2020
OUTLOOK

THE YEAR AHEAD IN HEALTH LAW

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Editor's Note: *The following information was originally prepared in January 2020. It is not intended to constitute legal advice.*

CHANGES & CHALLENGES

In healthcare, change is constant. The same can be said for the regulated environment in which the healthcare industry operates. Indeed, in some ways, a shifting legal landscape drives change just as much as scientific or technological innovation. As we look out at the year ahead, we see significant developments with respect to price transparency, value-based payment initiatives, the interoperability of health information systems, and the fraud and abuse landscape. In some cases, we expect past will be prologue — in all likelihood, some or all of the runners in the *Regulatory Sprint to Coordinated Care* will cross the finish line, False Claims Act enforcement will remain robust and focused on the healthcare industry, and small tweaks to payment policies will continue to incent the migration of care from inpatient to outpatient settings. Others will follow a path that is decidedly nonlinear — what will come of the Affordable Care Act, what proposals will come out of the election cycle, and so on.

In an effort to prepare for the challenges that lie ahead, we have prepared short summaries of a number of important developments that affect a broad range of healthcare industry clients. If you would like to learn more about these or other health law issues, please contact any of the attorneys in Bradley's Healthcare Practice Group.

MODERNIZING THE FRAUD AND ABUSE LAWS

In October 2019, the U.S. Department of Health and Human Services (HHS) unveiled significant proposals to modernize the regulations that implement the Stark Law and Anti-Kickback Statute. The proposed rules were seen by many industry observers as promising steps toward removing barriers to care coordination and facilitating the transformation of the U.S. healthcare system to one that pays for value. But, as is always the case when an agency heaps hundreds of pages of new rules atop the thousands already in existence, important questions remain, particularly with respect to the utility of the proposed exceptions and safe harbors for value-based arrangements. Given the broad scope of the underlying laws, and the great potential for these regulations to shape industry behavior, many eyes will be trained on this issue.

VALUE-BASED ARRANGEMENTS

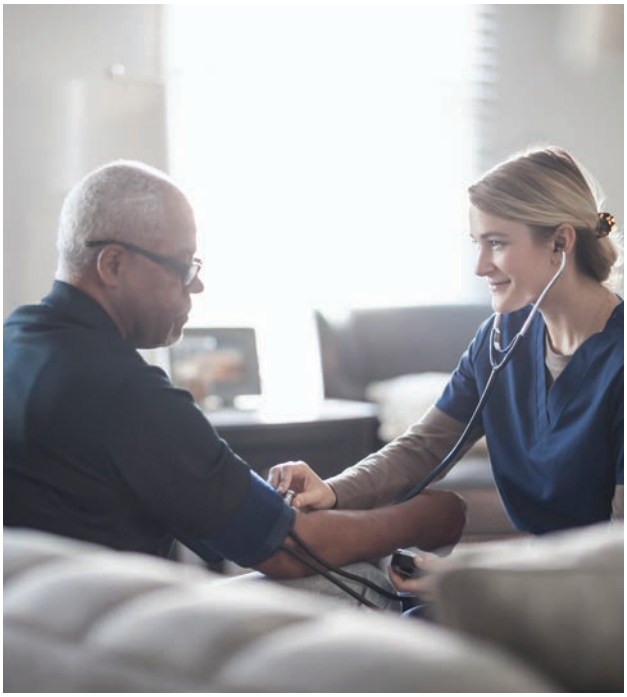
The proposed rules reflect a coordinated effort between the HHS Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) to advance the transition to value-based care. At the center of the proposed rules is a set of regulatory protections for value-based arrangements — i.e., arrangements intended to improve quality outcomes, lower or reduce the growth in costs, and increase health system efficiencies through care coordination.

The proposed protections take the form of three new Anti-Kickback Statute safe harbors and three new Stark Law exceptions. The safe harbors and exceptions follow a tiered structure in which the greater the level of financial risk assumed by the parties, the greater the flexibility afforded by the safe harbor or exception. More specifically, the protections are divided into three categories: full financial risk arrangements, partial risk arrangements, and arrangements in which the parties have no downside financial risk for the cost of care.

Although the proposed Anti-Kickback Statute safe harbors and Stark Law exceptions differ in important ways, they share some common vocabulary. All are intended to protect remuneration paid under qualified value-based arrangements, which are arrangements between participants in a value-based enterprise (or between the value-based enterprise itself and one or more of its participants) that involve a value-based activity for a target patient population in furtherance of a value-based purpose. Suffice it to say, the devil is in the details, and the details are in the definitions.

For value-based arrangements, the devil is in the details, and the details are in the definitions.

Broadly speaking, the proposed protections for value-based arrangements represent a major step forward in creating regulatory safe space for the kinds of innovative arrangements that are all but necessary in a changing reimbursement environment. With that said, key questions remain, among which



are whether certain industry players, such as pharmaceutical manufacturers, pharmacies, laboratories, and health technology companies, will be excluded from the new protections, and whether the OIG's proposed safe harbor for arrangements with no downside financial risk will be revised to be more consistent with its CMS counterpart.

SIGNIFICANT STARK LAW MODIFICATIONS

Although value-based arrangements take center stage, the proposed rule to modify the Stark Law regulations includes a number of highly significant changes and clarifications applicable to a wide range of financial relationships. In almost all respects, these changes and clarifications are welcome news for the healthcare industry, particularly hospitals and health systems.

Perhaps the most significant changes concern CMS's proposals regarding three concepts essential to many Stark Law exceptions: commercial reasonableness, fair market value, and the so-called "volume or value" standard. CMS's proposed definitions of these terms simplify their application and clarify their conceptual independence from one another. The proposed rule also directly confronts two positions that have been the subject of multiple enforcement actions brought under the False Claims Act (FCA): (1) that unprofitable physician compensation arrangements (i.e., arrangements in which compensation exceeds professional collections) cannot be commercially reasonable without considering referrals; and (2) that productivity-based compensation arrangements take into account the volume or value of referrals because corresponding designated health services are billed most of the time when the referring physician personally performs a service.

Whether and in what form these proposals will be finalized, and when, are open questions. Still, the proposed rules are the most significant regulatory development in healthcare fraud and abuse in many years. If finalized, we expect the proposed rules will provide steadier ground for the development of innovative value-based and care coordination arrangements, as well as strong defenses to certain well-worn positions in enforcement actions.

HOSPITALS GRAPPLE WITH CMS PRICE TRANSPARENCY REQUIREMENTS AND LEGISLATORS CONSIDER SURPRISE BILLING PROTECTIONS

Government efforts to increase price transparency will no doubt be the subject of considerable debate in 2020. In November, CMS issued a final rule that requires hospitals to post a detailed data file of charges for all items and services, as well as a consumer-friendly list of select charges, starting January 1, 2021, or pay fines. The agency also issued a proposed rule, in conjunction with the Department of the Treasury and the Department of Labor, that would impose price transparency requirements on health plans. The hospital price transparency rule was vigorously opposed by the hospital industry, and the American Hospital Association, along with other leading trade associations, announced that they would mount a legal challenge to the final rule shortly after it was published. The near-uniform industry opposition to the final rule juxtaposed against widespread public support for price transparency, especially in the realm of surprise billing, make this a must-watch issue in the year ahead.

PRICE TRANSPARENCY REGULATORY DEVELOPMENTS

Effective January 1, 2021, CMS will require hospitals to make available for download a data file of their charges for all items and services offered to patients during inpatient or outpatient care, including supplies, procedures, room and board, facility fees, and professional charges. For each item or service, hospitals will have to post corresponding "standard charges": gross charge, discounted cash price, and payor-specific negotiated charges, as well as the de-identified minimum and maximum negotiated charges for the item or service. While the data file will likely aid insurance companies and other industry stakeholders, it may not benefit the average patient seeking price information. Accordingly, the final rule also requires hospitals to select and post online in a consumer-friendly manner the charges for at least 300 services commonly provided to their patient population. At a minimum, hospitals must publish charges for 70 CMS-selected and 230 hospital-selected services that patients may schedule in advance. The postings must include a plain-language description of each service, along with the discounted cash price (or gross charge if discounted cash price is not available), payor-specific negotiated charges, and de-identified minimum and maximum negotiated charges for each. The new rule empowers CMS to impose a modest daily fine on hospitals that materially violate the new requirements and fail to comply with subsequent corrective action plans.

Whether, however, the rule takes effect remains to be seen. In December 2019, several hospital associations led by the American Hospital Association filed suit against HHS to challenge the final rule in federal court. Describing the rule as "unlawful, several times over[,]" the plaintiffs' complaint alleges it exceeds the agency's statutory authority, violates the First Amendment, reduces competition in healthcare markets, and confuses patients regarding their true out-of-pocket costs. The suit will continue to develop throughout 2020.

In a separate effort to promote price transparency, HHS issued a proposed rule in November 2019 that would require certain health insurance plan issuers to disclose patient cost-sharing information for covered items and services. Under the rule, the insurers would have to publish files on the internet containing

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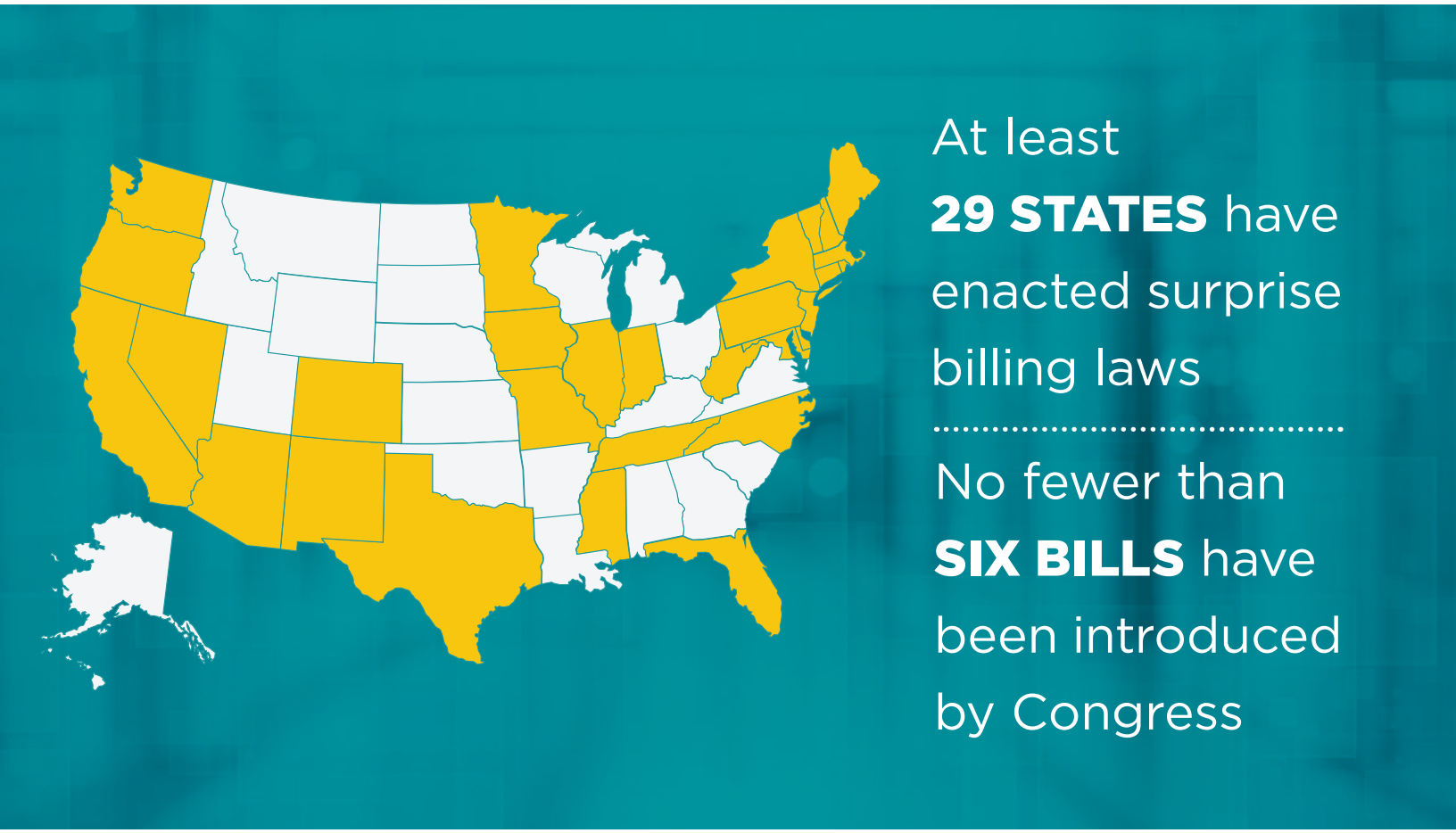

both in-network provider negotiated rates and historical out-of-network payments. In an effort to gain support for the proposed rule, HHS also proposed that the insurers receive credit in their medical loss ratio calculations for savings generated when enrollees shop for and receive care from lower-cost, higher-value providers.

SURPRISE BILLING LEGISLATION

While federal agencies work to increase price transparency through rulemaking, state and federal legislators continue their efforts to curb patients' surprise medical bills through new laws. At the start of 2020, at least 29 states had enacted surprise billing laws, and Congress had introduced at least six bills that prohibit both insurers and providers from balance billing patients for emergency or out-of-network services. Most surprise billing legislation includes a process for resolving payment disputes between providers and insurers, but enforcement mechanisms vary, with some legislation implementing civil monetary penalties and others enabling claims under state deceptive trade practice laws. Most of the recent federal legislation on surprise billing tends to defer to state law governing price disclosures by insurers, suggesting rules will continue to vary even as federal solutions move forward. Providers and insurers should stay tuned to surprise billing legislation and other government efforts that increase price transparency and empower patients to make cost-effective healthcare decisions.

ALLINA HEALTH AND THE FUTURE OF SUBREGULATORY GUIDANCE

In addition to the thousands of pages of regulations it brings to us through notice-and-comment rulemaking each year, HHS publishes no small amount of subregulatory guidance. Thanks to the Supreme Court's June 2019 decision in *Azar v. Allina Health Services*, we will see more debate on the weight of the latter in 2020.

Narrowly, *Allina Health* addressed whether HHS could change the manner in which it calculates disproportionate share (DSH) payments by including Medicare Advantage beneficiaries in the Medicare fraction without going through notice-and-comment. The Supreme Court held that it could not. According to the court, under the Medicare Act, any rule, requirement, or other statement of policy that "establishes or changes a substantive legal standard governing . . . the payment for services" must be promulgated through notice-and-comment rulemaking. Because the new DSH formula changed a substantive legal standard affecting payment, the court held, notice-and-comment rulemaking was required.

In reaching this conclusion, the Supreme Court roundly rejected the government's argument that the Medicare Act, like the Administrative Procedure Act (APA), exempts interpretive rules from its notice-and-comment requirement. Under the Medicare Act, the court explained, all rules, requirements, or statements of policy that establish or change a substantive legal standard must be promulgated through notice-and-comment rulemaking. Thus, the Medicare Act requires notice-and-comment in some circumstances where the APA would not.

Broadly, the Supreme Court's decision — and its rejection of the government's arguments — calls for a more nuanced examination of subregulatory guidance and rules. A recently released HHS memo analyzing the impact of *Allina Health* sets forth the framework through which HHS can be expected to analyze the validity and utility of subregulatory guidance. Much like the Department of Justice's (DOJ) Brand Memo released in 2018, the HHS memo concludes that subregulatory guidance, standing alone, cannot form the basis of enforcement actions. But where the guidance is tied closely to the governing statutory or regulatory standards, the HHS memo notes they can serve to provide additional clarity through guidance that does not itself establish a new non-statutory or non-regulatory norm. The touchstone, the HHS memo concludes, is whether the enforcement action could be brought absent the subregulatory guidance or rule. If so, the guidance can aid in demonstrating the governing standard and can be relevant in showing materiality and scienter.

The reach of Allina Health is yet to be seen.

The reach of *Allina Health* is yet to be seen. Already, though, at least one federal district court has relied on the Supreme Court's decision to conclude that a payment rule set forth in a Medicare manual could not form the basis of FCA liability. As *Allina Health* reverberates in the courts, look for fierce debates about whether certain instances of subregulatory guidance or rules set forth substantive legal standards or simply aid in demonstrating whether the relevant statutory and regulatory standards have, or have not, been met. In addition, we expect *Allina Health* to complicate, and likely chill, agency efforts to issue interpretive guidance outside of the notice-and-comment rulemaking process, particularly in the wake of the recent HHS memo.

JUSTICE DEPARTMENT CONTINUES MARCH ON FALSE CLAIMS ACT CASES

DOJ total recoveries from FCA prosecutions topped $3 billion in 2019, the vast majority of which came from the healthcare industry. That trend is expected to continue in 2020, along with several others that have emerged in the past year. We expect the government to continue to move to dismiss certain FCA suits that do not serve the government's interests. We expect defendants to increasingly assert arguments that the DOJ cannot base FCA claims on subregulatory guidance that did not go through notice-and-comment rulemaking. We also expect to see whistleblowers continue to try to assert FCA claims based on the findings of data analytics.

DOJ MOVING TO DISMISS ACTIONS USING "GRANSTON MEMO" FACTORS

In 2018, the DOJ's Granston Memo described the factors that the agency will consider in determining whether to seek dismissal of non-intervened *qui tam* suits. The factors include the desire to (1) curb meritless *qui tam* suits, (2) prevent parasitic or opportunistic *qui tam* actions that duplicate pre-existing government investigations, (3) prevent interference with agency policies and programs, (4) control litigation brought on behalf of the United States, (5) safeguard classified information and national security interests, (6) preserve government resources, and (7) address egregious procedural errors, such as when relators fail to properly serve the government or when relators breach the FCA's seal requirement.

Over the course of the past two years, the DOJ has applied these factors and increased its use of motions to dismiss *qui tam* complaints, and defendants have increasingly encouraged the DOJ to do so. This activity has given rise to a circuit split in the standard that courts should apply when the government moves to dismiss a whistleblower's complaint for which the government is the real party in interest. While the D.C. Circuit has held that the government has an "unfettered right to dismiss" an FCA case, the Ninth and Tenth Circuits have stated a higher standard. They hold that the government must be able to state both a valid purpose for dismissal and a rational relationship between dismissal and accomplishing that purpose.

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In 2020, we expect to see even more defendants advocating for the government to use its discretion to move to dismiss FCA actions, the government continuing to move to dismiss in cases where it suits its interest, and additional courts weighing in on the appropriate standard to apply to such a motion.

DEFENDANTS ARGUING AGAINST USE OF SUBREGULATORY GUIDANCE IN FCA CASES

The Supreme Court's decision in *Azar v. Allina Health* is expected to reverberate throughout healthcare FCA cases that involve subregulatory guidance. As described above, *Allina Health* held that any Medicare guidance that establishes or changes a "substantive legal standard" must go through notice-and-comment rulemaking. In an HHS memo analyzing the impact of *Allina Health* on its practices, HHS's Office of General Counsel states that "If [CMS] intends for a particular guidance document to be used in enforcement actions, then the guidance must comply with Allina [Health]." The memo further explains that the government "generally cannot use" violations of Internet-Only Manuals or similar guidance that "set forth payment rules

that are not closely tied to statutory or regulatory standards" in FCA actions. The memo admits that *Allina Health* makes enforcement actions based solely on the standards articulated in Local Coverage Determinations "generally unsupportable."

Note that, even where subregulatory guidance is established through notice-and-comment rulemaking consistent with *Allina Health*, the government still cannot not use violations of such guidance to justify an FCA action. Under the DOJ's 2018 Brand Memo, even guidance that is issued consistent with *Allina Health* "may not be used as the sole basis for an enforcement action," though it can be relevant to a determination of scienter or materiality. HHS reiterated this concept in its memo analyzing the impact of *Allina Health*.

FCA WHISTLEBLOWERS BASING CLAIMS ON DATA ANALYTICS

In 2019, two courts reached opposing conclusions on FCA claims that were founded almost entirely on a whistleblower's analytics of Medicare claims data, highlighting the hurdles and risks of FCA actions based on data analytics. In *United States ex rel. Integra Med Analytics v. Baylor Scott & White Health* and *United States ex rel. Integra Med Analytics, LLC v. Providence Health and Services*, the courts grappled with motions to dismiss complaints that presented analytics of government claims data to allege that hospitals' elevated levels of certain major complication or comorbidity (MCC) codes indicated fraudulent upcoding. The complaints also alleged that the upcoding resulted from the providers' clinical documentation improvement programs.

In *Baylor Scott*, the Texas district court granted dismissal, stating that the analytics showed elevated levels of certain procedures, but that providing "a certain treatment at rates higher than average, even significantly higher than average, is not by itself indicative of fraud or unnecessary treatment." The court also stated that allegations that the defendant provided documentation tip sheets and training to physicians to seek opportunities to code MCCs is equally consistent with an upcoding scheme as it is with an effort "to improve revenue through accurate coding of patient diagnoses in a way that will be appropriately recognized and reimbursed by CMS."

The California district court in *Providence* reached the opposite conclusion, stating that "while the coding rates alone likely would not be enough to state a claim for fraud," additional allegations were enough to give rise to a plausible inference that the increased coding rates were caused by upcoding. Notably, the court also found that the Medicare claims data analyzed by the whistleblower was a publicly disclosed government report, but that the other information — available on the internet — did not qualify as a public disclosure for FCA purposes.

$3 BILLION

in fraud recoveries in FY 2019

85%

of fraud recoveries came from the healthcare industry

REIMBURSEMENT CHANGES CONTINUE APACE

Suffice it to say, Medicare payment policy continues to evolve. Although 2019 did not bear witness to any seismic shifts, there were some significant developments, including a number of consequential lawsuits challenging payment cuts. Looking ahead, we see continued interest in policies that reward the performance of procedures in outpatient settings (or eliminate any benefit in performing them in inpatient settings), efforts to streamline documentation requirements and reduce regulatory burden, and the introduction of more bundled and other value-based payment models, perhaps with a willingness to require providers to assume some downside financial risk.

We see continued interest in policies that reward the performance of procedures in outpatient settings, efforts to reduce regulatory burden, and the introduction of more bundled payment models, perhaps with a willingness to require providers to assume downside risk.

CMS EXTENDS CUTS TO 340B DRUG PROGRAM PAYMENTS DESPITE PENDING APPEAL

CMS continues to pursue reimbursement reductions under the 340B drug program while it appeals a district court order to unwind existing reductions. In 2017, CMS announced it would significantly reduce reimbursement to 340B program participants, including safety net hospitals and other providers, beginning in 2018. Providers challenged the move in federal court, and in May 2019, the D.C. District Court held that CMS had exceeded its authority in imposing the cuts. The court remanded the impacted payment rules back to the government to determine how best to unwind the reductions. CMS has appealed the decision, but in the meantime, the agency must analyze existing data to determine how it might address the court's order if it is upheld. Providers will be keeping an eye on efforts to enjoin 2020's payment cuts, which also depend on the outcome of CMS's appeal.

CMS CUTS PAYMENTS AT PROVIDER-BASED DEPARTMENTS DESPITE COURT ORDER VACATING RULE

In September 2019, a federal district court vacated the portion of CMS's 2019 final rule that decreased reimbursement for evaluation and management services at excepted off-campus provider-based departments (PBDs), finding that those payment cuts exceeded CMS's statutory authority. CMS had reduced reimbursements for evaluation and management services by 30 percent in the 2019 final rule; in its 2020 final rule, it doubled down and reduced reimbursements by 60 percent. Undeterred by the court's decision, CMS emphasized in the final rule that the agency still has appeal rights and believes that during pending litigation it must "move forward with phasing-in" payment cuts "to appropriately control unnecessary increase in the volume of clinic visits" furnished in hospital outpatient PBDs. CMS's efforts to further reduce reimbursement in PBDs reflect its continued commitment to "site-neutral" payment policy.

COURTS GRANTING INJUNCTIVE RELIEF FROM CMS RECOUPMENT PENDING FULL ALJ HEARING

Providers continue to seek judicial relief related to the three- to five-year backlog of Medicare appeals cases waiting on an administrative law judge (ALJ) hearing. During this waiting period, CMS can begin recouping alleged Medicare overpayments. In light of the backlog, providers are seeking injunctions from federal courts to enjoin CMS from recouping alleged overpayments before the provider receives a full evidentiary hearing before an ALJ.

Previously, courts tended to dismiss such requests due to lack of subject matter jurisdiction, as the provider had not yet completed the administrative appeals process. In 2018, however, the Fifth Circuit ruled that a provider's procedural due process claim was "entirely collateral" to the issues to be decided through the administrative appeals process, and therefore the provider's request for an injunction could proceed on procedural due process grounds. A federal district court in Texas entered a judgment granting Family Rehab, a home health agency, a preliminary injunction against CMS, restraining it from withholding Medicare payments until Family Rehab's overpayment appeal could be heard in front of an ALJ.

In the year and a half since the Family Rehab decision, a circuit split has emerged regarding whether courts have jurisdiction over cases arising out of the Medicare administrative appeals process. In recent months, the Fourth and Sixth Circuits have held that jurisdiction exists, but that the providers were not denied due process and therefore not entitled to injunctive relief because the administrative delay complained of can be avoided by bypassing an ALJ hearing and obtaining judicial review pursuant to federal appeals statutes. We expect these issues to continue to play out in the courts in 2020.

EVALUATION AND MANAGEMENT PAYMENT CHANGES ON THE HORIZON

Evaluation and management (E/M) visits comprise approximately 40% of allowed charges for physician fee schedule services paid by the Medicare program. In its 2019 final rule, CMS included a number of coding, payment, and documentation changes for E/M visits to reduce administrative

burden and increase payment accuracy. The changes included replacing the five-tier payment system for E/M with a single payment rate for E/M outpatient visit levels 2 through 4 effective January 1, 2021.

In response to stakeholder comments, CMS walked back the E/M payment changes in its 2020 final rule. Beginning in 2021, CMS will keep the five-tier system for established patient E/M visits and move to a four-tier coding system for new patient E/M visits. CMS also adopted a single add-on code describing the work associated with E/M visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

The 2020 final rule also established that CMS will adopt the revised E/M code definitions developed by the American Medical Association's CPT Editorial Panel beginning January 1, 2021. These CPT code changes revise the time and decision-making guidelines for each level, and only require documentation of patient history and a medical exam when clinically appropriate. They also allow physicians to select the appropriate level of visit based on the extent of decision-making in the exam or based on time spent with the patient.

HEALTH INFORMATION PRIVACY AND SECURITY DEVELOPMENTS

FINALIZATION OF INFORMATION BLOCKING AND INTEROPERABILITY RULES

Providers likely will have a new final rule on information blocking to address in 2020. The Office of the National Coordinator for Health Information Technology (ONC) issued a proposed rule last year implementing the information blocking prohibition in the 21st Century Cures Act. The law prohibits healthcare providers, health information technology developers, health information exchanges, and health information networks from engaging in activities and practices that are likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information (EHI).

Under the proposed rule, ONC would establish seven exceptions to the information blocking prohibition for activities and practices that may meet the definition of information blocking but are deemed reasonable and necessary to further the law's goals. The seven exceptions include (1) preventing harm; (2) promoting the privacy of EHI; (3) promoting the security of EHI; (4) recovering costs reasonably incurred; (5) responding to requests that are infeasible; (6) licensing of interoperability elements on reasonable and non-discriminatory terms; and (7) maintaining and improving health IT performance. If an actor satisfies one or more exception, the activity or practice would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives related to such activity or practice.

On the same day that ONC released its information blocking proposal, CMS released a proposed rule focused on interoperability issues and patient access to health information. The proposed rule would require certain entities, including covered health plans, to implement application programming interfaces that allow patient information to be more easily shared between patients, providers, and payors. In addition, the proposed rule would impose on hospitals, as a condition of participation in the Medicare program, the requirement to send certain patient event notifications to other healthcare facilities or community providers.

The ONC and CMS rules have the potential to have significant impact on data sharing arrangements and other relationships among healthcare providers.

Final rules from both ONC and CMS have been under review at the Office of Management and Budget for several months now. Both rules have the potential to have significant impact on data sharing arrangements and other relationships among healthcare providers, as well as other industry stakeholders.

OCR ENFORCEMENT AND HIPAA RIGHT OF ACCESS INITIATIVE

The HHS Office for Civil Rights (OCR) reached settlements in 2019 with 11 entities alleged to have violated HIPAA, including health systems and healthcare providers, an electronic medical records company, a dental practice, a state health agency, and an ambulance company. Together, the settlements total over $15 million and provide essential lessons for 2020.

OCR's $2.175 million settlement with Sentara Hospitals, a 10-hospital health system, highlights the importance of having a business associate agreement (BAA) in place with a parent or affiliated company that is serving as a business associate. OCR began its investigation of Sentara in April 2017 after it received a complaint alleging that Sentara sent a bill to an individual containing another patient's protected health information (PHI). In addition to finding that Sentara mailed 577 patients' PHI to wrong addresses, OCR determined that Sentara allowed its

parent organization to create, receive, maintain or transmit PHI on Sentara's behalf, but did not have a BAA in place with the parent company. OCR alleged that Sentara provided services for its member hospitals involving the receipt, maintenance, and disclosure of PHI, but a BAA between Sentara and its member hospitals was not signed until late October 2018.

It is common in the healthcare industry for companies to provide services to or perform functions on behalf of affiliated entities that involve the use and disclosure of PHI. The Sentara settlement serves as a reminder that covered entities may also be business associates to the extent they perform functions on behalf of another entity that involve the use or disclosure of PHI, and that BAAs are required for affiliated entities as well as external ones.

OCR's enforcement activity in 2020 will also likely have an increased focus on alleged violations of the HIPAA individual right of access, under which covered healthcare providers must provide medical records within 30 days of receiving a request and may only charge a reasonable, cost-based fee for fulfilling the request. OCR announced its Right of Access Initiative early last year; by September 2019, it had announced its first enforcement action and settlement related to individual access rights, and a second was announced in December 2019. The agency has promised to vigorously enforce the rights of patients to receive copies of their medical records promptly and without being overcharged.

Providers that have received an initial data request from OCR in recent months related to an individual's complaint that their right of access has been violated may have noticed that OCR is requesting detailed financial information regarding the provider. When OCR receives a complaint, it begins its investigation into the complaint by issuing a letter to the entity against whom the complaint was filed, requesting information relevant to the complaint. In general, OCR's request for the entity's financial information may indicate that OCR intends to impose penalties related to the complaint, pending the findings of its investigation. Automatic requests for financial information in an OCR initial data request may reveal the seriousness with which OCR is seeking compliance with the individual access rights. We expect this increased focus to continue into 2020.

REVISIONS TO PART 2 REGULATIONS

In August 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) published its much-anticipated proposed rule to revise 42 C.F.R. Part 2 (Part 2), a set of federal regulations governing the confidentiality of substance use disorder (SUD) patient records. The proposed rule, which is part of HHS's broader *Regulatory Sprint to Coordinated Care* campaign, would not alter the basic framework of Part 2, but it would, if finalized, reduce confusion regarding certain existing requirements and ease restrictions on the sharing of patient information for certain purposes. Final regulations are expected to be released in 2020.

Some of the major changes and clarifications in the proposed rule include an exception permitting certain information to be shared between a Part 2 program and non-Part 2 providers for treatment purposes; a provision enabling patients to consent to disclosure of their Part 2 records to an entity without naming a specific individual as the recipient of the disclosure; a provision enabling non-opioid treatment program providers who have a treatment relationship with a patient to query a central registry to determine whether the patient is already receiving opioid treatment to avoid duplicate treatment or prescriptions; a new rule permitting opioid treatment programs and other lawful holders of Part 2 records to report data to prescription drug monitoring programs with the patient's written consent; and a provision to allow Part 2 programs to disclose certain Part 2 data for research purposes, provided that the data is disclosed in accordance with the HIPAA Privacy Rule.

FOREST PARK AND THE LONG ARM OF THE TRAVEL ACT

The federal government appears primed to extend the reach of its enforcement powers into the private payor arena after the successful use of the Travel Act to obtain convictions in the Forest Park Medical Center saga. The Forest Park case involved alleged kickbacks between referring physicians and a self-proclaimed "luxury" hospital in Dallas, Texas, that catered to commercial and privately insured patients. The hospital did not participate in the Medicare or Medicaid programs, but failed to successfully screen out all governmental payors. Originally, the hospital came under government scrutiny as the result of claims for the treatment of TRICARE and Federal Employee Compensation Act beneficiaries. However, the vast majority of tainted referrals involved private payors, so federal prosecutors turned to the Travel Act, which prohibits the use of interstate commerce to distribute proceeds of an "unlawful activity" — including bribery as defined under state law — as a means to prosecute the parties under Texas anti-kickback and commercial bribery laws, which apply equally to all payors.

Prosecutors alleged that the defendant physicians were given kickbacks in exchange for cherry-picking patients with generous insurance coverage and funneling them to Forest Park for lucrative out-of-network medical procedures. In court filings, the lead prosecutor noted that the indicted surgeons "treated their patients like commodities and failed to disclose these bribe payments to their beneficiaries. Such conduct is — and always has been — illegal under the laws of various states." Alleging that the hospital used sham marketing agreements to pay kickbacks to physicians and marketers with large numbers of referrals, federal prosecutors used the Travel Act to claim standing to target the healthcare providers for kickback schemes outside the scope of federal program payors. Ultimately, following a seven-week trial, a federal jury returned guilty verdicts for seven individuals implicated in the scheme. Ten other defendants had already pleaded guilty prior to the trial.

The Forest Park case was not the first of its kind — notably, prosecutors in the 2016 Biodiagnostic Laboratory Services case in New Jersey utilized the Travel Act to obtain a $15 million recovery and the criminal conviction of numerous defendants, including 38 physicians, related to an alleged kickback scheme to obtain and bill for laboratory test referrals — but it clearly identifies a new tool in the prosecutor's toolkit, and it may signal increased willingness to pursue suspect conduct regardless of payor source.

OPIOID BATTLE CONTINUES ON ALL FRONTS

The federal government continued its fight against the opioid crisis throughout 2019. The year brought significant enforcement actions, including dozens of criminal prosecutions and several major civil settlements. Individual states, particularly those hardest hit by the epidemic, have also entered the fray by passing legislation or partnering with federal agencies. We expect these trends to continue and intensify in 2020.

Providers and other healthcare industry stakeholders continue to grapple with the requirements of the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). EKRA was passed as part of a group of new laws aimed at fighting the ongoing opioid crisis. The law prohibits remuneration in exchange for referrals of patients to a recovery home, clinical treatment facility, or laboratory. EKRA has been described as an "all-payor" anti-kickback statute, meaning it applies to all healthcare benefit programs, including commercial insurance plans. As written, EKRA appears to apply to many commonplace arrangements in the healthcare industry — even some that would otherwise comply with the federal Anti-Kickback Statute and that are unrelated to the issues the law was written to address. While EKRA authorizes the attorney general to promulgate regulations in consultation with HHS, no regulations or official guidance have been published since its enactment.

Following EKRA's enactment, some states have passed similar prohibitions designed to address fraud in the context of opioid addiction treatment services. For example, both Utah and California passed legislation aimed at prohibiting the practice of patient brokering. Providers and other healthcare stakeholders — even those not directly involved in addiction treatment — should keep an eye out for similar state law developments in 2020 in addition to monitoring potential changes at the federal level, whether legislative or regulatory.

Federal and state law enforcement bodies also continue to bring charges against individuals across the country for alleged roles in distributing and dispensing medically unnecessary opioids. The Appalachian Regional Prescription Opioid Strike Force (ARPO) has wasted no time in utilizing its cross-agency resources: In April 2019, the group drove one of the largest opioid takedowns yet, resulting in charges against 60 individuals collectively responsible for over 350,000 prescriptions and over 32 million pills. As predicted, the ARPO has focused its resources on its own backyard. Most recently, in September 2019, ARPO announced charges filed against 13 individuals from a four-state area consisting of West Virginia, Tennessee, Ohio, and Alabama.

Similarly, the OIG announced in its Fall 2019 Semiannual Report to Congress that it had coordinated with the Department of Justice to bring charges against 58 people in Texas in connection with their alleged participation in various "pill mill" schemes. Criminal actions against illegal opioid distribution by ARPO and other law enforcement agencies across the country are expected to continue in 2020.

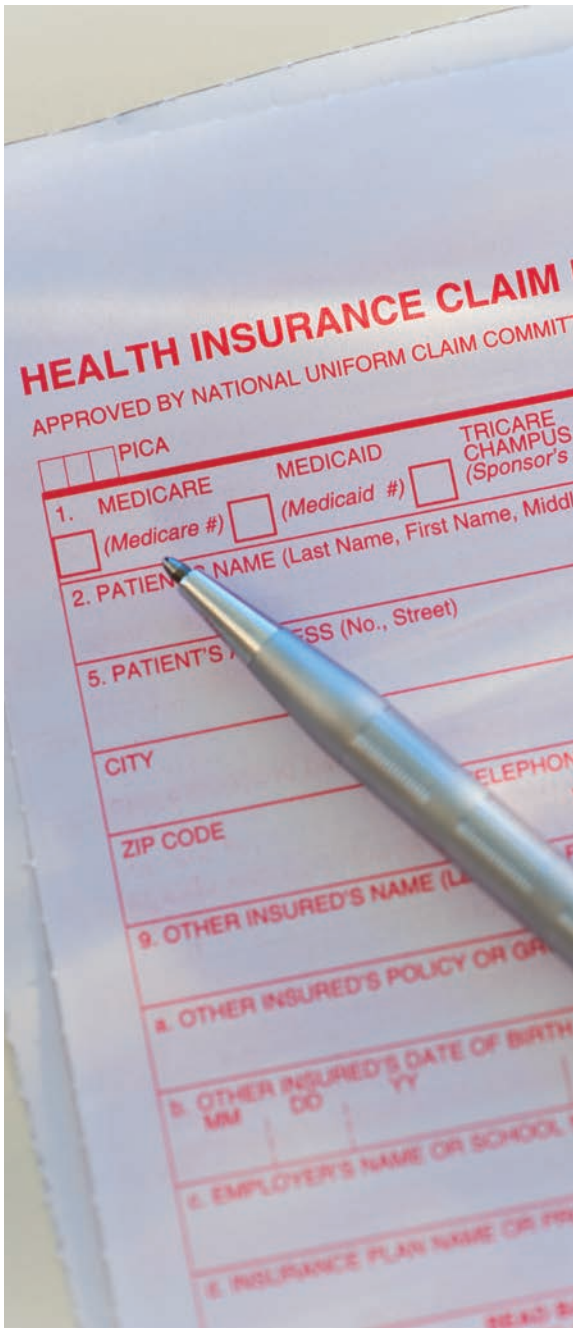
ACA BATTLES ITS WAY INTO A NEW DECADE

ACA HEADS BACK TO THE SUPREME COURT

The Affordable Care Act (ACA) may be celebrating its 10th birthday at the Supreme Court this year. After the Tax Cuts and Jobs Act of 2017 reduced to zero the tax penalty for individuals failing to maintain health insurance (the so-called "individual mandate"), multiple states filed suit in federal district court in Texas challenging the ACA's constitutionality. Several additional states joined as intervenor-defendants, but the DOJ filed a response declining to defend the individual mandate from prosecution. The district court ruled in favor of the plaintiffs, holding that because individual mandate no longer "triggers a tax," the law could no longer be upheld under Congress' tax power. Further, the court noted, because the individual mandate is considered an "essential provision" of the ACA, it is inseverable from the rest of the law. The defendants appealed to the Fifth Circuit, which heard arguments in the case in July 2019.

The Fifth Circuit issued its opinion in December 2019. The Fifth Circuit affirmed the lower court's holding that because the penalty enforcing the individual mandate had dropped to zero, it can no longer be considered a tax — and thereby removed the constitutional justification for the mandate. However, instead of deciding whether this finding invalidates the remainder of the ACA, the Fifth Circuit remanded the severability question back to the district court for further analysis. The plaintiffs appealed the ruling to the Supreme Court in early January of this year with a request that the court speed up its usual timeline in order to hear the case in April or May. If the request is approved by the court, the fate of the ACA could be decided for good before the end of the year.

The Affordable Care Act may be celebrating its 10th birthday at the Supreme Court.



INSURERS WAIT FOR DECISION ON RISK CORRIDOR PAYMENTS UNDER ACA

As the Supreme Court prepares to hear arguments regarding the ACA's fate, commercial insurers await the court's decision in their suit against the federal government for payments under one of its provisions. In December 2019, the court heard arguments in *Maine Community Health Options v. United States* and consolidated cases, which address whether the commercial insurers that offered policies on the ACA's health insurance exchanges are entitled to receive roughly $12 billion in compensation from HHS as part of the risk corridor program intended to incentivize commercial insurers to provide coverage to new populations.

The risk corridor program was designed to encourage insurers to offer individual and group policies on the exchanges by protecting insurers from the risks involved in entering a new market during the first few years of the exchanges' operation. Under the program, insurers that made money on their exchange plans would be required to make payments to the government; those that lost money on their exchange plans would receive payments from the government to lessen the blow. The original provision did not require the program to be budget neutral, and health insurance companies entered the exchanges with the understanding that the risk corridor payments would be paid out pursuant to the published HHS methodology regardless of how much money HHS received through the program. However, over the following years, Congress issued riders during its annual appropriations process requiring the program to be budget neutral, dramatically limiting the funds available to HHS to make the promised pay-outs.

Health insurance companies brought suit against HHS alleging losses of around $12 billion. Some of the health insurance companies who participated in the risk corridor program went bankrupt due to the inability to absorb the lack of payment; several others stopped offering ACA plans or charged significantly higher premiums. The case wound its way to the Federal Circuit, which ruled that HHS did not have to pay the health insurance companies the risk corridor payments as the obligation was suspended by the appropriation riders. The health insurance companies appealed the decision to the Supreme Court.

During oral argument, the insurers framed the issue as "a massive government bait-and-switch" that ultimately had dire consequences for many of the companies that participated in the exchanges. HHS countered that the Constitution's appropriations clause requires an appropriation for the agency to be authorized to draw money from the Treasury; because this authorization was removed by the appropriation riders, the government's hands were tied. Moreover, the agency pointed out, ruling otherwise would create unprecedented liability for the government. A decision is expected sometime this year.

CMS INCREASES PROVIDER REPORTING REQUIREMENTS — AND STRENGTHENS PENALTIES TO MATCH

Providers can look for some big changes to their Medicare enrollment and reporting responsibilities in 2020 and beyond. Last year, CMS published a final rule regarding certain Medicare program integrity enhancements to the provider enrollment process required under the ACA. The rule went into effect on November 4, 2019, but it will require additional roll-out before it impacts all providers. Under the rule, initially enrolling and revalidating providers must disclose any current or previous direct or indirect affiliation with a provider that has certain disclosable events, including any uncollected debt at the time of the disclosure; a payment suspension under a federal healthcare program; an exclusion from Medicare, Medicaid or CHIP; or a Medicare, Medicaid or CHIP billing privileges denial or revocation. Under the new provisions, if CMS determines that any of a provider's affiliations pose an undue risk of fraud, waste, or abuse, CMS may deny a provider's initial enrollment or revoke a provider's existing enrollment.

In light of this significantly expanded reporting requirement, CMS has outlined a phased-in approach. First, the agency will update the Medicare enrollment form to add an affiliation disclosure section, a process that will be subject to notice-and-comment rulemaking. Once the new form is effective, the rule will initially only apply to a subset of providers CMS identifies as holding at least one affiliation with another party with a disclosable event; CMS will then request those providers report at their next revalidation or other enrollment action. CMS estimates this initial phase of reporting-by-request will impact less than 1% of providers in the first several years after the effective date of the rule. A final deadline for the full roll-out has yet to be announced; CMS is seeking comment on how to implement several aspects of the new reporting requirement before it applies to all providers.

The phased roll-out is especially fortunate for providers because the final rule has sharp teeth: It raises the maximum reenrollment bar from three years to 10 years and empowers CMS to impose a maximum 20-year reenrollment bar if the provider has its enrollment revoked for a second time. Additionally, CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to three years if its enrollment application is denied because the applicant submitted false or misleading information on (or omitted information from) its application.

The new rule makes several other noteworthy changes. For one, CMS can deny or revoke a provider's Medicare enrollment if it determines that the provider is revoked under a different name, numerical identifier, or business identity and the applicable reenrollment bar has not expired. If such a determination is made, CMS may add up to three more years to the provider's reenrollment bar. Additionally, CMS may revoke a provider's Medicare enrollment, including all the provider's practice locations — even if they are under different enrollments — if the provider billed for services performed at or items furnished from a location that it knew or reasonably should have known did not comply with Medicare enrollment requirements. Finally, CMS has now made clear that it can pursue revocation for failure to report all information changes, not merely certain changes of information specified in federal regulations.

If CMS determines that any of a provider's affiliations pose an undue risk of fraud, waste, or abuse, it may revoke a provider's enrollment.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AUTHORS AND EDITORS

Travis G. Lloyd
Healthcare Practice Group Leader
Partner, Nashville
tlloyd@bradley.com
615.252.2306

Alicia Adlerz
Associate, Nashville
aadlerz@bradley.com
615.252.3563

Derick Blakely
Associate, Nashville
dblakely@bradley.com
615.252.3857

Justin K. Brown
Associate, Birmingham
jkbrown@bradley.com
205.521.8866

Alé Dalton
Associate, Nashville
adalton@bradley.com
615.252.3593

Elicia Grilley Green
Attorney, Dallas
eggreen@bradley.com
214.257.9764

Jay Hardcastle
Partner, Nashville
jhardcastle@bradley.com
615.252.2386

Judd A. Harwood
Partner, Birmingham
jharwood@bradley.com
205.521.8016

Stephanie M. Hoffmann
Associate, Nashville
shoffmann@bradley.com
615.252.3837

Holly S. Hosford
Associate, Birmingham
hhosford@bradley.com
205.521.8376

Amy S. Leopard
Partner, Nashville
aleopard@bradley.com
615.252.2309

Jordan Stivers Luke
Attorney, Nashville
jluke@bradley.com
615.252.3542

Daniel F. Murphy
Partner, Birmingham
dmurphy@bradley.com
205.521.8017

Janus Pan
Associate, Nashville
jpan@bradley.com
615.252.3810

John M. Perry Jr.
Partner, Nashville
jperry@bradley.com
615.252.2308

Brad Robertson
Partner, Birmingham
brobertson@bradley.com
205.521.8188

Wendi Rogaliner
Partner, Dallas
wrogaliner@bradley.com
214.257.9841

Scott Schardt
Counsel, Dallas
sschardt@bradley.com
214.939.8774

Sarah Staples
Associate, Nashville
sstaples@bradley.com
615.252.2394

Rachel E. Taylor
Associate, Nashville
retaylor@bradley.com
615.252.3824