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2018

THE HEALTH LAW YEAR IN REVIEW

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Editor's Note: *The following information was originally prepared in January 2019 as a review of important healthcare developments from 2018. It is not intended to constitute legal advice.*

CHANGES & CHALLENGES

Each year brings significant changes and challenges in the laws governing the healthcare industry, and 2018 proved to be no exception. The Department of Health and Human Services (HHS) signaled new directions in a number of areas, including a bundle of requests for comments regarding regulatory reform dubbed the "Regulatory Sprint to Coordinated Care," as well as several key changes in payment policy. The year also included significant developments in False Claims Act (FCA) litigation as well as Department of Justice (DOJ) policy regarding healthcare fraud enforcement. In addition, the opioid crisis gave rise to several noteworthy legal developments and promises more in 2019. And, yet again, as the year ended, the fate of the Affordable Care Act (ACA) hung in the balance.

In an effort to take stock of the year that was and 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 our Healthcare Practice Group.

ACA BATTLES THROUGH ANOTHER YEAR

After a tough 2017, the ACA faced challenges from all sides in 2018. Legislative and executive changes to the law's administration and enforcement took root over the course of the year, and in December, a federal court struck down the entire law as unconstitutional, embroiling 37 states in a challenge that likely heralds the ACA's return to the Supreme Court.

2017 TAX LAW STRIKES INSURANCE REQUIREMENT

Congress' Tax Cuts and Jobs Act of 2017 (the 2017 Tax Law) helped set the tone for reduced enforcement of the ACA in 2018 and guarantees that trajectory will continue into 2019. One of the central components of the ACA is its requirement that all individuals hold health insurance, a requirement known as the "individual mandate." Under the law, individuals must certify on their annual tax filing that they held insurance throughout the prior year or be subject to a "shared responsibility payment"—that is, a tax penalty. Among other provisions, the 2017 Tax Law slashes the shared responsibility payment amount to zero. Effective January 1, 2019, the move simultaneously nullifies the ACA's most potent enforcement mechanism and removes one of its essential revenue streams.

ACA HEADS BACK TO COURT

The 2017 Tax Law's elimination of the penalty also set the stage for a direct challenge to the Supreme Court's 2012 decision in *NFIB v. Sebelius*, in which the Supreme Court famously held the individual mandate constitutional—but only as an exercise of Congress' tax power. In a five-to-four split, the court held the ACA could not be upheld under the interstate commerce clause (on the grounds that the law compelled commerce rather than regulated it), but that, because the penalty was imposed through a tax penalty, it could be upheld under the tax power; the individual mandate—and the ACA itself—was saved. The Supreme Court's determination that the mandate was a tax was based on several factors, but relied heavily on the fact that it produces revenue for the government.

However, with the revenue-generating provision effectively terminating in 2019, the door to challenge *Sebelius* was open. In February 2018, 18 states and the governors of Maine and Mississippi filed suit challenging the ACA's constitutionality in a federal district court in Texas. In April, 16 states and the District of Columbia joined as intervenor-defendants. And, in June, the DOJ filed a response declining to defend the individual mandate and select other provisions of the ACA from prosecution.

The DOJ's move was unusual, but not entirely unexpected. It is the role of the DOJ to defend federal law on behalf of the federal government when laws are challenged in court. However, last year, the Trump administration issued statements, policies, and even executive orders stating it would neither enforce nor defend the ACA. While the administration argued that both the individual mandate and the law's prohibition against denial of pre-existing conditions were unconstitutional, the DOJ ultimately took a more moderate position in its filing, arguing that the mandate should be struck down and the rest of the law should remain intact. To date, two lawsuits have been brought against the Trump administration for its failure to defend the ACA.

After considering the challenge, Judge Reed O'Connor of the Northern District of Texas held in favor of the plaintiffs, ruling that because the individual mandate no longer "triggered 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. In a dramatic ruling on December 14, 2018, the court held that since the individual mandate is inseverable, the entire law must be struck down. Of note, although the judge struck down the ACA, he did not enjoin it, meaning the law is still in effect. Seventeen attorneys general have already filed notice of appeal to the Fifth Circuit, promising to keep the fight going in 2019.

FIGHT TO END THE OPIOID EPIDEMIC INTENSIFIES

Efforts to combat the nationwide opioid crisis continued in 2018 with the implementation of new enforcement mechanisms and a proliferation of opioid-related court battles. In October, President Trump signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment Support for Patient and Communities Act (the SUPPORT Act), a collection of individual acts related to fighting the ongoing opioid crisis.

One of these acts, the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), prohibits remuneration in exchange for referrals of patients to a recovery home, clinical treatment facility, or laboratory. EKRA applies to all "healthcare benefit programs," including commercial insurance plans, and has been described as an "all-payor" anti-kickback provision. However, EKRA does not apply to conduct already prohibited by the Anti-Kickback Statute. It also contains several exceptions, including for conduct meeting the requirements of the personal services and management contracts safe harbor to the Anti-Kickback Statute, good faith, non-routine waivers of patient coinsurance or co-payments, and discounts obtained by providers under a healthcare benefit program if properly disclosed and reflected in the costs claimed or charges made by the provider. Though aimed at combatting fraud in the context of opioid addiction treatment services, EKRA's prohibition is broad and may impact many common financial arrangements, particularly in the lab industry. It remains to be seen whether the DOJ will promulgate rules to implement the law.

Also in October, the DOJ Criminal Division announced the creation of the Appalachian Regional Prescription Opioid Strike Force (the ARPO Strike Force). The ARPO Strike Force will investigate healthcare fraud and prosecute the illegal prescription and distribution of opioids throughout the region by uniting the resources of several agencies, including the DOJ's Healthcare Fraud Unit, the FBI, the OIG, the DEA, and the U.S. Attorney's Offices of nine federal districts. The ARPO Strike Force will have hubs in Cincinnati and Nashville, and is likely to result in increased scrutiny of healthcare providers in the region.

2018 also saw the continuation of massive multidistrict litigation in the Northern District of Ohio before U.S. District Judge Dan Polster. The litigation is the result of a late 2017 consolidation of hundreds of cases from across the country involving allegations against various players in the opioid supply chain of improperly marketing opioid medications and failing to monitor and report suspicious orders of prescription opiates. Similar litigation is pending in courts across the country as all look for a resolution and end to the opioid epidemic.

CMS AND OIG WEIGH FRAUD AND ABUSE REFORM

For several years, the chorus of healthcare industry participants calling for the reform of fraud and abuse laws to accommodate the transition to value-based reimbursement systems has grown ever louder. From the outset of the current shift away from fee-for-service reimbursement (catalyzed by the ACA), stakeholders have pointed out the incompatibility of existing fraud and abuse laws with the types of care coordination required to drive value-based care delivery.

The clearest evidence that fraud and abuse laws have failed to keep pace with developing payment models has been the necessity for the Centers for Medicare & Medicaid Services (CMS) and the HHS Office of Inspector General (OIG) to issue waivers of the keystone federal fraud and abuse laws—the Stark Law, Anti-Kickback Statute, and Civil Monetary Penalties Law (CMP Law)—in connection with major integrated payor delivery models, such as ACOs. By issuing these fraud and abuse waivers, CMS and OIG have effectively recognized that succeeding under some transformative value-based care initiatives requires waiving enforcement of existing laws.

During the summer of 2018, rising industry clamor met with sympathetic ears in the Trump administration, which has aggressively sought to loosen regulations in a number of sectors. On June 25, 2018, CMS issued a request for information (RFI) concerning Stark Law regulatory reform with a goal of "reducing regulatory burden and dismantling barriers to value-based care transformation, while also protecting the Medicare program." The OIG followed suit on August 27, 2018, with an RFI concerning the Anti-Kickback Statute and CMP Law seeking suggestions for how to "foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse."

Hundreds of stakeholders submitted responses to the RFIs, many of which featured a shared focus on creating an overarching Stark exception and Anti-Kickback Statute safe harbor applicable to coordinated or integrated care organizations. Healthcare industry participants will closely watch the results of the fraud and abuse regulatory reform agenda heralded by the RFIs. While CMS and OIG have not issued any proposed rules as a result of the RFIs to date, HHS has framed the effort as a matter of some urgency, going so far as to brand the initiative the "Regulatory Sprint to Coordinated Care."

FALSE CLAIMS ACT REMAINS THE GOVERNMENT'S PRIMARY TOOL FOR HEALTHCARE ENFORCEMENT

Though the DOJ's total recoveries from FCA prosecutions fell in 2018, its recoveries from the healthcare industry increased—up to $2.5 billion from $2.1 billion last fiscal year. The year also saw several developments in FCA interpretation and enforcement, including new case law on the issue of materiality, a pair of new DOJ memos revealing the agency's evolving policies on overseeing and prosecuting FCA cases, and a new focus on cases against Medicare Advantage Plans.

MATERIALITY REMAINS A HOT TOPIC

In January, the Middle District of Florida overturned a $350 million jury verdict against the owners and operators of 53 specialized nursing facilities in *U.S. ex rel. Ruckh v. Salus Rehabilitation, LLC*. In the case, the relator alleged that, because the facilities failed to maintain a care plan and did not keep sufficiently detailed records, the defendants had billed Medicare for therapy that was never actually provided. A jury returned a verdict against the defendants, but the judge vacated the judgment on *Escobar* materiality grounds and ordered a new trial, noting that "[t]he evidence shows not a single threat of non-payment, not a single complaint or demand, and not a single resort to an administrative remedy or other sanction for the same practices."

The court held that, once the government's knowledge is demonstrated, a relator must submit proof of an affirmative action by the government to deter the practices in order to prove materiality. Mere "leniency or tolerance or indifference or perhaps [] resignation" by the government is insufficient. Evidence of how the government "behaved in comparable circumstances" is required to justify a jury verdict, and counterevidence by defendants that the government continued to make payment despite knowledge of the disputed practices is damning to an FCA case.

The relator's appeal of the order is currently pending before the Eleventh Circuit. In June, the Sixth Circuit revived, for a second time, *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.,* in which the DOJ alleged that a senior living company committed fraud when it failed to disclose that it had been late in obtaining required physician signatures for home health services it provided due to a paperwork backlog. The court held that the relator had sufficiently alleged that the delayed signatures were material to the government's payment decision, finding that the timing of the physician's signature went to the "essence of the bargain" between Brookdale and the government because the *timing* requirement was designed to help combat fraud. Though the relator had not alleged that the government had ever denied payment based on the timing of the physician's certification, the Sixth Circuit found that the lower court incorrectly used that fact to infer that the signature timing was immaterial to payment. The court's decision was two to one with a vigorous dissent; the defendants have petitioned the Supreme Court for certiorari.

"GRANSTON MEMO" PROVIDES FACTORS FOR DOJ TO CONSIDER MOVING TO DISMISS FCA ACTIONS

On January 24, 2018, an internal DOJ memorandum was leaked to the public that discussed the factors the agency will consider in determining whether to seek dismissal of non-intervened *qui tam* suits. The FCA authorizes the attorney general to dismiss *qui tam* actions over a whistleblower's objection, but historically DOJ has rarely done so. The memo represents DOJ's first formal articulation of guidance to prosecutors regarding when such dismissals might be appropriate.

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.

In the wake of the Granston Memo, DOJ has increased its use of motions to dismiss *qui tam* complaints. In November, the DOJ moved to dismiss *U.S. ex rel. Vanderlan v. Jackson HMA, Inc.* on grounds that the claims "lack merit" and the suit is "hindering

administrative settlement negotiations" between OIG and the defendants. In December, the DOJ moved to dismiss 10 kickback-related *qui tam* complaints filed against various pharmaceutical companies, stating that the relator has no inside knowledge, investigation has not found support for its allegations, and the allegations "conflict with important policy and enforcement prerogatives of the federal government's healthcare programs" in that the claims would "undermine common industry practices the federal government has determined are… appropriate and beneficial[.]"

Also in December, the solicitor general told the Supreme Court that if the *Gilead Sciences, Inc. v. United States ex rel. Campie* case were remanded back to the district court, the government would move to dismiss it to avoid "impinge[ment] on agency decisionmaking and discretion" and burdensome discovery and interference with government operations.

"BRAND MEMO" SAYS AGENCY GUIDANCE IS NOT BINDING IN AFFIRMATIVE CIVIL ENFORCEMENT CASES

The day following the Granston Memo leak, the DOJ issued additional significant FCA guidance in the Brand Memo, which states that the DOJ will no longer use "guidance documents" in civil enforcement cases such as FCA lawsuits. The change has particular resonance in healthcare, where National and Local Coverage Determinations by Medicare contractors were often asserted to have the force of law in FCA negotiations. While the Brand Memo carved out several exceptions for the appropriate use of informal guidance documents, it nonetheless ushered in a significant change by removing their binding effect. According to the DOJ's Justice Manual, prosecutors may continue to use a party's compliance or noncompliance with agency guidance as (1) evidence of the party's intent, notice, or knowledge, (2) evidence of whether the party has satisfied, or failed to satisfy, professional or industry standards, and (3) evidence directly relevant to the particular claims at issue in the lawsuit.

FCA CASES SPOTLIGHT MEDICARE ADVANTAGE PLANS

The DOJ exhibited a new focus on Medicare Advantage plans in 2018, resulting in several FCA opinions ruling on motions to dismiss. Because government payment under Medicare Advantage is structured differently than payment under Medicare Parts A and B, the government and relators have had to test out new theories of FCA liability in this area. With Medicare Advantage plans, the government shifts the risk of funding healthcare services onto private plans by paying a capitated rate to the plan to provide whatever care its enrollees need.

That capitated rate can be adjusted based upon the enrollees' "risk adjustment data," which reflects several factors, including the individuals' medical diagnoses. The government and relators had some initial success in 2018 in defeating motions to dismiss with allegations that providing unsupported diagnosis data to the government to increase risk adjustment payments violates the FCA. However, they were not successful in maintaining actions based on allegations that risk adjustment attestations were false certifications or that free, in-home physician examinations inflated payments by identifying additional diagnoses.

MEDICARE PAYMENT POLICY CONTINUES TO EVOLVE

Although the year was not filled with seismic shifts in Medicare payment policy, there were some significant developments, including important rulemaking activity, as well as several consequential lawsuits challenging payment cuts. The year ahead will no doubt include interesting developments in this area, including the refinement of value-based payment models and the resolution of lawsuits challenging cuts to the 340B program and to hospitals for certain outpatient services.

CMS ADOPTS SIGNIFICANT CHANGES TO ITS "SITE NEUTRAL" HOSPITAL OUTPATIENT PAYMENT POLICY

In its CY 2019 Outpatient Prospective Payment System (OPPS) final rule, CMS took yet another step in furtherance of the site-neutral payment provisions introduced in the Bipartisan Budget Act of 2015 (BBA). The final rule reduces payments for "clinic visits" provided in grandfathered off-campus hospital outpatient departments.

The cuts are intended to lower payments for evaluation and management visits furnished in grandfathered off-campus hospital departments to the rate for such services when rendered in non-grandfathered departments. Once fully implemented, this change is estimated to reduce OPPS payments to hospitals by 1.2 percent. The final rule also extends payment reductions for 340B-acquired drugs and biologicals that previously applied only to grandfathered off-campus departments to non-grandfathered departments. In addition, CMS announced its intent to collect data related to services furnished by off-campus, provider-based emergency departments. The announcement may well signal future limitations on payments to so-called "freestanding emergency departments" that are affiliated with hospitals.

Importantly, CMS did not finalize a proposal made earlier in the year to limit full OPPS payment to grandfathered sites only where the services rendered were in the same "clinical family of services" that the particular location had provided and billed for prior to November 2, 2015, the date the BBA was signed into law. Nevertheless, the fact that CMS proposed the limitation in this CY 2019 rulemaking cycle after doing so a couple years ago reveals continued interest in the issue.

These payment policy changes drew a swift negative reaction from many hospitals and their trade associations. In December, the American Hospital Association, along with the Association of American Medical Colleges and several member hospitals, filed a lawsuit against HHS for finalizing the policy of reducing payments for clinic visits rendered in grandfathered departments. The lawsuit asserts that, in doing so, CMS acted in violation of the Medicare statute's mandate of budget neutrality and that the clinic visit policy violates the statutory mandate that grandfathered and non-grandfathered hospital outpatient departments not be treated differently.

CMS FINALIZES REDESIGN OF MEDICARE SHARED SAVINGS PROGRAM

On December 31, 2018, CMS published its final rule setting forth a redesign of the Medicare Shared Savings Program (MSSP). The final rule, titled "Pathways to Success," requires ACOs participating in the MSSP to transition more quickly to two-sided models wherein ACOs are eligible to receive shared savings but are also responsible for shared losses. Prior to the changes contained in the final rule, ACOs were able to participate in the MSSP for a longer period under one-sided models, in which they are eligible for shared savings but are not at risk for losses. After analyzing MSSP data from the program's start in 2012, CMS concluded that ACOs improve quality of care and lower costs when they participate in two-sided models.

In the final rule, CMS replaces the MSSP's existing Tracks 1, 1+, 2, and 3 with two new tracks, "BASIC" and "ENHANCED." The BASIC track replaces Tracks 1, 1+, and 2, while the ENHANCED track replaces Track 3. The BASIC track contains five participation "levels" and offers ACOs a "glide path" to progress from the one-sided models to models with higher risks and rewards during the MSSP's new five-year agreement period. The ENHANCED track is a two-sided model for ACOs to take on the highest level of risks and rewards. Generally, ACOs in the BASIC track will advance to the next level each year; CMS anticipates that all ACOs will eventually participate in the ENHANCED track. Each level within the BASIC and ENHANCED tracks contains a different shared savings and shared loss rate, and an ACO's options for selecting between the BASIC and ENHANCED tracks – and the levels within those tracks – are determined by the ACO's revenue size and experience level.

In addition to establishing the new MSSP tracks, CMS finalizes other changes to the MSSP regarding beneficiary assignment and engagement, the repayment terms for ACOs participating in two-sided models, the methodology for determining the benchmark of Medicare expenditures, and changes to ACO eligibility for Alternative Payment Model bonuses and Merit-Based Incentive Payment System reporting requirements. The final rule also increases payments for telehealth services, further promotes interoperability among ACO providers and suppliers, and expands eligibility for ACOs to apply for a SNF three-day rule waiver. CMS is offering a one-time, six-month MSSP agreement period start date of July 1, 2019, and will resume the usual annual application cycle for five-year agreement periods starting on January 1, 2020, and each January 1 thereafter.

HEALTH IT DEVELOPMENTS CONTINUE APACE

ONC RELEASES DRAFT PLAN TO REDUCE REGULATORY AND ADMINISTRATIVE BURDENS OF HEALTH IT

Thanks in no small part to government incentives to adopt and utilize health IT, the use of electronic health records (EHRs) is now widespread in the healthcare industry. While EHRs have several advantages over paper records, many providers are frustrated at the time spent on data entry and tasks necessary to comply with regulatory requirements, which leaves less time to interact with patients.

Congress recognized this issue in 2016, when it passed the 21st Century Cures Act and directed HHS to develop a strategy to reduce EHR-related burdens that affect patient care. This past November, the HHS Office of the National Coordinator for Health Information Technology (ONC), in partnership with CMS, released a high-level strategy document entitled "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs." The draft outlines three goals intended to alleviate clinician burden:

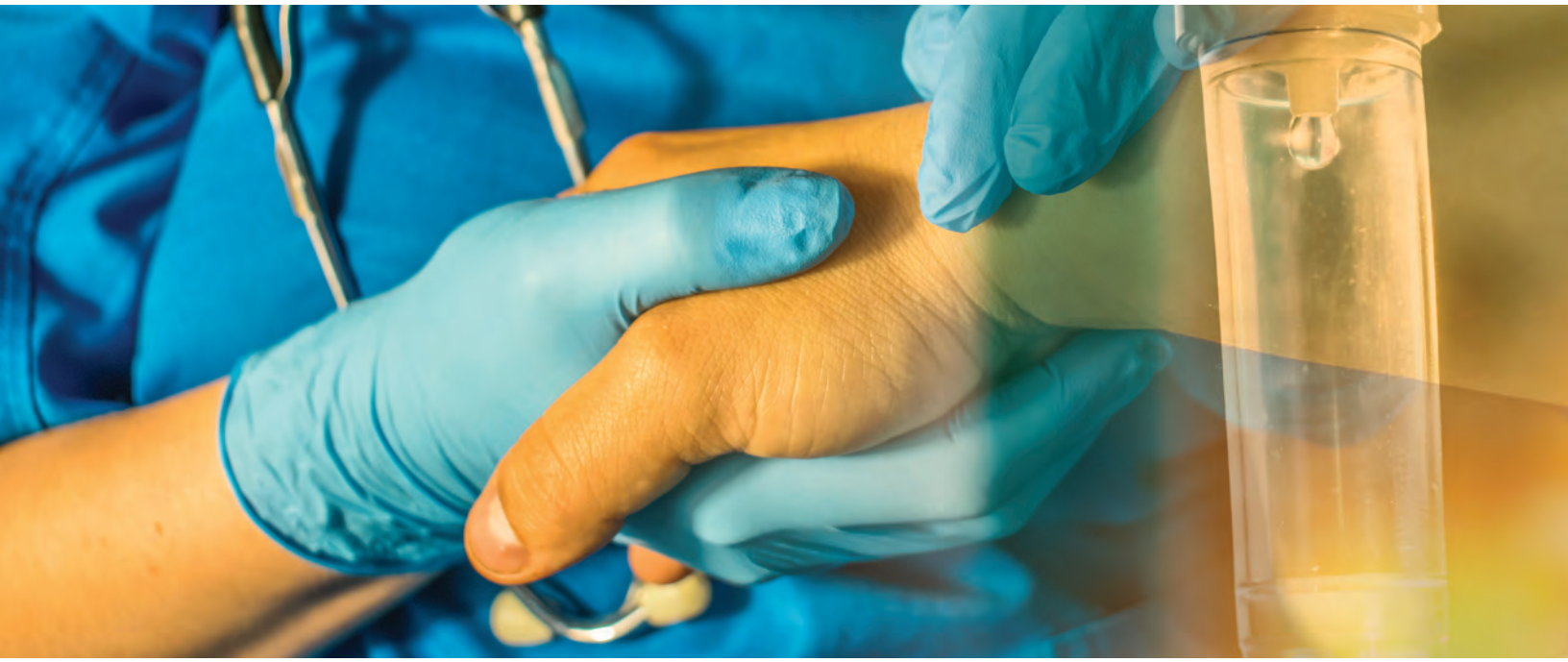
1. Reduce the effort and time required to record health information in EHRs for clinicians;
2. Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and
3. Improve the functionality and intuitiveness of EHRs.

A final version is expected in late 2019.

LARGEST HIPAA SETTLEMENT TO DATE

Also this year, the HHS Office for Civil Rights (OCR) announced that Anthem would pay $16 million and enter a robust corrective action plan to settle potential violations of the HIPAA Privacy and Security Rules. This settlement is the largest to date for a HIPAA violation—almost three times the next-largest penalty ever assessed by the HIPAA watchdog. Anthem was investigated by OCR after news reports indicated that it had experienced a sophisticated cyberattack. Anthem notified OCR that hackers had gained access to the electronic protected health information (ePHI) of over 78 million individuals, the largest health data breach in U.S. history. OCR's investigation found that, besides the impermissible disclosure of ePHI, Anthem failed to conduct an enterprise-wide risk analysis, to properly review and monitor information system activity, to identify and respond to suspected or known security incidents, or to implement adequate minimum access controls to prevent improper access to ePHI.

The settlement highlights a number of issues for covered entities and their business associates. First, due to the amount and sensitive nature of ePHI maintained, healthcare entities are targeted frequently and persistently by cyber criminals. Second, entities with numerous employees, subsidiaries, locations, and lines of business need to have processes in place to regularly audit and monitor activity in information systems to detect unauthorized access, unusual or suspicious activity, and exfiltration of ePHI. Third, entities should have controls in place to authorize and permit only role-based access to the information system. Lastly, security awareness training is important to prevent network access since phishing emails are a common way that cyber criminals gain access.



We anticipate OCR will continue the aggressive enforcement trend evident in 2018 when entities fail to complete a proper security risk analysis or manage identified security risks that materialize (such as portable media, software updates, backup and contingency planning, lack of auditing, and compliant business associate agreements), especially when there is a nexus to a breach required to be reported to OCR.

HIPAA REQUEST FOR INFORMATION REGARDING CARE COORDINATION

Following its annual security conference in October, OCR issued an RFI seeking public comment on how its rules could be revised to promote care coordination among providers—a request that falls within the ambit of HHS's broader Regulatory Sprint to Coordinated Care. OCR seeks input on how the HIPAA Privacy Rule in particular may impede information sharing for treatment, case management, and care coordination purposes.

At the annual security conference, OCR Director Roger Severino noted that the agency will consider requiring covered entities to timely transfer protected health information to other covered entities for these or other purposes and excepting these disclosures from the minimum necessary standard. Look for rulemaking in this space and the potential for burden reduction on the HIPAA notice of privacy practices, as well as the final HIPAA accounting of disclosures rules, in 2019.

OCR CYBERSECURITY GUIDANCE

OCR closed out the year by providing guidance and tools to the healthcare industry to manage cybersecurity risks. The OCR Cybersecurity Guidance is a multi-volume compendium of resources tailored to the size and scope of risks entities face. The materials identify and prioritize threats facing the industry and suggest practices for dealing with those threats by organization size.

While the OCR Cybersecurity Guidance is not binding on the industry, it both provides practical assistance to covered entities and sets expectations for the types of measures and safeguards that OCR believes these risks warrant. We expect to see continued debate in 2019 regarding industry best practices—debate that could lead to an enhanced standard of care for data security in future HIPAA and FTC enforcement actions and data breach lawsuits.

OUR TEAM

Bradley's Healthcare Practice Group is a nationally recognized, interdisciplinary team of attorneys and advisors who provide a comprehensive suite of services to virtually the entire range of health industry participants. Our Healthcare Practice Group is routinely relied on to guide major transactions, advise on complex regulatory matters, and handle high-stakes litigation. Many of the group's attorneys have served in high-profile industry leadership positions, including as president of the American Health Lawyers Association, and many have been recognized by leading legal industry referral guides, including *Chambers, The Best Lawyers in America®,* and *Super Lawyers.*

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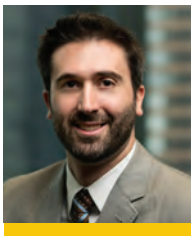

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