



## Health Law Issues 2016


### 1. Alternative Payment Models— Moving from Alternative to Mainstream —Robert D. Stone, Alston & Bird LLP

Since the passage of the Affordable Care Act (ACA) in 2010, the courts and general public have focused on the ACA's insurance reforms, such as the individual mandate, guaranteed issue, and insurance exchanges. But industry insiders always have understood the ACA's potential to fundamentally reshape health care lies as much, if not more, in its reimbursement reforms. In January 2015, Department of Health and Human Services (HHS) Secretary Sylvia Burwell announced a goal of tying 50% of traditional Medicare payments to alternative payment models, such as accountable care organizations (ACOs) or bundled payments, by the end of 2018. She also announced a goal of tying 90% of these payments to quality or value during

the same timeframe. As a result of these reforms, alternative payment models that have been maturing over the last five years are now poised to become mainstream. 2016 is shaping up to be a pivotal year for health care reimbursement.

#### **Increase in Risk-Based Models (Introducing Both the Carrot and the Stick)**

Many of the alternative payment methodologies that the Centers for Medicare & Medicaid Services (CMS) has rolled out, as well as many more in the pipeline, involve placing providers at financial risk with respect to efficiency and/or quality of care. These programs include ACOs, Bundled Payments for Care Improvement, Medicare Access and CHIP Reauthorization Act's (MACRA's) Merit-based Incentive Payment System and Alternative Payment Models, and readmission penalty programs, among others. In exchange for



taking on greater risk, many alternative payment models are allowing greater opportunity for providers to receive up-side reward or shared savings. This approach appears to be based on a belief that health care providers are uniquely positioned to make optimal spending decisions while maintaining or improving quality for patients. But this belief is largely untested. For providers to be successful under risk-based models, they will have to develop new skillsets and identify new tools. Whether they like it or not, the majority of health care providers will be operating under one (if not several) risk-based payment methodologies in the near future. The sooner they accept this new responsibility, the sooner they can begin preparing for it.

### **Bundled Payments Will be the “New Normal”**

Until recently, providers could rationally view bundled payment programs as quaint reimbursement experiments—interesting perhaps, but not necessarily on the radar screen of most Chief Financial Officers and in-house counsel. Early programs, such as the Acute Care Episode demonstration project and the Bundled Payment for Care Improvement initiative, only affected providers who chose to participate on a voluntary basis.

But with CMS’ announcement of the Comprehensive Care for Joint Replacement program (CJR) last July 1, everything changed. CJR is a five-year test model involving Medicare’s first mandatory bundled payment arrangements. Specifically, the model will require that certain hospitals participate in a retrospective bundling of (a) acute, (b) post-acute, and (c) physician services for Medicare beneficiaries receiving lower-extremity joint replacement or reattachment (primarily hip and knee replacements). All providers will be paid normally during the episode of care, followed by a post-episode reconciliation process. If CMS’ total spend is below a target price, CMS will make an additional payment to the hospital (which may then distribute the payment among contracted “collaborators”). Beginning in 2017, however, if the total spend is above the target, the hospital will have to make a payment back to CMS, *regardless of which provider was responsible for the expenditure*. This obviously represents a sea change in terms of CMS’ relationships with hospitals and hospitals’ relationships with their medical staffs and post-acute care providers. CMS reported that almost 800 hospitals across the country will be required to participate beginning on April 1, 2016.

CJR is a sign of things to come—and it’s going to be a game-changer. CMS intentionally made hospitals the lynchpin entities for bundling arrangements, meaning the hospitals likely will have to engage with physicians and post-acute partners to align incentives and implement “care redesign” efforts going forward. While the CJR model is limited in both geography (67 Metropolitan Statistical Areas) and scope of procedures (only two diagnosis-related groups), all signs point to a wide-scale implementation of retrospective bundled payments in the near future.



## **2. Fraud and Abuse Enforcement**

—Norman G. Tabler Jr., *Faegre Baker Daniels LLP*

Fraud and abuse enforcement concerns will cause more sleepless nights for health care providers and their lawyers. Developments in the recent past, together with some that are expected in 2016, will keep fraud and abuse near the top of the list of the industry’s legal concerns.

The list of important developments includes the following:

- » *The Yates Memo*. Last September, Deputy Attorney General Sally Yates released her memorandum to Assistant Attorneys General and U.S. Attorneys on the subject of “Individual Accountability for Corporate Wrongdoing.”<sup>2</sup> The essence of the memo is contained in the first sentence of the second paragraph: “One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing.” The memo cites six steps to strengthen the identification and prosecution of individual wrongdoing. Those six steps effectively enlist the aid of the corporate employer in making the case against the employee in question. Step one, for example, states that “to be eligible for *any* cooperation credit, corporations must provide . . . all relevant facts about individuals involved in . . . misconduct.”<sup>3</sup> This focus on individual liability, which also is reflected in contemporaneous amendments of the relevant sections of the *U.S. Attorneys’ Manual*,<sup>4</sup> may have a chilling effect on internal audit and compliance efforts in the coming year, as well as drive a wedge between an employer corporation and individual employees who may be targeted for wrongdoing.
- » *Reverse False Claims*. One of the lesser known provisions of the ACA requires that Medicare and Medicaid overpayments be reported and repaid within 60 days of “the date on which the overpayment was identified.”<sup>5</sup> An overpayment retained longer than 60 days becomes an “obligation” under the False Claims Act. Last summer brought the first published opinion interpreting the provision.<sup>6</sup> A vendor’s “software glitch” caused the defendant health system to mistakenly bill Medicaid 900 times for a total of less than \$1 million; and the system failed to repay the amount within 60 days after an employee—the whistleblower—put them on notice of the error. The United States, New York, and New Jersey joined the case. The court denied the defendant’s motion to dismiss, leaving it exposed to liability of *more than \$20 million*, including treble damages and per-claim penalties of \$11,000 for the United States and New Jersey and \$12,000 for New York.
- » *Implied False Claims*. Every Medicare and Medicaid bill is a claim for payment. Because of the sheer number of claims a provider submits, it always has been difficult to avoid submitting one that is explicitly erroneous. Now, though, providers must worry about claims that are *implicitly* er-

roneous. How can a claim be implicitly false? The theory of the implied false claim is that every claim is an implicit certification that the claimant is in compliance with all applicable contract provisions or regulations. If there is any noncompliance, the claim is a false claim. In *United States ex rel. Escobar v. Universal Health Services*,<sup>7</sup> the First Circuit allowed a case to proceed on the theory that a clinic's Medicaid claim constituted a false claim because the clinician was not licensed, as required by Medicaid regulations. On December 4, 2015, the Supreme Court granted the defendant's petition for *certiorari*, so this will be an important case to watch in 2016.

- » **Higher Fraud Penalties.** In light of the number of Medicare and Medicaid claims a provider submits each year, fraud penalties of \$5,500 to \$11,000 per claim seem absurdly high. But they're slated to get even higher this year. The Bipartisan Budget Act of 2015 includes the Federal Civil Penalties Inflation Adjustment Improvements Act mandating that agencies adjust penalties for inflation this year—17 years' worth of it—and that they readjust them each year.<sup>8</sup>
- » **Physician Compensation Cases.** It's impossible to ignore the recent uptick in the number of fraud cases tied to physician compensation, just as it's impossible to ignore the eye-popping settlements in these cases. Think *Tuomey Healthcare*,<sup>9</sup> *Halifax Health*,<sup>10</sup> and *Adventist Health*<sup>11</sup>—all cases in which compensation was found to be tied to the volume or value of referrals. What's more, the focus on physician compensation is consistent with the Yates memo and its emphasis on individual liability.

All in all, 2106 is shaping up as a tough year on the fraud enforcement front.




### 3. Provider Consolidation: Prescription for Surviving Antitrust Investigations

—Dionne Lomax, Mintz Levin Cohn Ferris Glovsky and Popeo PC

As health care delivery systems evolve, the industry continues to face significant scrutiny from federal antitrust enforcement authorities. In the last quarter of 2015 alone, the Federal Trade Commission (FTC) challenged hospital mergers in Harrisburg, PA, Huntington, WV, the North Shore area of Chicago, and a consummated merger between orthopedic practices in Berks County, PA. These enforcement activities capped off a year of high-profile health care antitrust litigation that saw the Ninth Circuit affirm the Commission's challenge to the acquisition of Saltzer Medical Group by St. Luke's Health System,<sup>12</sup> and the Supreme Court affirm the Fourth Circuit's opinion upholding the FTC's ruling that the state action immunity doctrine did not apply to the activities of the North Carolina State Board of Dental Examiners.<sup>13</sup>

Aggressive antitrust enforcement in health care matters has left a number of providers wondering how best to position themselves to compete in the evolving industry, while also ensuring that their activities do not run afoul of the antitrust laws. Several of the cases recently pursued by antitrust enforcers offer useful guidance for providers contemplating alternative forms of health care delivery, consolidations, and affiliations:

- » **Present a Robust Efficiencies Defense During the Investigation.** Prevailing on an efficiencies defense in litigation often can be an uphill battle. In *St. Luke's*, the Ninth Circuit found that a merger was not necessary to achieve the claimed efficiencies and held that the efficiencies were not merger-specific. According to the court, even if the efficiencies were merger-specific, the defense would still fail because there was no showing that the efficiencies "increased competition." This efficiencies standard places a significant burden on defendants that may be extraordinarily difficult to meet. Merging parties undoubtedly will face stringent efficiencies standards in future litigated cases. They should prioritize the efficiencies study early in the deal planning process and seek to present strong evidence of efficiencies to agency staff during the course of an investigation to persuade enforcement officials that the transaction, on balance, is procompetitive.
- » **Adopt Strategies for Navigating Disparities in Federal and State Enforcement Policy.** Parties to transactions should be prepared to scope out any disparities in federal and state antitrust enforcement theories of harm and properly arm themselves with effective remedies that might satisfy federal and/or state officials. As demonstrated by the FTC's case challenging Cabell Huntington Hospital's proposed acquisition of St. Mary's Medical Center (where the parties had already reached a settlement with the West Virginia Attorney General),<sup>14</sup> there is no guarantee that federal and state antitrust enforcers will reach the same conclusion on the competitive impact of a proposed transaction and the effective remedy. As such, providers should not assume that either the federal or state agency will be deterred by the other enforcer's decision not to challenge a particular matter or to accept certain remedies.
- » **Secure a Preliminary Antitrust Analysis to Properly Assess Litigation Risk.** As demonstrated by its recent enforcement efforts, the FTC is clearly willing to aggressively pursue litigation to challenge anticompetitive transactions. Parties may need to factor litigation risk into their deal calculus more so than before. Securing a comprehensive antitrust analysis early in the process is paramount. It will: (1) help parties determine the extent to which deal terms need to be crafted to shift or share certain aspects of the antitrust risk in transaction documents; (2) help parties gain an early understanding of potential remedies (e.g., magnitude and type of divestitures) that may be needed to resolve federal



and/or state antitrust concerns; and (3) help parties gain an appreciation for the type of data and information that will be required to support a strong antitrust defense.

- » *Ensure the Transaction's Structure Avoids Section 1 Issues.* Many providers are entering into affiliations and joint ventures that fall short of a fully integrated merger. If the parties in such transactions are not sufficiently integrated and capable of being deemed a single entity under Section 1 of the Sherman Act, any joint pricing conduct puts them at risk of a price-fixing violation. Whether or not parties are deemed a single entity for Section 1 purposes is a highly factual inquiry, largely determined by whether the parent has the ability to control the actions of the subsidiary (or affiliate) and whether there is a unity of economic interest between the parties. Early analysis of the structure will help minimize antitrust risk.

The merger wave of 2015 that garnered such close scrutiny from antitrust enforcement authorities is no longer limited to providers. The industry is watching closely two insurance mergers—Aetna's proposed acquisition of Humana and Anthem's proposed acquisition of Cigna—currently being investigated by the Department of Justice (DOJ) Antitrust Division. While the impact of these transactions remains to be seen, it is clear that antitrust considerations will play a key role in their outcome. The pending insurance mergers and ongoing provider realignment ensures that 2016 will make for another robust year of health care antitrust activity.



#### 4. Meaningful Use Stage 3 and Interoperability

—By Patricia A. Markus,  
Smith Moore Leatherwood LLP

As revelers celebrated the arrival of 2016, all indications were that Meaningful Use (MU) Stage 3 would proceed, despite ongoing, intense opposition to the program by physicians and health systems. After all, the Stage 3 final rule was just issued in early October 2015. But on January 11, Acting CMS Administrator Andy Slavitt stated that MU “as it has existed—with [the Medicare Access and CHIP Reauthorization Act, or MACRA]—will now be effectively over and replaced with something better.” Slavitt subsequently tweeted that in the future, CMS will reward outcomes, rather than the mere use of technology; permit physicians to customize goals around their individual practices to spur development of user-centered technology; promote use of open application program interfaces (APIs) to “level the tech playing field” and decrease vendor electronic health record (EHR) lock-in; and foster interoperability that builds on actual physician and patient interactions and prevents data blocking. Slavitt also suggested that on March 25, CMS will provide more details on future health information technology incentives that are focused on patient outcomes.

#### MU's Misaligned Incentives

MU program critics expressed dismay that the vast majority of the \$21 billion in Medicare incentives and \$10.2 billion in Medicaid incentives (through November 30, 2015) issued to hospitals and physicians for becoming so-called “meaningful users” of certified EHR technology simply helped providers to buy certified EHR technologies and electronically document the provision of health care, instead of driving actual data-sharing by requiring the use of EHR technologies that are interoperable (i.e., that share information with each other readily without the need for custom interfaces). Because the MU program paid physicians and hospitals to “show their work” in meeting detailed program measures and objectives (thereby incentivizing EHR vendors to focus programming on such detailed program requirements), rather than paying for actual interoperability among the most widely used certified EHR software systems, this unsatisfactory outcome was practically guaranteed. Additionally, providers struggled to adjust their workflows to match the requirements of their clunky EHR software products, which were not developed for their specific work processes but instead were tailored to meet program requirements. These and other difficulties resulted in 209,000 physicians and other practitioners receiving 2% Medicare payment cuts in 2016 for failing to meet MU program standards in 2014.

#### Is MU Dead?

Despite the apparent widespread relief with which Slavitt's comments were received by the health care industry, do those comments truly signal the end of the MU program? Not likely, as MU is codified in the Health Information Technology for Economic and Clinical Health (HITECH) Act. Further clarifications from CMS obviously are needed, and providers should not simply assume that they may terminate their MU efforts immediately. However, it is likely that any “replacement incentives” will be baked into the Merit-based Incentive Payment System (MIPS), which consolidated three quality incentive programs and, starting in 2017, will base portions of physicians' Medicare reimbursement on achievement of quality, cost, technology use, and practice improvement thresholds identified in future rulemaking.

#### Renewed Focus on Interoperability

In the meantime, a number of initiatives designed to promote interoperability are underway. In MACRA, the legislation enacted in April 2015 that repealed the Medicare Part B Sustainable Growth Rate reimbursement formula and replaced it with MIPS, Congress outlined a “national objective” to increase EHR interoperability so as to achieve widespread health information exchange by the end of 2018.<sup>15</sup> In October 2015, the Office of the National Coordinator (ONC) issued its Final Interoperability Roadmap, in which ONC proposes to have the U.S. health care system fully interoperable by 2024

through the adoption of federally recognized national interoperability standards. The Fast Health Interoperability Resources (FHIR) standards, created by the Health Level Seven International health care standards organization, may be a gateway to interoperability: the standards simplify data exchange by permitting the transfer of specific data elements (such as a patient's gender) instead of entire documents containing multiple data elements.<sup>16</sup> Instead of having to sift through pages of information to find one or two pieces of relevant data, a provider can request and receive the specific data elements needed. FHIR standards currently are being tested worldwide.

Health information technologies must be user-centric and assist physicians in caring for patients, rather than distracting physicians from interacting with their patients. CMS' transition to a focus on patient outcomes, rather than on the mere use of technology, appears to be an obvious end product of the ACA's requirements for risk-contracting and alternative payment models. This new focus also will enable providers to work with EHR and mobile health vendors and other tools (like APIs) to create new programs designed to measure those patient data and outcomes that truly lead to improvements in patient care and involvement. Observing how CMS, ONC, and other health care industry stakeholders jointly work in 2016 to spur and obtain tangible benefit from true interoperability should prove fascinating.



## 5. Cybersecurity

—Jennifer L. Rathburn and Jennifer J. Hennessy,  
Quarles & Brady LLP

Cyber attacks have shifted their focus to the health care industry. The Federal Bureau of Investigation has expressed concern that the health care industry is a prime target for increased cyber attacks by criminals<sup>17</sup> and, over the past five years, cyber attacks on the health care industry spiked over 125%.<sup>18</sup> The reason for the shift is simple: stolen health care information is lucrative.<sup>19</sup> The best way for health care organizations to protect patient data is to implement a cybersecurity program to help identify, protect, detect, respond, and recover from a cyber attack.

### HIPAA Security Rule and Other Cybersecurity Frameworks

An effective cybersecurity program starts with the selection and commitment to a cybersecurity "framework." Most health care organizations must comply with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, which requires covered entities and business associates to implement appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information (ePHI).<sup>20</sup> The HIPAA Security Rule also requires organizations to conduct a risk analysis of the potential risks and vulnerabilities to ePHI.<sup>21</sup> The Office for Civil Rights (OCR) has a record of penalizing organizations that have not

completed a risk analysis<sup>22</sup> and is expected to ask for completed risk analyses in the upcoming Phase Two HIPAA Audits.<sup>23</sup>

However, it is commonly accepted that the HIPAA Security Rule is only a baseline security framework. Organizations may need to consider other frameworks, such as the National Institute of Standards and Technology (NIST) cybersecurity framework, ("Framework for Improving Critical Infrastructure"), Payment Card Industry Data Security Standard (PCI DSS) requirements, 21 CFR Part 11, ISO 27001, HITRUST Common Security Framework, and the Food and Drug Administration's voluntary guidance regarding cybersecurity for medical devices. Determining what to adopt is often confusing for organizations. However, some guidance is on the way. The recent Cybersecurity Act of 2015 requires HHS to develop voluntary cybersecurity guidance for the health care industry—so stay tuned.<sup>24</sup>

### Best Practices

What best practices should organizations consider implementing to protect data? For example, organizations should consider encryption of data and data destruction practices that comply with OCR/NIST guidance, a vendor management program, logging and monitoring security related events, obtaining cyber liability insurance, and developing an incident response plan to guide an organization's activities in response to a cyber attack. In addition, organizations' Boards of Directors should be educated on cybersecurity, take preemptive measures to monitor cybersecurity risks to their organizations, and if a breach does occur, take proactive steps to address the breach and minimize exposure.

### Testing of Cybersecurity Program and Sharing of Information

To test their security capabilities, organizations should consider using table top exercises where participants discuss responses to a hypothetical cyber crisis and penetration testing to determine the ways a hacker can gain access to the organization's sensitive information. Organizations also should explore participating in threat information sharing programs.

### Potential Penalties/Enforcement Actions

In addition to the expenses related to data breaches, the OCR, FTC, and State Attorneys General and other consumer protection agencies can impose various civil and criminal penalties on organizations for violations. Organizations also can face class actions or other lawsuits. The best way for organizations to minimize this risk is to have a cybersecurity program that is continuously evolving by implementing risk management processes to evaluate new threats and vulnerabilities and communicating such changing risks throughout the organization. This undoubtedly will remain a major area of focus for health care organizations in 2016.



## 6. New Corporate Conduct Enforcement Guidelines

—By Michael Peregrine, McDermott  
Will & Emery LLP

New guidelines on corporate conduct that DOJ released on September 9, 2015 will impact the regulatory enforcement climate facing the health care industry.<sup>25</sup> These Guidelines, also known as the “Yates Memo,” reflect a substantially increased focus on individual accountability for corporate wrongdoing, both civil and criminal, and on the importance of corporate cooperation in the context of governmental investigations. It is not a “rifle shot” enforcement initiative focused solely on Wall Street or the broader financial sector. Rather, it is intended to apply across industry sectors (including health care). The Guidelines are likely to impact an organization’s approach to legal compliance, internal investigations, D&O insurance and indemnification protection, and interaction with management on matters of regulatory concern. They should, therefore, be taken seriously by senior leadership of health care companies.

### The Relevant Provisions

The Guidelines contain six separate policy statements. Those most relevant of the six statements (i.e., those that do not deal with internal DOJ operations) are the following:

- » *Cooperation Credit.* The new Guidelines provide that for a corporation to receive credit for its cooperation under existing DOJ prosecution principles, the corporation “must completely disclose [to DOJ] all relevant facts about individual misconduct.” This means that the corporation “must identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide [to DOJ] all facts relating to that misconduct.”
- » *Focus on Individuals.* Both civil and criminal prosecutors are directed to concentrate on individual wrongdoing *from the inception of the investigation* through the resolution of the corporation’s potential exposure.<sup>26</sup> This special focus is intended to maximize DOJ’s ability to identify individual wrongdoing, which DOJ experience suggests can be daunting when large, complex corporations are involved.
- » *No Routine Negotiated Releases of Individuals.* Except in extraordinary circumstances, the resolution between DOJ and a corporation with respect to a particular investigation will not include protection from civil or criminal liability to any individuals. In the context of settlement or other resolution agreements, DOJ prosecutors are directed to preserve the ability to pursue responsible individuals.
- » *Ability to Pay.* The Guidelines specify that the pursuit of civil enforcement actions against individual corporate wrongdoers should not be evaluated solely on the basis of an individual’s ability to pay. In other words, the government

will not be deterred from pursuing civil monetary penalties against lower-level employees who likely lack the ability to recompense the government for its alleged losses or for applicable civil penalties, if there is a long term deterrent factor associated with such action.

### Scope of the Guidelines

When originally introduced, the new DOJ policy was focused on individual accountability in matters implicating criminal and civil corporate fraud allegations. Since that time, comments by DOJ officials have publicly clarified that the policy will apply to individual conduct in the context of any corporate wrongdoing; e.g., to actions instituted under the False Claims Act, to health care and food safety cases brought under the federal Food, Drug and Cosmetics Act, and to civil and criminal violations of the federal antitrust laws—all of which is relevant to health care companies.

The provisions of the Guidelines have since been incorporated within DOJ’s “Principles of Federal Prosecution of Business Organizations.”

### DOJ’s Compliance Counsel

The new “Yates Memo” also should be considered together with DOJ’s creation of the position of “compliance counsel.” This counsel’s particular assignment will be to help determine whether corporations subject to DOJ investigation have maintained a good-faith compliance program. Public comments by DOJ officials made in connection with this appointment provide additional clarity on the metrics DOJ will apply in determining compliance program effectiveness. Especially when viewed together with the “Yates Memo,” DOJ is essentially making the “business case” for compliance.

DOJ’s new Guidelines on Corporate Cooperation—and their underlying emphasis on individual accountability—should receive close attention by health care company leadership. The new Guidelines could have long term implications on how leadership approaches matters that involve legal risk, and on the resources, support, and direction provided by the board in connection with informal decision making by management.



## 7. Medicaid Managed Care

—Robert Belfort, Manatt Phelps & Phillips LLP

Medicaid managed care is taking center stage in the country’s health care financing system. The number of Medicaid beneficiaries has grown substantially over the past few years due to Medicaid expansions implemented by many states under the ACA. At the same time, states are shifting away from fee-for-service toward managed care as a means of containing costs and improving quality for the growing Medicaid population. With the number of Medicaid managed care enrollees rising steadily, health insurers are increasing their focus on this market, states are experimenting with ways to use Medicaid

managed care to drive system-wide health care transformation, and the federal government is seeking to play a greater role in establishing regulatory parameters for the program.

## The Proposed Medicaid Managed Care Rule

The federal government's main initiative in this regard has been a notice of proposed rulemaking (NPRM)<sup>27</sup> to overhaul the regulations governing Medicaid managed care, which was issued on May 26, 2015 by CMS. The NPRM is significant in several key respects:

- » The NPRM continues the trend toward federalizing the regulation of health insurance. Together with CMS rule-making under the ACA governing commercial health insurance, the standards adopted by the federal marketplace and the longstanding Medicare Part C and D rules, the NPRM further establishes CMS as the central regulator of health care financing in the nation. While states still will have leeway to administer their own Medicaid programs, they will be operating under a stricter set of federal parameters.
- » In connection with the consolidation of regulatory authority at the federal level, CMS is seeking through the NPRM to substantially align Medicaid managed care rules with those that apply to Medicare Advantage plans and qualified health plans under the ACA. The standardization of operational requirements such as grievance and appeal procedures as well as medical loss ratio reporting should simplify administration for health plans and erode the historical operational barriers separating Medicaid, Medicare, and commercial insurance products.
- » CMS seems intent on using Medicaid managed care as a vehicle for enhancing the quality of services received by low-income Americans. The NPRM proposes to require states to establish stronger provider network adequacy standards, adopt a quality rating system, and adhere to tougher standards for developing actuarially sound premium rates that are sufficient to cover the reasonable cost of care.
- » The NPRM grants states substantial leeway in using Medicaid managed care plans as vehicles to drive system-wide payment reform. States are permitted to direct plans to adopt particular "value-based" methodologies for reimbursing providers, such as shared savings, bundled payments, and capitation. The autonomy of plans to manage reimbursement arrangements with their providers may be circumscribed as they become more integrated into state payment reform initiatives.

## What to Watch in 2016

While predicting the future is a particularly hazardous enterprise when it comes to the health care system, there appear to be at least three major developments to watch in 2016. First, states and Medicaid managed care plans will be waiting to see what changes CMS makes to the NPRM in the final rule. Areas

of possible change may include medical loss ratio requirements, actuarial soundness, program integrity standards, and default enrollment waiting periods. Second, it seems likely that a growing number of states will develop Medicaid-financed value-based reimbursement programs under the rubric of the Delivery System Reform Incentive Payment program and other waiver authorities as a means of reducing cost and improving quality. These programs will raise new questions about the respective roles of the state, managed care plans, and providers, potentially shifting responsibility up to the states and down to providers and away from plans. Third, the further growth of Medicaid managed care will be tied substantially to the number of new states that elect to implement a Medicaid expansion under the ACA. If the recent past is any guide, states expanding their Medicaid programs will rely heavily on managed care to do so.



## 8. Affordable Care Act

—Bianca Bishop and Lisa Salerno, AHLA

Nearly six years after enactment, the fate of the ACA continues to figure prominently on our annual Top Ten list. Looking back on prior years' coverage, the statute has weathered the problem-plagued rollout of the health insurance marketplaces in 2014, numerous repeal efforts in Congress (including legislation recently vetoed by President Obama that would have unraveled much of the ACA's core provisions), and make-or-break constitutional tests that were resolved by the Supreme Court.

So far in 2016, open enrollment through the health insurance marketplaces has gone relatively smoothly. As of this writing, the administration said some 11.3 million consumers have signed up for 2016 coverage, beating earlier government estimates issued in the fall of 2015, but falling short of expectations when the ACA was enacted. HHS reported that about 26% of enrollees were between the ages of 18 and 34. Whether this key demographic—the young and healthy—and other factors will sustain the marketplaces in the long term remains to be seen. In November 2015, UnitedHealth Group said it was evaluating whether to continue offering individual plans through the marketplaces beyond 2016. Last year also saw 12 of the 23 Consumer Oriented and Operated Plans (CO-OPs) fail, with many citing as a contributing factor the announcement that the government would pay only 12.6% of insurers' payment requests under the risk corridors program—one of three programs to help stabilize the individual insurance market during the launch and initial years of the ACA marketplaces.

All told, HHS has reported that more than 17 million have gained coverage under the ACA so far, including those who purchased coverage through the marketplaces and those who were added to Medicaid's rolls in the states that opted to expand their programs. Some of the statute's insurance market reforms, including guaranteed coverage and allowing children to stay on their parents' policies until age 26, remain popular.



Yet, whether the ACA will achieve its goals of bending the cost curve and making health care more affordable remains uncertain. The ACA also still faces significant hurdles—both in the courts and from Republican lawmakers who continue to call for the statute’s repeal.

In the spring, the Supreme Court again will consider an ACA-related challenge—this one brought by religious nonprofits who object to the contraceptive coverage requirement under the statute and its implementing regulations. And another lawsuit that could undermine the ACA is making its way through the courts. The House of Representatives is suing the administration over the alleged use of public funds for payments to insurers under the ACA’s cost-sharing reduction program. While the ACA authorizes the government to make direct payments to insurance companies to offset estimated costs incurred from providing cost-sharing reductions for certain beneficiaries, Congress has never appropriated any funds for these payments. The U.S. District for the District of Columbia recently allowed the lawsuit to go forward after rejecting the administration’s motion to dismiss for lack of standing.<sup>28</sup> The Supreme Court recently refused to review a challenge alleging the ACA’s individual mandate violates the Origination Clause of the U.S. Constitution, which requires that legislation raising revenue originate in the House. In July 2014, the D.C. Circuit rejected the lawsuit, finding the primary purpose of the individual mandate is not to raise revenue but to expand health care coverage.<sup>29</sup> As of this writing, another similar lawsuit remained pending before the Court.<sup>30</sup>

As 2015 came to a close, Congress finally succeeded in passing a budget reconciliation bill that would repeal many of the ACA’s key provisions, including the individual and employer mandates. In a separate measure, lawmakers also were successful in delaying a number of unpopular provisions, including the so-called “Cadillac” tax on high-cost health plans, which was postponed two years beyond its 2018 scheduled start date. While President Obama agreed to the delay of ACA taxes as part of a broad appropriations and tax package, he swiftly vetoed the ACA repeal measure. With the presidential election in November, 2016 promises to be another pivotal year for the ACA.



## 9. Drug Costs

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

During this past year, there has been an increased focus on the cost of prescription medications, specifically in the specialty drug market, which generally includes high-cost drugs and biologics that treat rare and/or complex disease like hepatitis C, certain cancers, HIV, rheumatoid arthritis, and hemophilia. In particular, the entry into the market of several breakthrough treatments for hepatitis C (typically costing upwards of \$95,000 for one 12-week treatment),<sup>31</sup> drew significant attention. Much

of this focus was spurred by a study released by the IMS Institute for Healthcare Informatics, indicating that in 2014, drug spending increased 13.1%, up to \$373.9 billion, which is the highest it has been since 2001.<sup>32</sup> Of that percentage, specialty drugs contributed to most of that spending occupying about one-third of overall drug spending.<sup>33</sup> Much of the spending on specialty drugs resulted from a significant increase in the number of patients entering treatment for hepatitis C than in previous years.<sup>34</sup>

Last year also saw the continuation of at least one lawsuit filed against drug sponsors over alleged price-gouging. In that suit, plaintiffs alleged that the drug sponsor overpriced hepatitis C drugs for the U.S. market while discounting the same active ingredient abroad, resulting in unjust enrichment. The case was dismissed in May 2015.<sup>35</sup> In addition, a number of lawmakers have called on drug sponsors to justify the costs of their products. For example, several state legislatures considered pharmaceutical cost transparency bills in 2015. Some of the bills required that drug sponsors provide additional disclosures to the state of drug costs associated with manufacturing, advertising, and marketing.<sup>36</sup> At least one of these bills was postponed, and a number have been placed under committee review.<sup>37</sup>

In late 2015, House Oversight and Government Reform Committee Ranking Member Elijah Cummings (D-MD) asked the Committee Chairman to issue a subpoena to one drug sponsor requesting documents related to large price increases that happened “overnight.”<sup>38</sup> This was in response to the drug sponsor’s previous refusal to provide requested documents to the Committee.<sup>39</sup> This action was in addition to the Senate’s Special Committee on Aging’s determination to investigate drug pricing practices by a number of drug sponsors whose drug prices underwent dramatic increases over short periods of time.<sup>40</sup>

Industry also took action in response to dramatic increases in drug costs during the past year. Specifically, one pharmacy benefit manager (PBM) announced that it contracted with a compounding pharmacy for a \$1.00 alternative to Turing Pharmaceuticals’ Daraprim, which recently increased in price from \$13.50 per pill to \$750 per pill.<sup>41</sup> Although welcomed by many patient access advocates, this type of compounding may carry risks under Section 503A of the federal Food, Drug and Cosmetic Act, which allows a licensed pharmacist or licensed physician in a traditional compounding pharmacy, not an outsourcing facility, to compound a drug product based on an individual patient prescription if he/she “does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are *essentially copies of a commercially available drug product*.”<sup>42</sup>

As 2015 came to a close, DOJ and the U.S. Attorney’s Office for the Eastern District of Pennsylvania also made public its interest in investigating drug costs and pharmaceutical companies’ relationships with pharmacies. A number of drug



manufacturers received requests from DOJ regarding how they report product prices to the Medicaid program for rebate purposes. In addition, DOJ launched an inquiry into how one manufacturer contracts with and makes drug pricing determinations as they relate to PBMs.<sup>43</sup> Drug pricing will be a subject to watch in 2016.



## 10. Mental Health Reform

—Paige M. Steffen and Gerald “Jud” DeLoss, Clark Hill PLC

Several bills to watch in 2016 have been introduced in Congress with the goal of improving our mental health system. Although the general consensus is that the current mental health system is broken, there is little agreement on how to fix it.

### Pending Federal Legislation

The Helping Families in Mental Health Crisis Act (H.R. 2646) was introduced on June 4, 2015 by Representatives Tim Murphy (R-PA) and Eddie Bernice Johnson (D-TX). It is arguably one of the most comprehensive mental health bills that has been introduced recently. The bill includes early intervention programs, strengthens community behavioral health clinic services, allows family members to gain access to other family member’s mental health crisis information, and proposes cut backs of many Substance Abuse and Mental Health Services Administration (SAMHSA)-funded programs.

The Mental Health Awareness and Improvement Act (S. 1893) was introduced on July 29, 2015 by Senators Lamar Alexander (R-TX) and Patty Murray (D-WA). The bill recently passed the Senate on December 18, 2015 and will now go to the House for consideration. The bill supports federal suicide prevention programs, mental health awareness and training for teachers, and children’s recovery from traumatic events.

Another measure, the Mental Health Reform Act (S. 1945), was introduced on August 5, 2015 by Senators Bill Cassidy (R-LA) and Chris Murphy (D-CT). The lawmakers have described the legislation as a companion bill to the Helping Families in Mental Health Crisis Act. Generally, the bill attempts to strengthen the mental health care system by addressing the current lack of resources, improving coordination, and providing solutions for families affected by mental illness.

The Mental Health and Safe Communities Act (S. 2002) was introduced on August 5, 2015 by Senator John Cornyn (R-TX). This bill provides additional resources for identifying and responding to people with mental illness in the criminal justice system and enhancing programs that promote collaboration between these persons and the criminal justice system to improve outcomes and increase safety.

Many of the bills discuss similar key issues in mental health, such as patient privacy, lack of funding, enforcement of mental health parity, and controversial involuntary treatment.

### 42 CFR Part 2

Several of the bills include provisions to reform 42 CFR Part 2 to streamline the patient consent process for sharing of addiction treatment information with their health care providers. Supporters of the bills claim that patient privacy will be protected by these amendments and that they will ensure that patients will still be required to provide consent for their records to be shared with providers. These protections will be in addition to those provided under state law. For example, The Helping Families in Mental Health Crisis Act creates a new exception for Health Information Exchanges (HIEs), Medicare ACOs, Medicaid Health Homes, and other integrated care arrangements. The Mental Health Reform Act helps streamline the consent processes for these integrated care arrangements. As such, the bills would permit patients, if they choose, to provide written patient consent on an annual basis for the disclosure and re-disclosure of their records by and to all health care providers in any integrated care arrangement. State laws governing HIEs generally require that a patient “opt in” to allow providers to share health information or “opt out” if they do not wish to have their information shared within the HIE. This additional requirement creates a dual-consent process allowing greater control over the information by the patient.

### HIPAA

In addition to proposed 42 CFR Part 2 patient privacy protection revisions, some of the pending federal legislation attempts to update and/or clarify HIPAA regulations. For example, the Helping Families in Mental Health Crisis Act provides that caregivers for seriously mental ill individuals can qualify as such individual’s personal representative for purposes of HIPAA. It further permits disclosure of education records to caregivers of individuals if determined to be reasonably necessary by the mental health professional. Additionally, the Mental Health Reform Act clarifies circumstances in which HIPAA permits health professionals to communicate information to family members or other caregivers, and supports training of health care providers about the circumstances in which information can be shared with caregivers.


### Funding

Mental health advocates maintain that recent budget cuts at both the federal and state levels have left less-than-adequate funding to support our mental health system. To respond to such cuts, most of the pending federal legislation addresses the lack of funding for treatment, services, and research in mental health. For example, several of the bills authorize grants for states to facilitate more effective integration of physical and mental services, stimulate early intervention and mental health treatment, and increase funding for research.

## Parity

People with mental health and/or addiction challenges generally have a more difficult time receiving treatment compared to individuals seeking other medical care, and, historically, some health insurers put greater restrictions on mental health treatment and charged higher amounts than for other types of medical care. In response to this inequality, the Mental Health Parity and Addiction Equity Act (MHPAEA) was passed in 2008, requiring health insurance plans to cover mental health and physical health benefits equally. However, the enforcement of MHPAEA has been inconsistent and complex, and many patients still do not have access to timely care by in-network providers. To better enforce and regulate parity, some of the pending federal legislation requires that additional regulations and reports be created to further ensure and monitor compliance with MHPAEA.

## Assisted Outpatient Treatment

Some of the bills include controversial Assisted Outpatient Treatment (AOT) provisions. AOT, also referred to as Involuntary Outpatient Commitment, involves the court ordering of a person with a serious mental illness to follow a specific treatment plan, usually requiring medication and resulting in their institutionalization if they refuse. The AOT program was first authorized in 2014, but it has not yet been implemented due to lack of funding. The proposed extension of the AOT grant programs through 2020 and the authorization of incentive payments through federal Mental Health Services Block Grants have been controversial. 

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