McGUIREWOODS

Healthcare Headaches: 8 Key Legal Issues Facing General Counsel Offices in 2022

TABLE OF CONTENTS

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Without a doubt, the past few years have been exceptionally challenging for healthcare organizations. Health systems and providers have demonstrated remarkable resilience in responding to the challenges of COVID-19, and their leaders have adeptly navigated new legal requirements and temporary flexibilities. Now, as we prepare to exit the public health emergency, the challenges continue. Regulatory flexibilities that enabled new care delivery models may terminate, labor and supply costs are up, revenues are down, vaccine and provider-relief fund demands persist, and government enforcement seems to be heating up in many key areas. Additionally, disruption and private equity investment across the industry is impacting traditional business models. As organizations seek to adapt to these changes, evaluate opportunities to drive health equity, comply with price transparency and other CMS mandates, and implement growth strategies, there is an expanding number of issues bring tracked by healthcare counsel. Here, we provide a quick look at eight of the key issues at top of mind for our clients.

COVID-19 VACCINE STAFF MANDATES REMAIN IN EFFECT

Timothy Fry, Stephanie Kennan, Rebecca Rieckhoff

As variants wane and life generally gets back to normal without most pandemic-related safeguards, it is easy to lose sight of the fact that the Centers for Medicare & Medicaid Services' (CMS) interim final rule continues to require many Medicare- and Medicaid-certified providers and suppliers to vaccinate their entire staff against COVID-19. After the Supreme Court permitted CMS to enforce its rule while staying (or prohibiting) the separate COVID-related masking and vaccine rule (ETS) issued by the Occupational Safety and Health Administration (OSHA), CMS enforcement has begun across the whole country through surveyor/accreditation processes. For hospitals, particularly, this enforcement creates significant risk as CMS has noted its sole enforcement remedy for non-compliance for such "acute and continuing care providers is termination" from the Medicare and Medicaid programs, although its "primary goal is to bring health care facilities into compliance."

At this point across the entire nation, CMS' interim final rule requires that all facility staff (broadly defined to include all employees other than those solely working remotely and any individuals that provide patient care including medical staff members and volunteers, and not just paid employees) be fully vaccinated against COVID-19. Fully vaccinated means that it has been two weeks or more since the relevant staff member received two doses of Pfizer or Moderna-made vaccines or one dose of the Johnson & Johnson vaccine. Only staff members that are eligible for limited exemptions due to applicable federal law (i.e., based on disability or medical condition contraindicating vaccines required by the Americans with Disabilities Act, or sincerely held religious beliefs, practice or observance required by Title VII of the Civil Rights Act of 1964) or who fall under the CDC's recommendation of delaying vaccination due to clinical precautions caused by an earlier COVID illness may continue to work for a hospital without full vaccination. Such requirements are not only for current staff members but also all new hires.

Affected providers and suppliers must establish policies and procedures ensuring: (a) all eligible staff have received vaccinations, absent an exception, (b) added precautions intended to mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated, (c) the organization tracks and securely documents COVID-19 vaccine status of all staff, including boosters recommended by the CDC (even though the CMS rule does not, at this time, mandate such boosters), and (d) an exemption process based on applicable federal law, along with a system to track and securely document those that were granted such exemptions, among other requirements. Further, while CMS does not require vaccine boosters, some state and local vaccine requirements may require such boosters; general counsel offices should ensure they know and follow their state and local vaccine mandates, if any, in addition to the CMS rule. Surveyors will

request this information in subsequent inspections (other than those that were solely life and safety code complaints), which will require health systems to have this information ready before the inspector arrives. If your system has not fully implemented these protocols today, you should prepare now. In addition, human resources departments will want to include requests for information on vaccination status or a viable exemption during the hiring process, with a process that considers various federal discrimination rules.

Meanwhile, despite the Supreme Court stay of the ETS, OSHA continues to explore rulemaking for healthcare providers. OSHA held hearings April 27 through May 2, 2022, and allowed additional comments from the public through May 23, 2022, to finalize rulemaking to protect healthcare and healthcare support service workers from occupational exposure to COVID-19 in settings where people with COVID-19 are reasonably expected to be present. Such rulemaking would apply in non-CMS facilities as well and suggests the Biden administration continues to seek regulatory avenues to fight the COVID-19 pandemic. Many health systems have faced difficulty in employing staff members and have concerns that the vaccine mandate would lead staff to seek other healthcare providers not subject to such mandates. The OSHA efforts may provide some relief to those systems if it enforces more widespread vaccine/COVID-19 mitigation efforts for healthcare staff not subject to the CMS mandate (such as physician organizations). However, other general counsel offices will surely be concerned that the sustained uncertainty created by ongoing rulemaking followed by court review will continue to make it difficult to plan and recruit during the COVID-19 public health emergency (PHE).

Additional Resources:

- CMS Vaccine Mandate Enforcement Begins — Understanding the Three Deadlines
- Supreme Court Upholds CMS Vaccine Mandate: Next Steps for Healthcare Providers
- Takeaways From New CMS Interim Rule Requiring COVID-19 Vaccination for Healthcare Providers and Suppliers

FOUR KEY CONSIDERATIONS WHEN DECIDING BETWEEN TAX-EXEMPT AND TAXABLE BONDS

Kay McNab, T.W. Bruno, Lisa Medina Williams

The Internal Revenue Code of 1986, as amended (the Code), permits nonprofit organizations that are 501(c)(3) organizations to utilize tax-exempt financing for capital improvement projects. The Code and the regulations promulgated thereunder contain several requirements that must be satisfied before and after the issuance of tax-exempt bonds. These requirements include, by way of example and not limitation, the requirement that the borrower maintain its status as an organization described in Section 501(c)(3) of the Code, restrictions on the use, expenditure and investment of the proceeds of the tax-exempt bonds and the use of the property financed by the tax-exempt bonds, limitations on the source of the payment of and the security for the tax-exempt bonds, and the obligation to rebate certain excess earnings on the gross proceeds of the tax-exempt bonds to the United States Treasury.

Generally, tax-exempt bonds bear interest rates that are lower than taxable debt because investors are willing to accept a lower interest rate on tax-exempt bonds as, generally, investors do not pay federal income tax on the interest earned on tax-exempt bonds. Although a hospital or hospital system is a qualified 501(c)(3) organization, the decision to issue debt on a tax-exempt or a taxable basis is not purely an economic decision. The following are some considerations that should be given when deciding to issue debt on a tax-exempt or taxable basis:

- ***How fast does the hospital or hospital system need funds?*** While a 501(c)(3) organization may access the tax-exempt market, it can only do so by going through a state or local governmental issuer. Section 147 of the Code governs the public approval process for the issuance of 501(c)(3) tax-exempt bonds and gives the public an opportunity to provide input before such tax-exempt bond is issued. This process generally requires a public hearing, approvals by the governmental unit that is serving as the issuer for the tax-exempt bonds and approval by the governmental unit having jurisdiction over the area in which the project is located. This public approval process can be time consuming and is dependent on the meeting schedule of one or more governing bodies that may or may not meet on a regular basis.

However, taxable debt of a 501(c)(3) organization may not have a governmental unit involved and is not subject to this public approval process. The requisite corporate approvals of the 501(c)(3) organization are typically all that is required. Therefore, consideration should be given to the time frame in which the public approval process will take if funds are needed quickly.

- ***Does your hospital system need to finance projects in multiple jurisdictions?*** As mentioned above, the public approval process requires the approval of each governmental unit having jurisdiction over the area in which the project is located. Therefore, if a hospital system is looking to issue debt to finance projects in multiple jurisdictions, the public approval process may require engaging with more governmental units and holding multiple public hearings. This process can become costly and time consuming depending on the number of jurisdictions.

- ***Does your hospital need to finance certain working capital costs?*** Since the onset of the COVID-19 pandemic more hospitals and hospital systems have been issuing debt (or at least considering such issuance) to finance working capital expenses or to have guaranteed liquidity in a volatile financial market. While the Code permits the issuance of tax-exempt bonds for working capital expenditures, these financings are limited and the requirements are difficult to satisfy. However, taxable financings are only limited by the requirements of the lender providing the funds. Therefore, most hospitals or hospitals systems opt to issue taxable debt for the purpose of financing their working capital needs.

- ***Can our hospital issue debt on a taxable basis now and refund the debt on a tax-exempt basis later?*** The short answer: maybe. Hospitals or hospital systems that are considering issuing debt on a taxable basis should still consider whether they may want to refund such debt on a tax-exempt basis in the future. This strategy has been used now that the 2017 Tax Cuts and Jobs Act prohibited the issuance of tax-exempt bonds for advance refunding transactions. Such an approach requires care and health systems will likely want to engage bond counsel in advance to determine the intended use of the proceeds and whether there is an opportunity to refund such debt on a tax-exempt basis in the future. If there is an opportunity to preserve this ability, management will need to keep good records regarding the expenditures financed with the taxable debt as an analysis will need to be done at the time of the issuance of the tax-exempt debt for bond counsel to deliver its bond counsel opinion on the tax-status of the bonds.

THE CMS ACUTE HOSPITAL CARE AT HOME PROGRAM AND THE FUTURE OF ADVANCED CARE AT HOME MODELS

Kristen McDermott Woodrum, Kristen Chang

The COVID-19 pandemic catalyzed the evolution of healthcare delivery models and thrust acute hospital care at home from relative obscurity to the forefront of current health policy discussions. To address hospital capacity and infection control concerns, CMS introduced the Acute Hospital Care at Home Program (HaH Program) in November 2020 as an expansion of its Hospital without Walls initiative launched in March 2020. The HaH Program allows approved hospitals to provide hospital acute care services outside the traditional hospital setting and within a patient's home for the duration of the public health emergency (PHE). As of June 1, 2022, 237 hospitals within 103 health systems are approved to provide acute hospital care at home services.

Given the widespread adoption of this model, and massive investments to launch these programs, the healthcare industry is focused on how this care model may continue at the conclusion of the PHE when the current HaH Program waivers expire. This article provides a brief overview of the care model and developments that could impact its future viability.

Overview

Health systems worldwide have been experimenting with acute care at home models for decades. In 1995, researchers at Johns Hopkins University Schools of Medicine and Public Health developed Hospital at Home® as an innovative way to manage the acute care needs of older patients. While a number of promising pilots and national demonstrations were conducted, including a 2014 "HaH-Plus" study by the Icahn School of Medicine at Mount Sinai Medical Center, which was funded by a Centers for Medicare and Medicaid Innovation (CMMI) grant, the model was not expanded. The HaH-Plus study focused on a possible 30-day bundled payment rate for services, with a goal of increasing quality of care and reducing costs. In reviewing the proposal, the Physician Focused Payment Model Technical Advisory Committee (PTAC) concluded that it held promise, satisfying 9 out of 10 criteria established by the Department of Health and Human Services (DHHS), but required stronger safeguards for patient safety and incentives for quality. Though services were not covered by traditional fee-for-service Medicare, some health systems within the United States piloted programs for acute home care. Participation centered on integrated systems with health plans that could design payment models and risk-bearing entities. As technology for telehealth and remote monitoring improved, companies such as Contessa and Medically Home Group emerged to partner with providers and payers, offering technology platforms, evidence-based protocols and supply chains support for clinical and non-clinical services. Significant investment activities in such companies and health system programs have occurred in the past two years.

The structure of programs operating under the "HaH Program" varies by participant, based on the patient population and health care system needs, but most include in-person nursing visits, remote monitoring and other telehealth services. Additionally, pharmacy and infusion, laboratory, diagnostic imaging, and physical therapy and other services may be provided in the patient's home. The list of clinical conditions appropriate for services is expansive, but some providers limit their programs to specific treatments or disease conditions (*i.e.*, treating and monitoring those with lingering COVID-19 symptoms or caring for patients with diseases that have well-defined treatment protocols such as chronic obstructive pulmonary disease or congestive heart failure). Certain providers include holistic care that may include screens for social isolation and factor in care from community-based organizations.

The HaH Program operates as a waiver of Medicare conditions of participation requiring 24-hour nursing services and the immediate availability of a registered nurse for patients of acute-level hospital services, allowing the substitution of virtual care. Participating hospitals are reimbursed the full inpatient DRG payment for services. The HaH Program is not a blanket waiver and requires a waiver request for each hospital, including for each hospital within a larger health system. Experienced hospitals that have treated at least 25 patients meeting the inpatient admission criteria may go through an expedited process for participation. Hospital executive-level personnel must attest to their responsibility for each hospital within the HaH Program. Also, as a condition of participation in the HaH Program, CMS requires hospitals to submit monitoring data on a weekly basis. Only patients seen in emergency departments or admitted to inpatient wards are eligible for services under the HaH Program.

The Future of Advanced Care at Home

The HaH Program will expire when the federal COVID-19 PHE ends. On April 15, 2022, DHHS extended the PHE for another 90 days to July 14 and indicated the agency would provide states with 60 days' advance notice prior to the termination of the public health emergency. It is not clear yet whether DHHS will again extend the PHE. Hospitals participating in the HaH Program are facing a cliff and taking efforts to preserve their full ability to offer and be reimbursed for services.

Advocacy efforts are underway for the implementation of a CMMI model to replace the HaH Program. In March 2022, Senators Tom Carper (D-Delaware) and Tim Scott (R-South Carolina) and Representatives Earl Blumenauer (D-Oregon) and Brad Wenstrup (R-Ohio) introduced bipartisan legislation that aims to extend the HaH Program flexibilities for at least 2 years following the end of the COVID-19 PHE. Under the proposed Hospital Inpatient Services Modernization Act, CMS would waive the 24-hour nursing requirement as a condition of participation for Medicare as well as certain safety code requirements for homes and temporary residences. Under the proposed legislation, DHHS would be required to evaluate the "new" HaH Program and make additional recommendations and evaluations to establish health and safety requirements, analyze data related to waivers, and assess care quality, patient outcomes, beneficiary access, health disparities, patient safety, cost, and utilization.

Supporters of the proposed CMMI model and legislation have cited to data supporting claims that the HaH Program has the potential to drive quality, reduce readmissions, increase patient satisfaction, eliminate hospital-acquired infections, and reduce the cost of care. Still, there are many questions and issues to address, including the extension of regulatory flexibilities at the state level. Many providers anticipate that states and commercial payors will follow the lead of CMS. There is additional focus on how the model addresses issues of access and health equity, ensuring appropriateness of clinical care, the possible role of home health providers in this model, and impacts on the hospital industry. For a deeper dive into these issues, check out the 2022 AHLA Annual Meeting session, *The Jetsons: Coming to a Hospital Near You!* presented by Kristen McDermott Woodrum (McGuireWoods), Priya Bathija (American Hospital Association), and Stephen M. Parodi, M.D. (Kaiser Permanente).

Additional Resources:

The Jetsons: Coming to a Hospital Near You! presented by Kristen McDermott Woodrum (McGuireWoods), Priya Bathija (American Hospital Association), and Stephen M. Parodi, M.D. (Kaiser Permanente) at the 2022 AHLA Annual Meeting Monday, June 27th from 2:00-3:00 (and available with program materials).

GOVERNMENT ENFORCEMENT; FALSE CLAIMS ACT UPDATES

Brett Barnett, Edwin Childs, Brandi Howard, Laura Colombell Marshall, David Pivnick, Michael Podberesky

FY 2021 Second Largest Annual Recovery

At its inception, the False Claims Act (FCA) was designed to combat fraud against the government, particularly in connection with military contractors. At present, the majority of federal *qui tam* actions relate to alleged healthcare (by far the largest numbers, largely due to Medicare and Medicaid), procurement, and mortgage fraud. Indeed, in FY 2021, the Department of Justice (DOJ) recovered over $5.6 billion under the FCA, its second largest recovery period ever, albeit over half of that amount came from a single settlement. These lawsuits, which can be brought by *qui tam* whistleblowers, can lead to significant penalties – three times the amount the government paid to the contractor plus per claim fines of more than $25,000 (which acts as a cudgel since healthcare providers will have thousands of claims at issue in most FCA cases, yielding massive potential liabilities).

In FY 2021, more specifically, the DOJ recovered $5,650,026,663 under the FCA. That is more than double the $2.3 billion recovered in FY 2020. Healthcare-related recoveries accounted for almost 90% of the total FY 2021 settlements and judgments amount with over $5 billion recovered in healthcare matters. This is the largest annual healthcare-related recovery on record, although that was inflated by the massive $3 billion settlement with an opioid manufacturer (of course, such an outlier settlement was true of the earlier largest annual settlement amounts). Take out that "unicorn" settlement, and the remaining healthcare recoveries total only $2 billion, a slight uptick from the $1.9 billion in healthcare recoveries in FY 2020, but about 20% below the average $2.5 billion healthcare-related amounts recovered per year in the preceding five years.

Looking beyond the dollars recovered, much can be gleaned from the number of new matters opened last year. The FY 2021 new matter data is essentially the mirror image of the dollar recoveries – the FY 2021 new matters are slightly below the FY 2020 numbers, but about the same as the average of the preceding five years. In FY 2021, 801 new FCA matters were opened, including 598 *qui tam* matters brought by whistleblowers and 203 non-*qui tam* matters initiated by the DOJ. That is down about 15% from the total matters opened in FY 2020, but in line with the average for the preceding five years. The 203 non-*qui tam* cases initiated by the DOJ is down from the 259 in FY 2020 but is 30% higher than the average number of non-*qui tam* matters opened in each of the last five years, suggesting that the concerted, years-long effort at the DOJ to be more proactive in identifying fraud schemes using artificial intelligence and sophisticated data mining tools, as opposed to merely reacting to *qui tam* suits brought by whistleblowers, continues to pay dividends. Correspondingly, recoveries in non-*qui tam* matters, which are higher on average than recoveries in whistleblower-initiated matters, should increase in the forthcoming years as many of these new matters turn into settlements and judgments.

In addition, FY 2021 was a transition period for the DOJ and the picture described above may reflect that. There was a change in administration and the DOJ's Civil Division, whose Civil Fraud Section prosecutes FCA cases, still does not have a nominated head, let alone a confirmed one, after President Biden's original nominee dropped out. Numerous U.S. Attorney's Offices, which also play a pivotal role in investigating and prosecuting FCA matters, also lacked confirmed appointees over the past year. With a new administration, the DOJ's enforcement priorities may be shifting and press announcements telegraph that among other priorities, it is focusing efforts on: (1) combatting the opioid epidemic, (2) COVID-related fraud enforcement and (3) cybersecurity. Each of these focuses will significantly impact healthcare providers, particularly the last two, and large hospital systems. The DOJ has requested additional funding from Congress to support its COVID-19 Fraud Enforcement Task Force, which both the President and Attorney General have placed emphasis upon in the effort to combat corporate crime.

Two California cases provide key FCA reminders with respect to the AKS

Two opinions issued in February 2022, in different U.S. district courts in California, provide key reminders on FCA cases involving the Anti-Kickback Statute (AKS). The AKS can be the basis for an FCA case as compliance with the AKS is a precondition of Medicare payment, which the Affordable Care Act (ACA) made explicit by providing that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for the purposes of [the FCA]." Much of the recent AKS case law stems from FCA allegations, not criminal prosecution. Indeed, in these two cases, key reminders and legal development come out of an FCA allegation, not criminal prosecution. Both are important reminders for providers in structuring relationships—Fair Market Value (FMV) payments are not enough by themselves to avoid AKS allegations and such AKS violations can lead to significant FCA penalties.

In the first case, the defendant device company moved for dismissal arguing, in part, that the plaintiff-relator had failed to allege that payments the device company made to physicians exceeded FMV under the proctoring program at issue in an AKS-focused FCA case and, accordingly, that the plaintiff-relator had failed to address the applicability of the personal services safe harbor under the AKS. The DOJ filed a statement of interest in the case, urging the court to deny the motion to dismiss, noting that the lack of FMV is not an element of AKS violations. The court agreed with the DOJ, finding that FMV payments for actual services performed may still violate AKS where those payments were intended to induce referrals. The court noted that such an intent "take[s] the payments out of the safe harbor, regardless of whether those payments were made at fair market value." This ruling is a strong reminder that healthcare organizations should ensure they document the justification for a financial arrangement and not simply rely on formalities like valuations or contract language.

In the second case, the court agreed with the DOJ in holding that compliance with the AKS was per se material to Medicare reimbursement from billed claims that were both pre and post the ACA's 2010 enactment. In reaching this decision involving a physician-owned distributorship that argued the any AKS violations were not material under the Supreme Court's Escobar holding, the court was able to cite the ACA provision quoted above and First Circuit opinions to determine that the ACA "obviate[ed] the need for a plaintiff to plead materiality." In addition, the district court collected cases involving claims pre-dating the ACA to hold that "[t]he legislative history suggests that the 2010 amendment was intended to codify the link between AKS violations and false claims within the meaning of the FCA." As such, the California court agreed with most court decisions in holding that compliance with the AKS was per se material for claims predating the enactment of the ACA and granted the government's motion for partial summary judgment. The partial summary judgment stemmed not from materiality, on which the court agreed with the government and certain facts regarding claims, the court determined there remained a triable issue of fact as to the alleged status of the four physicians as physician-investors during that period.

Additional Resources:

- Analysis of DOJ's 2021 FCA Statistics and the Trends Therein
- DOJ Ramps up Resources and Renews Focus on Combatting COVID-19 Related Fraud in 2022
- California Court: Fair Market Value Payments May Not Avert Anti-Kickback Liability
- District Court finds that AKS Violations are Per Se Material

DIGITAL HEALTH FOCUS AREAS FOR HEALTH SYSTEMS

Andrea Linna, Garrison Ambrose, Varsha Gadani, Michael Paluzzi

Telehealth enforcement after significant PHE-era expansion

To facilitate access to healthcare services during the PHE, CMS modified telemedicine requirements to expand telehealth and telemedicine access. Since then, enforcement actions and statements by the Department of Health & Human Services (HHS), Office of Inspector General (OIG) and the DOJ suggest that government telemedicine compliance scrutiny will continue.

OIG continues to list telehealth services in its Active Work Plan Items.[1] Comments by OIG also demonstrate its concern that the benefits of telemedicine may be undermined by fraud schemes. For instance, last year, OIG's Principal Deputy Inspector General Christi Grimm commented in an open letter that while "OIG recognizes the promise that telehealth and other digital health technologies have for improving care coordination and health outcomes," it is critical to ensure "that new policies and technologies with potential to improve care and enhance convenience achieve these goals and are not compromised by fraud, abuse, or misuse." Grimm noted that "OIG is conducting significant oversight work assessing telehealth services during the public health emergency," and "will continue to vigilantly pursue . . . 'telefraud' schemes and monitor the evolution of scams that may relate to telehealth."

Similarly, the DOJ has prosecuted various telehealth-related fraud schemes. One such scheme involved dozens of durable medical equipment (DME) supply companies that were alleged to bribe physicians to approve a high volume of telehealth claims when the physicians had no telehealth interaction with the beneficiaries. The DOJ settled that case for $20.3 million. In a similar fraud scheme, telemedicine executives were alleged to pay physicians to order unnecessary DME, genetic and diagnostic testing, and pain medications, causing an alleged $4.5 billion in false claims submitted to federal healthcare programs and private insurers by 86 criminal defendants in 19 judicial districts.

More recently, the U.S. Attorney's Office for the Eastern District of New York subpoenaed a virtual mental health startup for potential violations of the Controlled Substances Act. Prior to the subpoena, the startup had already faced a lawsuit from a former executive, who had alleged he was terminated after complaining about the startup's prescribing practices. The subpoena requires the startup to produce documents pertaining to its policies and procedures regarding controlled substances and procedures concerning the company's relationship with its preferred online pharmacy. In the wake of the startup's subpoena, the online pharmacy announced that it is pausing filling all Schedule 2 controlled substance prescriptions.

Considering the government's concerted scrutiny of telehealth arrangements, healthcare providers should take steps to decrease the risk of facing OIG or DOJ scrutiny. Hospitals should audit and continuously monitor their telehealth procedures, arrangements, and claims and continue to track regulatory changes. Many of the allegations to-date are akin to historic fraud schemes, which suggests health systems may not even need to develop significantly different protocols than those they use for off-line care; general counsel offices should start by ensuring their current procedures apply to such telehealth initiatives.

Cybersecurity as a mitigating factor for HIPAA and HITECH fines

A year after Congress amended the Health Information Technology for Economic and Clinical Health (HITECH) Act to require HHS to consider covered entities' (most healthcare providers, health plans and clearinghouses) or business associates' "recognized cybersecurity practices" when determining fines, audits and remedies for HIPAA violations, HHS now seeks public comment on the topic. Specifically, HHS Office for Civil Rights (OCR) is requesting public comments on how covered entities and business associates voluntarily implement security practices, to assist it in determining what the "recognized cybersecurity practices" are and proper mitigating factors when auditing and fining covered entities and business associates for violations. OCR will want the industry to go beyond simply establishing and documenting the adoption of security practices, but instead develop security practices that are active and in consistent use. OCR hopes that this will allow the industry to accomplish Congress' goal that they do "everything in their power to safeguard patient

[1] Ntd: Work Plan | Office of Inspector General | U.S. Department of Health and Human Services (hhs.gov), https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp#example=fteleh.

data." Health systems will want to monitor this rule as it develops since hospitals have been a key target of cybersecurity fraud and face significant costs in implementing such defenses for their system and this potential mitigating factor for HIPAA/HITECH fines.

Additional Resources:

- As HIPAA, HITECH Undergo Modernization, NIST Seeks Comment on Security Standard Guidance
- OCR Seeks Input on "Recognized Security Practices" as Mitigating Factor for HIPAA and HITECH Fines

KEY LABOR ISSUES TO SUPPORT YOUR ORGANIZATION'S STAFF

John Thomas, Timothy Fry

The so-called *Great Resignation's* impact on healthcare providers has been profound. Growing exponentially during the pandemic, travel nursing has made it difficult for many health systems to retain their nursing staff. A national unemployment rate of 3.6%, with record low unemployment insurance claims, has made it difficult to hire even unskilled labor. This comes after two-plus years where many health systems faced energy sapping COVID-surges, followed by a public shift from supporting staff as "frontline heroes" to pushback stemming from pure exhaustion with anything COVID-related and a reluctance to adhere to any limitation or mitigation efforts. These trends created tension within healthcare organization staffs and forced our industry to spend significant time on recruiting, retention and supporting its staff.

During recruitment efforts, legal counsel needs to be aware that the Biden administration (after earlier efforts in 2016) has focused on increasing competition, including the competition for talent. These federal policies could cut against key recruitment and retention efforts. A Biden executive order issued this past fall encouraged the Federal Trade Commission (FTC) to exercise its rulemaking authority "to curtail the unfair use of non-compete clauses or agreements that may unfairly limit worker mobility" and revise the Antitrust Guidance for Human Resource Professionals to "better protect workers from wage collusion." Physician contracts are one place where most such employees have non-complete clauses, which makes any further FTC activity of particular concern for the healthcare industry. Furthermore, while a jury acquitted the defendants in a groundbreaking antitrust trial this spring alleging conspiracy in implementing "no poach" deals from the defendants' staffs, more investigations will likely follow. These changes make it even more difficult for health systems to line up their future employees, considering whether certain traditional non-compete clauses and other retention tools could face scrutiny in the future. Traditionally, human resources offices have not been trained by lawyers in antitrust enforcement (leaving such discussions for health system's business development teams), but as scrutiny increases, general counsel offices may want to expand training on these areas of law to more parties within their organization.

At the same time, traditional labor issues, including union negotiations, continue to create headaches for most healthcare clients. Hospitals, home healthcare agencies, physician practices, and other healthcare providers continue to confront increased scrutiny from the Department of Labor, state labor agencies, and private plaintiffs for violations of the Fair Labor Standards Act (FLSA) and similar state wage-and-hour laws. By way of example, our team has been working with healthcare clients on each of the following recently:

- ***Overtime for advanced practice providers:*** As healthcare positions have evolved, so have legal challenges regarding the positions' exempt from overtime requirements. For example, healthcare providers should be mindful that courts have required nurse practitioners and physician assistants to be salaried (not hourly) to be exempt from overtime requirements because they do not "practice medicine" like physicians do. This is despite shifts in such clinicians' abilities, training, and independence, as well as a pay structure that often reflects physician compensation in an organization (with reductions for the difference in typically lower collection numbers), e.g., wRVU, percentage of collections, and other traditional physician payments. On the other hand, certain healthcare professionals may take advantage of the "learned professional" exemption if their work requires advanced knowledge in a field of science

or learning, which one would anticipate, but courts have not always agreed, would apply to advanced practice providers referenced above. By proactively evaluating a system's positions and hires through internal audits and other controls with respect to labor areas that are most likely to be targeted by the Department of Labor, healthcare providers can seek to manage legal risk from exempt employee challenges in the future.

- ***Independent contractor misclassification:*** Healthcare providers, particularly home health agencies, remain in the sights of the Department of Labor for independent contractor misclassification. Across the country, the Department of Labor has filed lawsuits against home healthcare agencies, big and small, for misclassifying workers as independent contractors. The Department of Labor has obtained large verdicts and settlements in many of these cases, and the agency shows no sign of slowing down its pursuit of misclassification cases in the industry. Employers found to have "willfully" failed to pay overtime are subject to double-damages but can seek to avoid such damages if they show they have a reasonable, good faith belief they are not violating the FLSA. One way healthcare providers can avail themselves of this defense is to obtain a precise legal opinion from an experienced employment attorney opining that the practice does not violate the FLSA. However, recent court opinions teach that it is imperative that the healthcare practice obtain this opinion before the Department of Labor initiates an investigation. In addition to Department of Labor challenges, we often see misclassifications during transactions involving physician practices—physicians often desire independent contractor status for tax structuring purposes but are truly working full-time and under the control of the practice entity. General counsel offices should work with their business teams to review such relationships in any potential deals and begin conversations about transitioning to employment early in such dealmaking to protect the organization within traditional labor law.

- ***Caregiver registries to avoid employment determinations:*** Another area where home health agencies, particularly, see significant differences from other employers is if they provide a "matchmaking" service between patients and caregivers, which can avoid liability under the FLSA if the agency qualifies as a "caregiver registry." The Department of Labor recognizes registries as agencies that do not provide actual home care services. Instead, a registry typically provides matchmaking and referral services to the client by providing access to its database of qualified, pre-screened, and vetted caregivers. A registry may confirm caregiver credentials, conduct background checks, contact professional references, and engage in other quality-control measures. A registry also typically obtains information from the caregivers about the type of work they are willing to perform, their target compensation, their availability, and other personal preferences when working with clients. A registry may also interview the client to learn, for instance, the amount and type of services the client needs, the client's budget, and the client's personal preferences. After the introduction, the caregiver and/or the client have no obligation to accept the referral. A registry may act as the liaison between the caregiver and the client, but does not typically negotiate the terms or conditions of the job on either party's behalf or control the financial terms or conditions of the home care relationship. Nor does the registry typically control, supervise, or provide training or equipment to the caregiver. Rather, after the match occurs, it may be the client's responsibility to manage the care. Agencies that seek to avail themselves of the legal protections of being designated a "registry," including health systems that provide these services for post-acute care opportunities, should carefully consider if they are structured in such a manner and as appropriate, give up any billing or reassignment rights, to avoid an adverse determination from the Department of Labor. I.e., that in practice they are matchmaking, not just on paper, to utilize this for FLSA protection.

Additional Resources:

- Biden Signs Sweeping Executive Order Designed to Expand Antitrust Regulation and Increase Enforcement
- Raising Red Flags: DOJ and FTC Issue Antitrust Guidance for HR Professionals

NO SURPRISES ACT CREATES NEW PAPERWORK REQUIREMENTS

Varsha Gadani, Colin McCarthy

The federal No Surprises Act (NSA), enacted at the end of 2020, has placed numerous administrative burdens on hospitals related to billing patients since it and its regulations, went into effect on January 1, 2022. Many client hospitals have been working to incorporate policies and adjust workflows to meet the requirements of the NSA.

The NSA's key goal was generally prohibiting balance billing patients for out-of-network emergency services and out-of-network services provided at in-network facilities. In such cases, the patient can only be billed the in-network cost-sharing, with certain exceptions, as discussed below. The balance billing prohibition applies to patients with group and individual health plans.

For emergency services, certain post-stabilization services can be balance billed if the patient is in a condition to receive notice and provide consent to such out-of-network care, and the attending physician determines the patient can safely travel to a participating provider using non-medical and non-emergency transportation. In the case of a nonparticipating provider at a participating emergency facility, the notice must include a list of participating providers at the participating emergency facility who can provide the services. Notwithstanding the above, a non-participating provider will always be subject to the balance billing prohibition for services furnished stemming from unforeseen, urgent medical needs that arise at the time an item or service is furnished, as well as certain ancillary services such as anesthesia and laboratory facilities.

If out-of-network services will be provided for non-emergent services (except for ancillary services), and a provider wants to receive payment from the patient, federal law requires written notice with consent. In relevant part, the notice must indicate the provider is nonparticipating, include a good faith estimate of charges, and state that consent to receive services from the nonparticipating provider is optional. The consent of the patient or an authorized representative must be provided voluntarily, in the form required by HHS, and not be revoked prior to receipt of services. There are also regulatory guardrails regarding timing for such notice.

In addition, most facilities and providers must give a general disclosure regarding balance billing protections, including state balance billing laws, and contact information for state and/or federal agencies that an individual can contact to report a suspected violation. The notice must be posted on signage and facilities' and providers' websites so that all patients are aware. The disclosure must also be provided to individuals who are enrollees of group and individual health plans.

A healthcare provider or facility must inquire if an individual who schedules an item or service is insured and, if so, whether such individual is seeking to have his/her claims for such item or service submitted to their health plan. Individuals who do not have health coverage and those who do but are not filing a claim are considered uninsured (or self-pay) and are entitled to a good faith estimate (GFE) for expected charges upon scheduling an item or service. A similar GFE statutory requirement for insurance companies (to allow the insurance company to work with the patient directly) has not yet received a proposed or finalized regulatory process, and HHS noted that it would not enforce the statutory provision until such rulemaking is issued (asking the states, which can also enforce the NSA, to give the same enforcement discretion).

Until the finalized insurance GFE process, the NSA regulations require a provider or a facility to inform all uninsured (or self-pay) patients of the availability of a GFE of expected charges upon scheduling an item or service or upon request. The GFE must include expected charges for the items or services that are reasonably expected to be provided, including the primary item or service and any related items or services (e.g., imaging, laboratory services). To the extent other providers or facilities are reasonably expected to provide items or services related to the primary item or service, their GFEs must be included in the GFE to the patient, so those providers and facilities must be contacted by the primary provider within one business day of receiving a patient's GFE request to gather all necessary information. These co-providers are required to respond within one business day of receiving the request for information. Note that for GFEs

provided to uninsured patients from January 1, 2022, through December 31, 2022, HHS has indicated it will exercise enforcement discretion in situations where a GFE provided to an uninsured patient does not include expected charges from other providers and facilities that are involved in the individual's care. Health systems will want to utilize this discretionary enforcement period to strengthen collaborations with independent physicians and other care providers to fulfill this paperwork production process.

Additional Resources:

- Overview of rules & fact sheets | CMS
- Model Disclosure Notice Regarding Patient Protections Against Surprise Billing Instructions for Providers and Facilities (cms.gov)
- Standard Notice and Consent Documents Under the No Surprises Act (cms.gov)
- Good Faith Estimate Notice and Template | CMS

COVID-RELATED FUNDING ISSUES

Timothy Fry, Stephanie Kennan

Provider Relief Fund deadlines loom this summer

- ***June 30, 2022:*** Any healthcare provider that received at least $10,000 from the Provider Relief Fund during the first half of 2021—Period 3—must use such funds for a permissible purpose by June 30, 2022. The Provider Relief Fund payments may be used for eligible expenses or lost revenue attributable to COVID-19 that are not reimbursed from another source. HHS has provided guidance on eligible expenses, which are generally those used to prevent, prepare for, and respond to COVID-19, including services rendered to COVID-19 patients and certain other healthcare-related and administrative expenses, including taxes paid on amounts received from the Provider Relief Fund. HHS places the burden on the provider to adequately document support for its expenses and lost revenue calculations and ensuring the spending was appropriate under the Provider Relief Fund's terms and conditions.
- ***July 1-Sept. 30, 2022:*** For those providers that received funds in Period 3, discussed in the preceding paragraph, they must report on its use of those funds by Sept. 30, 2022. To facilitate these reports, HHS will open its reporting portal on July 1, 2022. While HHS has not yet provided specific information on Period 3 reporting, for those providers that reported on Period 1 or 2 payments, the reporting portal should look familiar. HHS has slowed the number of updates it makes on its frequently asked questions (FAQ) reporting page since it released its June 11, 2021, guidance, but we anticipate such previous guidance will continue to apply.
- At least one additional reporting period for funds received during the second half of 2021 (Period 4) (and potentially a fifth reporting period for funds received in early 2022) will come in early 2023. For providers that received funds in Period 4, funds must be expended for permissible purposes by the end of this year.

Additional Resources:

- Provider Relief Fund Reporting Guidance

Additional COVID-19 funding outlook

A COVID-19 funding package with wide-spread agreement in the Senate in April was held up because of Republicans' effort to tie the funding to the extension of certain border protections. The stalled $10 billion COVID-19 package would have been used for increased testing, therapeutics, and vaccinations. Due to the lack of funds, HHS ended its COVID-19 Uninsured Program and Coverage Assistance Fund for testing and treatment and vaccine administration respectively in March and April 2022. The stalled deal may fall apart even further because many of its "pay-fors" – the funding provisions that would have raised funds – have now largely been used for other initiatives.

As the healthcare industry and its lobbyists continue to argue for more funding relief in Washington, D.C., as well as increased flexibility in paying back some funds, the road ahead continues to look bleak with no clear path forward. Senate Democrats would prefer for the House of Representatives to move aid first to provide a pathway to passage of such COVID-19 relief. However, as every new policy crisis arises – war in Ukraine, the leaked abortion opinion, the infant formula shortage, and now guns – COVID-19 funding pushes farther and farther towards the back of the line for consideration.

While such COVID-19 funding falls further down the list of potential actions, policymakers confront an array of healthcare issues including workforce shortages, flexibilities in the speed in which Medicare Accelerated and Advanced payments must be repaid, and ACA-related insurance expansion support for lower income Americans in past COVID-related funding bills that covered different socioeconomic brackets than prior to the Public Health Emergency (PHE). The loss of such results will mean millions of Americans that were able to obtain such coverage during the PHE will lose their insurance. Further complicating this picture, once the PHE ends, states will be required to redetermine Medicaid eligibility for those who now are on Medicaid, which also received additional financial support. This means that many will lose their healthcare coverage unless states can develop an alternative mechanism for these individuals and families.

Ultimately, Washington, D.C. faces significant healthcare issues throughout the second half of 2022, which could have a significant impact on healthcare organizations in the years to come.

Prepare for the end of the Public Health Emergency

While finalizing reports from the COVID period government funding, general counsel offices also need to begin to prepare for the end of the PHE. Originally declared in January 2020, the PHE has been renewed on 90 day increments currently through mid-July. While the Biden administration has vowed to give governors 60 days' notice before the PHE ends, to the extent hospital systems have staff available this summer, we strongly recommend they begin to prepare for the PHE's end. Many providers have taken advantage of CMS waivers, including waivers of certain provisions of the federal physician self-referral law (the Stark Law) and certain hospital conditions of participation.

Health system counsel should ensure it has concurrent documentation relating to any federal or state waivers the system utilized during the PHE period. During subsequent accreditation inspections or any litigation, whether pursuant to FCA cases described above or otherwise, contemporaneous documentation from this period will be critical to defending the health system or wider organization. Further, in some cases, entire programs were developed in the last two years that had COVID-era waivers at their base, particularly those involving telemedicine. Not all those waivers will remain, and policymakers continue to struggle with what flexibilities they want to continue post-PHE. Staff should prepare to transition operations back at the end of the PHE. Programmatic review may be necessary, led or encouraged by each system's counsel office. Further, to the extent systems do not need to continue any emergency protocols/operations to serve their community, operators may want to begin to transition back to standard procedures before they are required to do so to ease the transition. With the end of this unique period, general counsel offices can and should plan to avoid the crash course that was the beginning of the COVID-19 era. The more that is done today, the easier the PHE's end will be.

TEAM OVERVIEW

McGuireWoods' Healthcare Group is one of the top healthcare practices in the country. Our seasoned lawyers understand the competing interests placed on our clients by the dynamic healthcare marketplace, including the pressure to maximize profits while maintaining compliance with an ever-changing array of healthcare laws and regulations. We counsel clients in virtually every area of law impacting a healthcare organization, including corporate organization, mergers, acquisitions and joint ventures, regulatory compliance, securities, labor and employment, intellectual property, and litigation. McGuireWoods' Healthcare Group and our attorneys have been repeatedly recognized by leading industry organizations, such as *Chambers USA, Legal 500, The Best Lawyers in America, Bloomberg, Refinitiv, Super Lawyers* and *JDSupra*. The cross-functional nature of our healthcare practice allows us to provide comprehensive representation, including litigation, antitrust, labor and employment, and tax issues presented by any health system.

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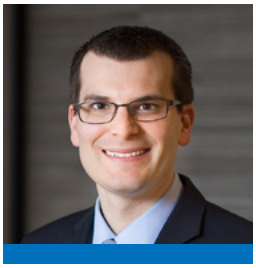

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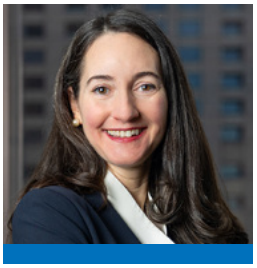

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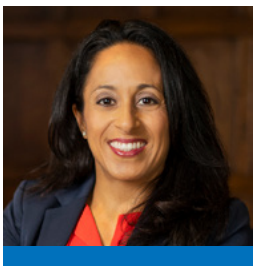

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