how to obtain those aids and services;
 - Contact information for an employee responsible for compliance, investigation, and grievances;
 - How to file a grievance or a discrimination complaint with OCR.
- » “Taglines” regarding the availability of language assistance services must be posted in the top 15 non-English languages spoken in the state. Providers may rely on OCR’s list of the top 15 languages used in each state and territory, accessible on OCR’s website.
- » Notices and taglines must be posted:
 - In a “conspicuously-visible font size”;
 - In a location where the provider interacts with the public;
 - On the provider’s website, accessible from the home page; and
 - In significant publications and communications that are larger than a postcard/trifold brochure.
 - Smaller publications must include a limited non-discrimination notice, and taglines for the top two non-English languages in the state, rather than 15.
- » Websites
 - A link to the notice of nondiscrimination AND a separate link in each of the required 15 languages must be present on the provider’s home page.
 - The language links that direct the individual to the full text of a specific language tagline need to be written in that particular native language. For example, the link to the “Haitian Creole” tagline should appear as “Kreyòl Ayisien,” not “Haitian Creole.”

OCR’s website provides several resources to assist covered entities with compliance, including sample notices and taglines translated into 64 languages.⁶⁴

Funding for OCR enforcement under the new administration is not guaranteed, and the likelihood of significant OCR activity is unknown. Importantly, however, OCR does not appear to have the exclusive authority to enforce Section 1557. Early federal district court decisions conclude that the statute creates a private right of action for individuals claiming discrimination. Unless OCR repeals the final rule, covered entities should continue to heed its requirements in 2017 to avoid exposure to litigation.



10. Property Tax Exemptions for Nonprofits

—Elliot B. Pollack, Pullman & Comley LLC

Health care providers in 2016 continued to question the viability of the not-for-profit hospital tax exemption. In 2015, efforts by the New Jersey town of Morristown to overturn the property tax ad valorem exemption of a 700-bed hospital were successful at the trial court level. The bombshell was followed by a settlement that, together, sent shock waves through New Jersey and beyond. Similar battles in West Virginia and Pennsylvania have increased the concern of the not-for-profit health care industry percolating since 2010 when the Illinois Supreme Court upheld the revocation of Provena Covenant Medical Center’s ad valorem exemption.

The classic attribute of a not-for-profit organization eligible for a municipal ad valorem exemption is that it performs functions that the governmental entity would otherwise be required to assume. As a result, there is a strong nexus between the exemption and the mission of the entity. The rule has been augmented over the years by grafting on concepts from the Internal Revenue Code (IRC). Among other matters, the Code prevents the improper inurement of the income or the assets of an exempt entity to a private party. Intermediate sanctions buff up the authority of the Internal Revenue Service to impose penalties on key insiders for improper transactions.

Arising from the ACA, new IRC Section 501(r) requires not-for-profit hospitals to assess and address community health care needs. “Needs” are expected to be something more than supplementing the charges paid by governmental third-party payers.

While the recent cases were decided largely on the inability of hospitals to sustain their burdens of proof, there is great concern in this age of huge health care systems carrying on both traditionally not-for-profit as well as for-profit activity, coupled with the frequent attention given to the salaries paid to health care executives, that the not-for-profit hospital exemption may be going the way of the dodo. Litigation is pending in 38 New Jersey municipalities. A stream of commentary frequently appears in the legal, trade, and national press questioning the continued viability of the exemption.

Health care providers relying on ad valorem exemptions should anticipate challenges to those exemptions in 2017 and beyond given perceptions like those articulated by Jennifer Carr in the October 2016 issue of *The Exempt Organization Tax Review*: “There really does not seem to be much of a difference between how . . . large, so-called nonprofit hospitals operate and their for-profit counterparts . . .” and she asserts, “with so little offered in what could be considered charitable care, it is also understandable that local governments would question the status of large entities with significant annual revenue.” **C**

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Endnotes

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- 61 S. 2484, 114th Cong. (2016). As of November 29, 2016, the bill is with the Senate Committee on Finance. S. 2484—CONNECT for Health Act, Congress.Gov, <https://www.congress.gov/bill/114th-congress/senate-bill/2484/text> (last visited Nov. 29, 2016).
- 62 See S. 2484, 114th Cong. (2016).
- 63 *Franciscan Alliance, Inc. v. Burwell*, No. 16-cv-108 (W.D. Tex. Dec. 31, 2016).
- 64 See <http://www.hhs.gov/civil-rights/for-individuals/section-1557/>.