



SPECIAL REPORT

# 2019 HOSPITALS AND HEALTH SYSTEMS YEAR IN REVIEW

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## TABLE OF CONTENTS

- 3 Introduction
- 4 Hospitals and Washington: Still at Odds
- 5 Hospital Bankruptcies, Distress and Closures
- 6 Antitrust Litigation
- 8 Value-Based Enterprises and Payor-Provider Collaboration
- 9 Collaborative Clinical Service Ventures: Rise of Less Integrated Health System Transactions
- 10 Medicare Sub-Regulatory Enforcement Development
- 11 Hot Topics in Privacy and Security: Increase in Ransomware Attacks
- 12 OCR Enforcement Highlights
- 12 Groundbreaking Changes in State Privacy Laws-California
- 13 State Medical Information Privacy with Expansive Applicability
- 13 Evolution of Innovation Centers
- 15 Increasing Scrutiny of Provider-Based Arrangements
- 16 Emerging Cannabis Issues

## INTRODUCTION

The past year required hospitals and health systems to simultaneously focus on improving quality, increasing and diversifying revenue sources, and accelerating innovative ways to deliver care to the patients and communities they serve. The forecast for 2020 is no different, presenting both demands and opportunities for every hospital owner and investor across the United States.

This *Special Report* summarizes notable legal actions and trends affecting hospitals and health systems in 2019 and prognostications for 2020, including:

- Trends in Washington, DC
- Antitrust litigation
- Value-based enterprises and payor-provider collaborations
- Federal enforcement focus areas
- Innovation centers
- And much more.

## HOSPITALS AND WASHINGTON: STILL AT ODDS

In 2019, the Trump administration and Congress embarked on a steady flurry of transformative regulatory changes and disruptive legislation. The administration proposed new regulations that threatened to reduce revenue streams and destabilize markets: site-neutral Medicare payments for outpatient services, further cuts to outpatient payments for drugs purchased under the 340B program and requirements that hospitals disclose negotiated payment rates were just a few of the changes targeted at hospitals.

The hospital community struck back in lawsuits challenging these changes, but the administration is appealing losses in key lawsuits and implementing payment reduction policies notwithstanding adverse court decisions. Even if they survive appeal, victories in court may be short-lived. Where policies have bipartisan agreement in Congress (*e.g.*, site-neutral payment), court victories could be undone with congressional action.

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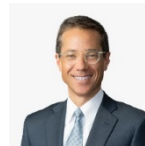
Heading into 2020, significant action around health information sharing and protections can be anticipated.

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The administration is expected to release sweeping rules stopping information blocking and encouraging greater sharing of health information. At the same time, some provider data sharing practices have come under congressional scrutiny and have faced pushback from privacy advocates. Expect stakeholders to clash over

readiness, consumer protections and competition around data platform services. The administration also is expected to further challenge providers with a series of alternative payment models from the Centers for Medicare and Medicaid Services (CMS) Innovation Center.

Congress also left 2019 with some unfinished business to which it is likely to return in early 2020. Congress came close to enacting legislation protecting patients from unexpected bills arising from care provided by out-of-network facilities and physicians in emergency situations, and from out-of-network physicians at in-network facilities in non-emergency situations. These so-called surprise bills offended policymakers and led to a raft of bipartisan bills designed to insulate patients and specify how payor-provider payment disputes would be resolved. Rapidly advancing legislation inspired a pitched lobbying battle between providers and the payor and employer communities, and momentarily stalled congressional action. But the pressure to act remains and may ultimately break the congressional impasse.



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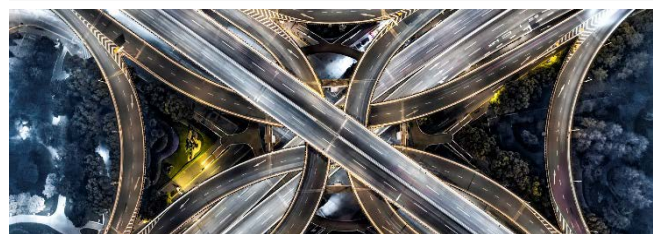
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## HOSPITAL BANKRUPTCIES, DISTRESS AND CLOSURES

Bankruptcy filings in the healthcare industry have been on the rise since 2010 despite an otherwise generally healthy economy, and have increased most dramatically in the past three years. Causes are varied and include payment delays; reimbursement changes; overexpansion; consolidation; increased costs associated with adapting to new regulatory requirements and implementing new technology; and tort, labor and other litigation. Although upcoming elections at both federal and state levels will have a significant impact on healthcare winners and losers, the levels of distress likely will continue to rise, along with the number of healthcare filings.

Distressed facilities, whether filing for bankruptcy or not, are at an increased risk of closure. The pace of hospital closures continued to increase in 2019, with almost two dozen hospitals closing in 2019.

Expect to see an increase in rural hospital bankruptcy filings and closures in particular, especially in the Southeast, which accounted for approximately half of all healthcare bankruptcies over the past year. This industry segment faces unique challenges, stemming in part from lower profit margins and continued increase in uninsured patients. Reimbursement rate changes<sup>1</sup> will also likely cause an increase in both in- and out-of-court restructurings in behavioral health, addiction treatment and home health. Attempts to consolidate what is currently a fairly deconsolidated industry also might increase, as consolidation may offer opportunities to realize efficiencies.

In hospital bankruptcies, the current hot button issue is whether a provider can transfer its Medicare and Medicaid provider agreements free and clear of any pre-transfer overpayment, civil or other liabilities. Two recent cases from Delaware and the Central District of California found that a provider agreement is a statutory entitlement akin to an asset that can be transferred free of liability. Both decisions have been appealed, however, leaving the current state of the law uncertain. As a result, a purchaser that takes assignment of a provider agreement must be aware that it may be responsible for pre-transfer liabilities, or settle in for a protracted fight on this issue with CMS.



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<sup>1</sup> Dobson DaVanzo & Associates, LLC, Estimate of Federal Payment Reductions to Hospitals Following the ACA: 2010-2028, Estimates and Methodology (June 14, 2018).

## ANTITRUST LITIGATION

### PAYOR CONTRACTING

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2019 provided a pointed reminder that hospitals and health systems should continue to be mindful of their managed care pricing strategy and contracting practices.

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The year 2019 provided a pointed reminder that hospitals and health systems should continue to be mindful of their managed care pricing strategy and contracting practices. In March 2018, the California Attorney General's office brought a civil antitrust action under California state law against Sutter Health alleging violations of California's Cartwright Act.<sup>2</sup> The California Attorney General alleged that costs in northern California rapidly increased as a result of Sutter Health's managed care pricing practices, including:

- Preventing insurers from using steering and tiering to reduce costs
- Forcing payors to contract with all Sutter Health facilities
- Prohibiting payors from providing incentives to patients to use competing facilities
- Prohibiting the disclosure of Sutter Health pricing prior to a service being rendered and billed.

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<sup>2</sup> *State of California v. Sutter Health*, CGC-18-565398 (CA Sup. Ct. Mar. 28, 2018).

California's lawsuit followed a private action filed almost four years prior by the United Food and Commercial Workers International Union and Employers Benefit Trust on behalf of a class of plaintiffs. The two cases were consolidated. Under the terms of a settlement agreement announced in December 2019, Sutter Health must pay \$575 million. The settlement agreement also prohibits Sutter Health from engaging in certain managed care contracting practices.

Federal antitrust enforcement agencies have also taken an interest in this issue. In November 2018, the US Department of Justice (DOJ) and the North Carolina Attorney General settled a suit that challenged certain terms of Atrium Health's payor contracts.<sup>3</sup> The government alleged that Atrium Health:

- Imposed steering restrictions in its payor contracts
- Prohibited insurers from tiered narrow networks that include only Atrium Health's competitors
- Restricted payors from providing comparative provider cost and quality information.

The final judgment voids certain contractual provisions in Atrium Health's payor contracts and provides that certain other contractual provisions in payor contracts will not be used to prohibit steered plans or transparency, only carve-outs. The final judgment further prevents Atrium Health from entering into any contractual provision that would prohibit or penalize steered plans or transparency, including express prohibitions thereof, requirements for prior approval for the introduction of new benefit plans, and requirements that Atrium Health be included in the most-preferred tier of benefit plans. Finally, Atrium Health is prohibited under the final judgment from penalizing

<sup>3</sup> *U.S. and the State of North Carolina v. The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System* Case 3:16-cv-00311 (W.D.N.C.)

payors for providing transparency or offering steered plans. The final judgment also includes certain compliance requirements.

The outcomes of both *Atrium* and *Sutter* suggest that activity in this area of enforcement will continue into 2020.

## COVENANTS NOT TO COMPETE AND “NO-POACH” AGREEMENTS

Hospitals and health systems should continue to be mindful of the scope and context for any covenants not to compete and no-poach agreements, particularly in employment agreements. On January 9, 2020, the Federal Trade Commission (FTC) held a policy workshop on employee covenants not to compete. The stated purpose of the workshop was to “examine whether there is a sufficient legal basis and empirical economic support to promulgate a Commission Rule that would restrict the use of non-compete clauses in employer-employee employment contracts.” DOJ held a similar workshop in September 2019.

State attorneys general have also taken an interest in this issue. In July and November 2019, numerous state attorneys general sent letters to the FTC encouraging the agency to use its rule-making authority to end the use of covenants not to compete in employment agreements. In May 2019, the state of Washington passed legislation that limits the types of employees that can be subject to non-competes and outright prohibits no-poach clauses in franchise agreements. The law followed a Washington Attorney General investigation of numerous corporate chains regarding the use of no-poach agreements, and a

subsequent agreement by those firms not to enforce the agreements in Washington.<sup>4</sup>

There has also been private litigation in this area in the form of a class action lawsuit alleging a no-poach agreement between Duke University and the University of North Carolina (UNC).<sup>5</sup> UNC allegedly declined to offer a position to a radiologist employed by Duke because of a “no hire” agreement between Duke and UNC. The DOJ intervened for purposes of a settlement agreement with Duke announced in September 2019. Under the terms of the settlement agreement, Duke was required to pay \$54.5 million.

These enforcement actions serve as a reminder of the 2016 DOJ and FTC guidance “Antitrust Guidance for Human Resource Professionals,” which stated that “[g]oing forward, the Justice Department intends to criminally investigate naked no-poaching or wage-fixing agreements that are unrelated or unnecessary to a larger legitimate collaboration between the employers.” We anticipate further activity in this area of the law in 2020.

Watch Now: [Navigating Antitrust Scrutiny of Health System Deals and Beyond.](#)



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<sup>4</sup> <https://www.atg.wa.gov/news/news-releases/ag-ferguson-s-initiative-ends-no-poach-clauses-four-more-corporate-chains>.

<sup>5</sup> *Seaman v. Duke University et al.*, 1:15-CV-462 (M.D.N.C.)



## VALUE-BASED ENTERPRISES AND PAYOR-PROVIDER COLLABORATION

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In 2019, large-scale strategic collaborations between payors and providers were once again on the upswing, motivated by cost and quality pressures, lower antitrust scrutiny of vertical (rather than horizontal) alignment, and the impact of market disruptors on the health insurance industry.

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These collaborations take a variety of forms, ranging from value-based payment arrangements to investments, joint ventures and acquisitions.

More than 40% of US healthcare payments flow through alternative payment models, including accountable care organizations, shared savings and risk arrangements, bundled payments and episode-of-care models, and other arrangements across the value-based spectrum. Many hospitals and health systems in particular are taking on greater risk from payors in the form of global capitation and virtual risk pool arrangements.

Other hospitals and health systems are looking beyond value-based payment arrangements, by either acquiring or starting up their own health plans in an effort to gain control of the full premium dollar. The phenomenon of the provider-sponsored health plan, which was prevalent in the 1980s and 1990s, has re-emerged as a viable and attractive option for many health systems.

While a number of the previous factors that drove hospitals and health systems to establish health plans are again present in today's healthcare market, the shift from traditional fee-for-service payment systems to value-based, bundled and population-based payment models is motivating many hospitals and health systems to move back into the provider-sponsored health plan business. In addition, as Medicare Advantage and Medicaid managed care have proven to be stable, profitable lines of business, more provider-owned health plans see them as a natural fit for narrow provider networks built around a single health system or clinically integrated network. We anticipate growth in these areas in 2020 and beyond.



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## COLLABORATIVE CLINICAL SERVICE VENTURES: RISE OF LESS INTEGRATED HEALTH SYSTEM TRANSACTIONS

The past year saw a surge of new and renewed interest in affiliations and collaborations among health systems involving low to moderate clinical, financial and operational integration between the parties, with no change of control of either party. These types of health system transactions are often referred to as “less integrated” or “loosely affiliated” provider transactions. They range from service line joint operating arrangements (designed to create a shared bottom line with respect to one or both parties’ service line assets with no change in ownership of those assets) and clinical integration arrangements with the parties maintaining separate bottom lines to (for instance) fee-based clinical oversight arrangements with significant branding components. Common features of these less-integrated health system transaction structures include:

- Each party’s retention of ownership of their assets with no change in control
- Reduction or avoidance of any impact on the parties’ credit positions
- Reduction or avoidance of the need for regulatory approvals (establishment/change in control) for purposes of licensure or accreditation, consolidated financials, bondholder or other lender approvals, or extensive pre-closing due diligence.

As greater innovation takes place in such structures, there is a more robust track record of their characteristics, risks and benefits. Motivations for pursuing such loosely affiliated transaction structures include:

- Maintaining local control of assets
- Creating economic synergies without a full merger or member substitution affiliation
- Allowing for a “toe-hold” in potential future targets
- Producing a defensive move against competitors
- Managing risk by keeping certain liabilities at the partner health system
- For smaller health systems in collaborations with larger, more sophisticated, and often academic systems with strong brands, benefitting from the “halo effect” of affiliating with the other system and securing access to other systems’ clinical policies, best practices and protocols.

Key countervailing considerations tempering pursuit of these structures in favor of those producing greater structural integration include:

- The lack of an immediate or near-term assurance of financial support for financial stability generally
- The lack of an immediate or near-term assurance of the transaction’s ability to meet the parties’ long-term strategic and operational needs
- The need to retain flexibility to pursue collaborations with more than one partner, versus exclusivity with one partner
- The likelihood of antitrust counsel concluding that the structure lacks sufficient integration to support joint managed care contracting for hospital and/or physician services, as well as support for clinical service rationalization
- The prospect of impeding, rather than facilitating, cultural integration between the systems.

Despite these limitations, health systems' recent experience with loosely affiliated health system transactions has demonstrated that such transactions can create meaningful relationships with other systems in pursuit of each system's long-term strategic goals, and that these relationships can readily evolve toward greater clinical, financial and operational integration over time.



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## MEDICARE SUB-REGULATORY GUIDANCE ENFORCEMENT DEVELOPMENTS

Following the Supreme Court's 2019 decision in *Azar v. Allina Health Services, et al.*, No. 17-1484, In November 2019, the Office of General Counsel (OGC) at the US Department of Health and Human Services (HHS) issued a memo to CMS officials stating that certain Medicare payment rules that did not go through notice-and-comment rulemaking cannot form the basis for an enforcement action, including an overpayment finding.

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Significant questions have been raised about the enforceability of Medicare sub-regulatory guidance.

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The Supreme Court held that if Medicare sub-regulatory guidance represents a change in a "substantive legal standard," then notice-and-comment procedures are required. OGC concluded that CMS guidance documents setting forth interpretive payment rules that create a substantive legal standard (such as the Medicare Internet-Only Manuals) are legally nonbinding and may not be used as the basis of an enforcement action. For example, if a "broadly worded statute or regulation can be interpreted a variety of ways," sub-regulatory policy statements found in a Manual may create a new substantive rule that are not enforceable under the Court's decision. According to OGC's memo, enforcement actions can still be brought if the CMS guidance document is "closely tied to a statutory or regulatory requirement." Further, even if the sub-regulatory guidance is not specifically enforceable, the agency can still attempt to use it for other purposes, such as scienter or materiality, as stated in the Department of Justice Brand Memo and the Justice Manual.

OGC clarified that it does not believe local coverage decisions require notice-and-comment rulemaking. Such decisions reflect payment determinations of the local Medicare Administrative Contractor and are not binding on HHS, and therefore they cannot be solely used as the basis for a "government enforcement action," including an overpayment demand.

The primary takeaway is that health care organizations, including providers and health plans, should examine carefully the basis for any enforcement action, including an overpayment determination, to determine whether the decision is based on sub-regulatory guidance that offends the Supreme Court standard. A recent district court case shows the potential value of the Court's new Medicare guidance test, finding that the manual provisions concerning inpatient status criteria issues prior to the "two midnight" regulation

were not enforceable.<sup>6</sup> The industry should also be on the lookout for CMS attempts to codify sub-regulatory guidance in notice-and-comment rulemaking in order to prospectively avoid this problem.



## HOT TOPICS IN PRIVACY AND SECURITY: INCREASE IN RANSOMWARE ATTACKS

Healthcare providers, including health systems and hospitals, have seen a recent rise in ransomware attacks. Ransomware is a malicious software that attempts to deny access to a user's data through encryption. Ransomware attacks can inflict devastation on hospitals and systems by preventing them from accessing patient medical records and other data that is essential to operations. Recent attacks have targeted specific providers and involved a particularly sophisticated malware called Ryuk.

In its fall 2019 Cybersecurity Newsletter<sup>7</sup>, the HHS Office for Civil Rights (OCR) addressed the rise of ransomware attacks and provided guidance on security measures required by HIPAA that can prevent or reduce the impact of these attacks. Security officers for hospitals and health systems should review the newsletter to understand how certain HIPAA Security Rule requirements can help their organizations prevent and mitigate the effects of ransomware attacks.



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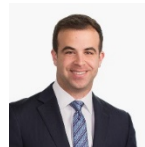
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<sup>6</sup> *Jesse Polansky M.D., M.P.H. v. Exec. Health Res., Inc.*, 2019 WL 5790061, at \*1 (E.D. Pa. 2019).

<sup>7</sup> <https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-fall-2019/index.html>.

## OCR ENFORCEMENT HIGHLIGHTS

While the first half of 2019 was relatively quiet in terms of HIPAA enforcement activity, in the second half of the year, the OCR announced three settled cases with hospitals and health systems and the imposition of civil monetary penalties in another case where a settlement was not reached.

In September 2019, the OCR announced its first action and settlement relating to failure to provide access to records—an area on which the OCR promised to focus in early 2019. The settlement involved a large hospital and arose out of allegations that the hospital failed to provide a mother with timely access to prenatal records. In December 2019, the OCR settled a second failure to provide access case involving a non-hospital provider. Expect to see more enforcement action and investigations relating to failure to provide access, since the OCR previously announced this as an initiative area.

The other 2019 settlement and civil monetary fine imposition against hospitals and systems arose out of alleged violations of the Security and Breach Notification Rules, and included the following:

- Failure to report a HIPAA breach
- Failure to conduct an enterprise-wide risk analysis and implement security measures, including failure to encrypt mobile devices.

Given continued enforcement and attention in these areas, hospitals and health systems should ensure that they have policies and procedures in place to provide individuals, upon request, with access to their protected health information. They should also

review their Security and Breach Notification Rule compliance.

[Read more: Significant Increase in Ransomware Attacks on Healthcare Industry-OCR Offers Guidance](#)



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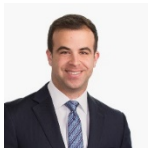
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## GROUNDBREAKING CHANGES IN STATE PRIVACY LAWS- CALIFORNIA

Effective January 1, 2020, the California Consumer Privacy Act (CCPA) is a sweeping new law that enhances the privacy rights afforded to California residents and creates significant operational requirements for an expansive list of regulated entities. Although the CCPA specifically excludes certain entities and information governed by HIPAA or other laws, health

industry businesses and their service providers should evaluate the extent to which their activities fall within the CCPA’s reach. For example, health industry businesses processing de-identified data will need to carefully analyze inconsistencies in standards between HIPAA and the CCPA.



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## STATE MEDICAL INFORMATION PRIVACY WITH EXPANSIVE APPLICABILITY

California’s Confidentiality of Medical Information Act (CMIA) was enacted to enhance the confidentiality of medical information obtained from a California patient by a health care provider. The CMIA provides stronger privacy protections for medical information. Unlike HIPAA, which only applies to covered entities and business associates (as defined by HIPAA), the CMIA applies to an expansive list of regulated entities, including more expected categories such as health care providers, health insurers, and contractors. However, the CMIA also applies to businesses that offer certain medical record software or hardware to consumers and to certain recipients of medical information. Note that unlike HIPAA, the CMIA provides individuals a private right of action for disclosures of medical information in violation of the CMIA.



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## EVOLUTION OF INNOVATION CENTERS

Hospitals and health systems have long been a hub for research and development, but of late, have transformed and centralized their innovation efforts to capitalize on opportunities and accelerate the introduction of novel products and services to the market. In 2019, more healthcare systems embarked on efforts to centralize their innovation efforts in an “innovation center,” whatever form that may take, to be a key and growing part of their strategy.

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Through their innovation centers, health systems are undertaking the difficult and challenging work of reimagining how healthcare is delivered, and partnering with novel partners to achieve those goals.

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By leveraging unique resources such as clinical and research data, provider workforce, or relationships with consumers and patients, innovation centers can further an organization’s overall mission and vision, build and maintain its organizational reputation, and generate growth opportunities outside core business lines. In addition to the myriad benefits of investment in innovation, however, health systems should consider the potential challenges of innovation, such as risks of failure and possible waste of valuable resources,



competing opportunities with less enterprise risk, difficulty assessing or managing legal and regulatory exposure, and conflicting goals and risk tolerance with strategic partners. To that end, as health systems invigorate existing innovation efforts or begin to develop an innovation center, they should broadly assess such activities from a governance, financial, strategic, cultural and legal perspective.

While the numerous legal issues are beyond the scope of this summary, special issues for consideration by hospitals and health systems related to innovation center activities include:

- Identification of innovation center structure and governance within the health system's corporate structure
- Structure of innovation investments in third parties, including start-ups
- Development of an opportunity assessment process for innovation investments, including tailored due diligence and identification of key legal and regulatory issues
- Conflicts of interest associated with co-investment by health system insiders.

Each of these topics and more are covered in more detail in our Focus on Innovation Centers. Read the series:

- Avoiding Pitfalls In Data-Focused Collaborations
- Co-Investment Arrangements
- Startups: Understanding Pathways For Hospital And Health System (HHS) To Investment
- Tax Exemption Considerations For HHS Innovation Investments
- FDA-Regulation

- Due Diligence For Collaborative Ventures

As innovation centers become an increasingly important part of health system strategy in 2020 and beyond, health systems should have a well-developed business plan for these initiatives and anticipate inquiries about innovation initiatives from board members, lenders, rating agencies and others.



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## INCREASING SCRUTINY OF PROVIDER-BASED ARRANGEMENTS

A majority of hospitals in the United States have some level of “provider-based” operations on or off campus that are billed as hospital outpatient services under the hospital’s provider number. As commonplace as such services may be, regulatory activity in 2019 suggests that hospitals that fail to prioritize compliance with the requirements of this status do so at their own peril.

“Provider-based” is a Medicare term that carries particular significance for Medicare reimbursement and beneficiary cost-sharing liability with respect to healthcare services furnished at locations determined to be provider-based. Medicare has historically paid for services furnished at provider-based locations under the payment methodology applicable to the main provider to which the location is considered “provider-based,” rather than the rate that would apply to services furnished at the location if it were considered “freestanding” (*i.e.*, not part of a provider).

In response to significant growth in the number of provider-based outpatient locations and the resulting potential for higher costs to the Medicare program and Medicare beneficiaries (in the form of higher cost-sharing obligations), Congress implemented a series of “site-neutral” payment reductions intended to disincentivize the creation of new provider-based outpatient locations. While these site-neutral payment rules have limited such payments for new off-campus locations and some services at all off-campus locations, the payment differential and patient care opportunities associated with provider-based outpatient services remain important sources of revenue for many hospitals.

Provider-based status is also relevant with respect to services covered and paid by non-Medicare payors, and for purposes of the 340B drug pricing program for participating covered entities that wish to register a provider-based facility as a “child site” eligible to purchase drugs at 340B prices. The only way to treat a provider-based location as a 340B child site is for the costs and charges associated with the provider-based location to be reported on a Medicare-allowable line on a filed Medicare cost report of a 340B-eligible hospital.

A Medicare regulation establishes a lengthy list of detailed operational and administrative requirements that must be satisfied in order for a site to qualify as a provider-based location (provider-based regulations). Ranging from requirements involving licensure, operational and financial control, to clinical integration and related decision-making, the provider-based regulations are intended to ensure that all provider-based locations function as an integral part of the main provider to which they are provider-based.

To accompany the payment changes intended to reduce the number of provider-based outpatient locations, regulatory activity in 2019 demonstrated a renewed interest in compliance in this area to ensure that



locations operating as provider-based outpatient locations meet the relevant requirements. Triggered in part by a 2016 Office of Inspector General report identifying “vulnerabilities” in the provider-based structure, and borne out in more recent investigatory and enforcement activity, arrangements that once may not have been given a second look are now more likely to be subject to scrutiny.

Expect increased oversight, inquiries and threats of enforcement in this area in 2020—a trend that reinforces the need for hospitals to pay close attention to compliance with the provider-based regulations. Proactive identification and remediation of provider-based compliance concerns require resources, but are far less costly than over-payment refunds and government settlements after an investigation. Further, for those hospitals that participate in the 340B Program, loss of provider-based status may result in ineligibility for 340B purchasing at the location and potential repayment obligations to drug manufacturers. Hospitals are well advised to include as part of their compliance efforts audits and monitoring of provider-based locations, and in particular existing arrangements that may have inadvertently fallen out of compliance with the passage of time.



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## EMERGING CANNABIS ISSUES

As more states consider legalizing the use of cannabis-containing products under a variety of frameworks, there is increasing interest in how cannabis-containing products can be used to treat a variety of healthcare conditions—in particular as an effective alternative to opioids to manage pain. Although public debate often focuses on whether to “legalize,” the issues surrounding the safe and effective use of cannabis-containing products in the healthcare context raises complicated and interlocking issues for hospitals, health systems and other providers.

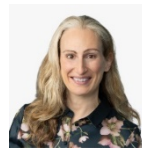
Surgeon General Jerome M. Adams recently addressed the increasing use of marijuana-containing products in the United States and the need for “research aimed at understanding the public health effects of marijuana use at all stages of life.” During his October 2019 Senate testimony, the surgeon general explained that, without further research on the safe and effective use of cannabis-containing products, the public’s use of such products amounts to a “poorly informed and enormous public health experiment.” While Surgeon General Adams emphasized the use of cannabis-containing products by adolescents and pregnant women, a growing number of US residents are using these products for medicinal purposes, largely without the benefit of appropriate medical guidance.

While there are risks in such unmanaged use, some early studies have shown that properly guided use of cannabis-containing products can, for example, alleviate the nausea and vomiting that often follows chemotherapy, relieve muscle spasms for those with multiple sclerosis, improve the appetite of patients with cancer or AIDS, and reduce neuropathic pain caused by a number of conditions without the now widely understood addiction and other risks associated with opioid use. Nonetheless, additional research and treatment oversight is necessary to ensure that individuals and providers consider cannabis-containing products with appropriate information in hand.

Hospitals and health systems (along with many other healthcare stakeholders, such as app developers) have a vital role to play in conducting research to establish and implement clinical care guidelines and to assist in the development of new products for US Food and Drug Administration (FDA) approval. To do so, institutional providers and their partners must navigate an array of regulatory issues since under the Controlled Substances Act, 21 USC § 801 et seq. (“CSA”), marijuana is a Schedule 1 substance, meaning that its manufacture, distribution and possession is a felony under federal law. The federal government has the power to investigate and prosecute a researcher or clinician for possession of marijuana, even if the research or distribution fully complies with state law.

Hospitals and health systems should ensure that they understand the different classification systems for cannabis-containing products, including marijuana. They should also review current regulatory considerations that must be addressed if institutions wish to undertake such research, including:

- Current Drug Enforcement Administration/DOJ policy
- FDA classifications of cannabis-containing products
- Specific challenges related to informed consent
- Part 2 considerations
- Conditions of participation and other CMS considerations.



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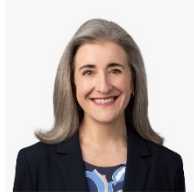
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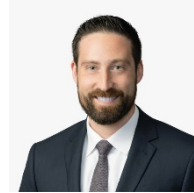
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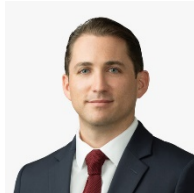
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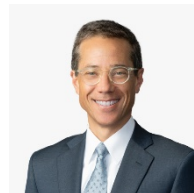
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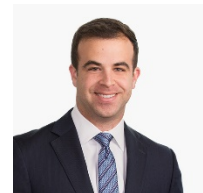
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