Healthcare Industry Team – 2023 Year in Review

BakerHostetler's Healthcare Industry team is a Chambers-ranked full-service healthcare law firm with a national presence. We pride ourselves on our ability to strategically guide clients through the ever-changing challenges of the industry, enabling them to respond with agility and foresight.

As we approach the conclusion of another transformative year, we are excited to present our comprehensive year-end review, shedding light on the trends shaping the healthcare market in 2023. Our team's keen insights and dedication to staying at the forefront of developments allow us to provide a perspective on the intricate dynamics influencing healthcare today. Join us as we explore the multifaceted landscape of healthcare, delving into the key trends that have defined the year and offering insights that empower our clients to make informed decisions in the face of uncertainty.

Healthcare Transactions

Charlene McGinty

- **Corporate Transparency.** We have been tracking the Corporate Transparency Act (CTA) since its passage by Congress on Jan. 1, 2021, as part of the National Defense Authorization Act for Fiscal Year 2021 (H.R. 6395). The CTA, which became effective Jan. 1, 2024, is a tool to assist law enforcement agencies in combating money laundering, terrorism financing and other illicit activities conducted through anonymous shell companies. As of Jan. 1, all new and existing entities, unless otherwise exempt, need to report information about their beneficial owners to the U.S. Department of the Treasury's Financial Crimes Enforcement Network (FinCEN). The CTA contains 23 listed exemptions; accordingly, all entities formed or registered to do business in the United States will need to either (i) confirm they qualify for an exemption or (ii) timely submit a beneficial ownership report to FinCEN. The reporting requirements and timing vary depending on what type of entity it is and when it was formed. Also be wary of state laws – New York has passed a transparency act and California is considering its version of a transparency act.

- **Private Equity in the Crosshairs.** Congress and government agencies such as the Federal Trade Commission (FTC) and Department of Justice (DOJ) are concerned with the effect of private equity investment in the healthcare industry.
  - » Sens. Whitehouse and Grassley have opened investigations into the impact of private equity transactions involving rural healthcare facilities and the effect on patient care.
  - » The FTC filed a complaint against Welsh, Carlson, Anderson & Stowe and its portfolio company, U.S. Anesthesia Partners, alleging a multiyear anti-competitive scheme to consolidate anesthesia providers in the Texas market, thereby driving up anesthesia prices to boost profits. The FTC is alleging a novel theory that roll-up transactions may violate antitrust laws.
  - » The Internal Revenue Service (IRS) is continuing its review of the "friendly doctor" structure to determine if there is sufficient control for purposes of "affiliated group" rules on consolidation of tax returns.
  - » Private equity (PE) firms investing in the healthcare industry are becoming a point of focus for the DOJ and whistleblowers under False Claims Act (FCA) claims. A PE firm is most likely going to be a target of FCA liability in the following scenarios:

failure to remedy regulatory violations of which it becomes aware (whether in due diligence or otherwise); at the portfolio company level, failure to take an active role in operational/strategic decision-making or sit on the board; or failure to implement proper internal controls to eliminate fraudulent conduct. As scrutiny of PE firms investing in the healthcare industry continues to grow, PE firms should carefully monitor their investments and be compliance minded and vigilant.

- » Bankruptcy woes: Even the federal bankruptcy courts have gotten into the action where PE healthcare is concerned. Envision Healthcare Corp. and certain of its wholly owned subsidiaries (Envision) filed for Chapter 11 bankruptcy protection in Texas. Envision, through a series of transactions over multiple years, was one of the largest emergency medicine staffing companies in the United States and likely represented the largest healthcare-related bankruptcy case. Envision has since emerged from bankruptcy, but with a much smaller footprint.
- » Corporate practice of medicine doctrine: Envision is also being sued by the American Academy of Emergency Medicine Physician Group in federal court in California in a suit challenging the legality of the Envision business model under the corporate practice of medicine doctrine.

- **HSR Filing Requirement.** Proposed changes to the Hart-Scott-Rodino (HSR) filing requirements include providing the following documents: drafts of deal documents; documents analyzing the deal; strategic plans; information about board members, suppliers and employees; rationale for the transaction; and relevant product/geographic markets and prior transactions (with a 10-year lookback period). Other proposed changes include elimination of the ability to submit an HSR filing based on a preliminary agreement, such as a letter of intent, indication of interest or agreement in principle, without providing a term sheet or a sufficiently detailed agreement (to confirm that the transaction is not simply "hypothetical").
- **Healthcare Trends – Transactions.** We continue to see significant interest in mergers, acquisitions, joint ventures, affiliations and other transactions in/involving the healthcare industry:
  - » Outpatient providers are in play – ambulatory surgery centers, urgent care centers, physician practices and continued employment of physicians.
  - » Nontraditional players are more interested in the healthcare sector – PE firms, retail giants (such as Walmart) and technology firms.
  - » Care continuum opportunities – vertical integration to provide services across the care continuum.
  - » Digital health interest – telehealth, AI technologies and emerging technologies.
  - » Survival of the fittest – hospital mergers or affiliations where nonprofitable hospitals or systems are acquired by or affiliate with stronger, top-tier systems.

Healthcare Privacy

Lynn Sessions

- **Technology Tracking.** The American Hospital Association (AHA) is challenging the December 2022 Guidance on tracking technologies, which has plagued covered entities and business associates since its issuance. We predict that healthcare providers led by the AHA's lawsuit will prevail on this issue curtailing the Office for Civil Rights' (OCR) overreach in this area.
  - » BakerHostetler's defense of healthcare providers in multiple OCR investigations and class action litigation – along with the AHA's challenge to the OCR Guidance – will likely force the OCR to change its position on tracking technologies, providing much relief to healthcare organizations as they meet their information-blocking obligations and communicate with their patients where they go to get information – online.
  - » OCR and plaintiffs' attorneys scrutinized healthcare entities' use of tracking technologies for 18 months. Class action litigation continues to be filed as older cases are making their way through the courts around the country.
- **Artificial Intelligence.** We anticipate intrigue will continue to grow among clients. Our clients have inquired about the use of AI related to:
  - » Assistance with provider burnout by using AI in medical records dictation.
  - » Business associate's use of AI without considering the privacy implications.

- HIPAA (Health Insurance Portability and Accountability Act) and state privacy law implications associated with AI and the risk associated with the use of AI for multiple purposes.

- **State Action.** State regulators continue to become more active. We've seen an uptick in Attorney General (AG) investigations from New York, New Jersey, Florida, Connecticut and Utah. These AGs are also following through on civil monetary penalties, even when OCR does not find any violations worth penalizing.
  - Additionally, various state legislators have become very interested in privacy and security issues. We are seeing more and more states passing comprehensive privacy laws that impact healthcare organizations as providers and employers.

Healthcare Regulatory/Billing and Reimbursement

Amy Fouts

- **Medicare RAC Activity.** This year brought an increase in Medicare Recovery Audit Contractor (RAC) activity. While RAC audits practically halted during the COVID-19 pandemic, activity has picked up substantially following the end of the public health emergency (PHE). Additionally, we are seeing RAC audits expand to include more outpatient services, in addition to the inpatient DRG reviews.

- **Split/Shared Visits.** A split (or shared) visit is an evaluation and management (E/M) visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner who are in the same group. A physician can bill for the service – and get the increased reimbursement – if they perform a substantive portion of the encounter in a facility setting. Historically, the substantive portion of a visit could be met by any of the following elements: history, physical exam, medical decision-making or time spent. In previous rulemaking, the Centers for Medicare & Medicaid Services (CMS) planned to phase in a time-only definition for split/shared E/M visits by allowing the substantive portion of a visit to be performed by the provider who spent more than half the total time or who performed the history, physical exam or medical decision-making portion of the visit in CY 2022, and then moving to a time-only definition on Jan. 1, 2023. CMS subsequently delayed implementing the time-only definition through 2024. For CY 2024, CMS revised its definition of "substantive portion" of a split/shared visit to mean more than half the total time spent by the physician or nonphysician practitioner performing the split/shared visit or a substantive part of the medical decision-making. CMS continues to say that this is a delay until 2025, when only time can be used.

- **340B.** In November 2023, CMS finalized the rule to pay back 340B providers for illegally underpaying 340B providers from January 2018 to September 2022. This final remedy is the result of a yearslong litigation led by the AHA that ultimately concluded with a unanimous decision from the U.S. Supreme Court holding that the payment reduction was unlawful. The final rule will result in 340B entities collectively receiving roughly $9 billion in the first quarter of 2024 (CMS already paid roughly $1 billion for 340B claims billed in 2022). Although this is a significant win for 340B entities, the final rule's method for funding the repayments remains controversial because CMS also implemented rules that made the remedy budget neutral, meaning that CMS will recoup $10 billion from all hospitals (not just 340B entities) over the next 16 years to fund this repayment. The AHA and numerous hospitals firmly opposed this part of the proposed rule, and further litigation on the budget neutralization portion of the rule is anticipated. Despite the Supreme Court's holding and the remedy established by CMS, many Medicare Advantage payors have also refused to make a lump-sum payment to hospitals or to otherwise reimburse hospitals for the underpayments the insurers previously made based on the unlawful rate cuts. The BakerHostetler Healthcare Litigation team is actively helping hospitals pursue litigation and other remedies against Medicare Advantage payors to recover those underpayments, and we expect further litigation on these issues in the coming year.
  - In another 340B development, a group of hospitals sued the Health Resources and Services Administration (HRSA) on Oct. 31 for improperly adopting the rule for its child site policy. Historically, HRSA required 340B entities to list a new off-site outpatient facility on their most recently filed Medicare cost report and register the facility in Office of Pharmacy Affairs (OPAIS) before the new facility could be treated as part of the 340B entity for reimbursement purposes. These requirements meant that it could take between eight and 23 months before a new outpatient facility could participate in the 340B program. During the COVID-19 PHE, HRSA announced a change in this policy that would allow new outpatient facilities to access 340B coverage faster. Plaintiffs argue that HRSA's change during the PHE was not temporary or tied to the duration of the PHE, and the complaint seeks injunctive relief based on HRSA allegedly (1) improperly adopting a legislative rule; (2) conducting an

agency action contrary to law; and (3) acting in an arbitrary and capricious manner. While this litigation has only just started, it is part of a growing trend in contentious litigation involving the 340B program.

- **COVID-19 Program Auditing.** During the COVID-19 PHE, the federal government established numerous programs and waivers to support healthcare entities and other businesses amid the many atypical needs during the pandemic. Congress funded many of these programs via the CARES Act, and such programs included the Provider Relief Fund and the Payroll Protection Program. CMS also established a demonstration project to deliver throughout the country COVID-19 test kits directly to Medicare beneficiaries. The PHE officially ended in May 2023, but the federal government is just getting started on its auditing and investigations of how PHE program funds were used. In April 2023, the DOJ announced its Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud. This coordinated action resulted in numerous indictments and adverse administrative actions against providers for alleged false billings to federal programs and theft from federally funded pandemic programs. In August 2023, the DOJ announced the launch of two new COVID-19 Fraud Strike Forces. Per the DOJ's press release, "the COVID-19 public health emergency may have ended, but the Justice Department's work to identify and prosecute those who stole pandemic relief funds is far from over."
- **FCA Development in *SuperValu*.** In June, the U.S. Supreme Court issued its opinion in the much-anticipated *SuperValu* case. Prior to this decision, there was a circuit split in FCA litigation regarding whether an objective or subjective standard should be used to establish the knowledge element under the FCA. The Court unanimously held that "[t]he FCA's scienter element refers to [the defendants'] knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed." This holding is important for healthcare providers because the FCA is a primary tool for government enforcement actions involving allegedly false billings to federal health programs such as Medicare, Medicaid and TRICARE. Accordingly, this holding means that to prove a healthcare provider violated the FCA, the government (or a relator on the government's behalf) must be able to show that the provider subjectively believed that a claim was false at the time the provider submitted the claim to a federal program. Put another way, the provider's subjective mental state in submitting a claim is the relevant evidence to prove an FCA violation, not whether the provider's action was objectively reasonable.
- **Abortion Legislation and Litigation.** Following the Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health Organization*, the landscape of abortion access has been continually changing and varies drastically by state. Some states are taking action to restrict abortion access. For example, in October 2023, the Georgia Supreme Court allowed H.B. 481, a ban on abortion after approximately six weeks of pregnancy, to remain in effect. Similarly, in December 2023, the Texas Supreme Court ruled against a woman's petition to receive a health-preserving abortion. On the other hand, some states are acting to preserve abortion rights. New York state legislators approved an Equal Rights Amendment to the New York state constitution that aims to extend constitutional protections to guarantee the right to abortions. In the same vein, California has also expanded access and protections for reproductive healthcare.
  - » The FDA's approval of the abortion drug mifepristone has also been at the center of conflicting lawsuits since April 2023 following a Texas decision that blocked prescribing and dispensing of mifepristone nationwide, while a Washington decision on the same day enjoined the FDA from altering the status quo. On Dec. 13, the Supreme Court granted the petition for a writ of certiorari. These examples are only a fraction of the 2023 litigation and legislation activity on abortion.

FDA

- **Drug Shortages.** Drug shortages continued to be a substantive issue in 2023 and will continue to be a focus of the FDA and Congress in the 2024 election year. Various root causes have been expressed by government task forces, including lack of incentives for manufacturers to produce less-profitable drugs, a market that does not recognize and reward manufacturers for mature quality management systems, and logistical and regulatory challenges that make it difficult to recover after a supply disruption. For its part, the pharmaceutical industry believes that root causes include shifts in clinical practices, raw material shortages, changes in hospital and pharmacy contractual relationships with suppliers and wholesalers, natural

Winston Kirton

Lee Rosebush

disasters, and PHEs, to name a few. What all parties agree on is that quality and manufacturing issues play a key role in drug shortages. And the FDA will be ramping up its oversight of quality and manufacturing of pharmaceuticals with an increase in on-site inspections expected in the new year.

The FDA continues to work with industry on reporting and notification requirements aimed at early detection of shortages. The FDA has also prioritized and expedited the review of certain applications and inspections to help mitigate and prevent shortages. The FDA even considered allowing temporary importation of chemotherapy drugs from overseas manufacturers that are not currently approved to distribute in the United States.

Not to be outdone, Congress has gotten more involved with the introduction in 2023 of four bipartisan bills focused on preventing and mitigating drug shortages: the Mapping America's Pharmaceutical Supply Act (which would create a plan for the FDA and Department of Defense to map the U.S. pharmaceutical supply chain and use data analytics to identify and predict supply chain vulnerabilities and other national security threats); the Pharmaceutical Supply Chain Risk Assessment Act (which would require an interagency risk assessment of the U.S. pharmaceutical supply chain to help avoid supply shortages and disruptions before they occur); the Rolling Active Pharmaceutical Ingredient and Drug Reserve Act (which would award contracts to eligible generic drugmakers that require them to maintain a six-month reserve of critical generic drugs and their active pharmaceutical ingredients to ensure adequate supply in the event of a shortage); and the Drug Shortage Prevention Act (which would require manufacturers to notify the FDA of increased demand for critical drugs and disruptions to the supply of their ingredients).

Manufacturers are encouraged to continue early and open dialogue with the FDA regarding supply chain disruption and potential shortages; create, update and maintain risk management plans; and most certainly qualify and monitor third-party suppliers.

- **FDA Proposed New Laboratory Developed Test (LDT) Rule Will Impact Biopharma Drug Developers.** In September, the FDA announced a proposed rule titled Medical Devices; Laboratory Developed Tests (LDTs). The proposed rule seeks to amend the FDA's regulations to make explicit that in vitro diagnostics (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA proposed a policy under which the FDA intends to provide greater oversight of LDTs, through a phaseout of its general enforcement discretion approach to LDTs.

The FDA believes this proposal would also advance responsible innovation by both laboratory and nonlaboratory IVD manufacturers alike by better assuring the safety and effectiveness of IVDs offered as LDTs and removing a disincentive for nonlaboratory manufacturers to develop novel tests. The FDA has used the following guiding principles as the basis for the new rule:

1. IVDs Offered as LDTs Have a Significant Impact on Modern Medical Care.
2. Current Information Raises Serious Questions About Whether Patients Can Rely on IVDs Offered as LDTs.
3. Greater FDA Oversight Is Needed to Protect the Public Health.
4. The FDA Should Increase Oversight in a Manner That Recognizes the Current State of the Testing Market.

The Medical Device Amendments of 1976 (the MDA) amended the FD&C Act to create a comprehensive system for the regulation of devices intended for human use. In implementing the MDA, the FDA has generally exercised enforcement discretion such that it generally has not enforced applicable requirements with respect to most LDTs. Enforcement discretion for LDTs developed as a matter of general practice. However, the FDA believes that the risks associated with LDTs are much greater today than they were at the time of enactment of the MDA. Today's LDTs are generally used more widely by a more diverse population, with an increasing reliance on high-tech instrumentation and software, and more frequently for the purpose of guiding critical healthcare decisions. And today's LDTs are also more commonly manufactured with instruments or other components not legally marketed for clinical use and are more often used to inform or direct critical treatment decisions, to widely screen for common diseases, to predict personal risk of developing certain diseases, and to diagnose serious medical conditions such as cancer and heart disease.

Biopharmaceutical manufacturers developing complex medicines involving life-threatening diseases, such as cancer, neurological diseases, cardiovascular illness, infectious diseases and rare diseases that rely on companion diagnostics, will need to

take note of the impact of this rule on their development and commercialization programs in 2024.

Healthcare Litigation

S. Derek Bauer

- **Opioid Litigation.** In recent years, several large healthcare companies have faced a wave of legal action related to the opioid epidemic, including public nuisance claims brought by state governments and deceptive marketing claims. The BakerHostetler Healthcare Litigation team has assisted with several of these cases, including by serving as local counsel and securing a complete defense verdict in a first-of-its-kind jury trial where 21 individual plaintiffs sought to hold three pharmaceutical distribution companies liable for harms caused by their relatives' opioid abuse under the Georgia Drug Dealer Liability Act.
- **Ethylene Oxide Litigation.** There have been a significant number of new toxic tort lawsuits relating to healthcare companies' use of a medical sterilizer called ethylene oxide (EtO). In these cases, plaintiffs claim that they suffered various injuries as a result of exposure to EtO from the companies' facilities. The BakerHostetler Healthcare Litigation team has leveraged experience from multiple practice groups, including the Environmental and White Collar teams, to aggressively defend an international distributor of medical products and pharmaceuticals in over a dozen EtO cases first brought in the Southern District of Georgia, and earned an initial victory in prevailing in a motion to dismiss without prejudice.
- **Medical Cannabis Litigation.** As the medical cannabis industry continues to grow, the number of lawsuits involving cannabis companies is also on the rise. A common category of litigation in this nascent industry includes licensing disputes or disputes challenging the legality or constitutionality of a state's cannabis licensing regime. In Georgia, for example, over 15 unsuccessful applicants have filed numerous cases and appeals challenging the Georgia Access to Medical Cannabis Commission's decision to award production and distribution licenses to the six successful bidders. The BakerHostetler Healthcare Litigation team has been at the forefront of this litigation and is well-versed in the gamut of issues affecting medical cannabis companies.
- **"Specialty Pharmacy" Provider-Payor Disputes.** National payors are increasingly seeking to reduce costs and increase profits by implementing national policies, protocols and benefit plan design changes that seek to require providers to obtain certain specialty medications only from the payor's designated corporate affiliates or contracting partners (instead of the provider's on-site pharmacy or local pharmacy) and/or to have those medications administered only by the payor's designated providers. The BakerHostetler Healthcare Litigation team has been successfully litigating these issues on behalf of hospitals for the past several years and knows the payors' strategies well, having sued multiple national payors for breach of contract, illegal patient steering, false advertising and damages related to such specialty pharmacy programs.

Pharmacy

Lee Rosebush

Marc Wagner

- **Part D Drug Price Setting – Inflation Reduction Act.** On Aug. 29, CMS issued the inaugural list of drugs selected for price setting under the Inflation Reduction Act of 2022 (IRA). Those selected drugs are Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara and Fiasp.

  The IRA established an unprecedented system of drug price controls, under which "maximum fair prices" (MFPs) will be set. Categorical discounts ranging from 25 percent to 60 percent of the average sales price are mandated by the statute. The categories are defined by the products' time on the market. The IRA requires that "the Secretary shall develop and use a consistent methodology ... that aims to achieve the lowest maximum fair price for each selected drug." Thus, MFPs are likely to be set below the categorical discounts. The most recent CMS guidance on pricing methodology was issued on June 30. Under the methodology, prices will be set by fiat, not true negotiation. This is due to IRA-mandated penalties, lack of judicial review of key CMS decisions and other aspects of the price-setting process.

  Multiple lawsuits challenging the constitutionality of the IRA's drug-pricing provisions have been brought by members of the

pharmaceutical industry and trade organizations. Although some motions for preliminary injunction or summary judgment have been made, the lawsuits have yet to be resolved.

Several deadlines and other milestones have passed during this initial price-setting round. Manufacturers of selected drugs (Primary Manufacturers) will receive CMS' initial offer price by Feb. 1, 2024. By March 2 – just one month later – they must be ready to accept that price as the MFP or commence the so-called negotiations. Such negotiations will conclude by Aug. 1, and CMS will publish MFPs by Sept. 1, 2024. Those MFPs will become effective on Jan. 1, 2026. A detailed list of deadlines is available.

To develop a record supporting the highest available MFP, Primary Manufacturers should focus on demonstrating the high therapeutic value of the selected drug versus the value provided by therapeutic alternatives. Factors such as therapeutic advance and unmet medical need will be crucially important, especially in key user populations specified by the IRA (disabled, elderly, terminally ill, children, etc.).

To develop a record upon which to contest an unacceptable MFP, Primary Manufacturers additionally should focus on factors such as low quality of available comparative efficacy/safety evidence, reliance on anecdotal/opinion evidence over controlled evidence, inappropriate weight on real-world versus experimental evidence, reliance on inappropriate treatment outcomes, and cherry-picking of data by CMS. Many more important factors should be assessed.

Primary Manufacturers that face upcoming rounds of IRA price setting should begin preparing very early to meet mandatory data submission guidelines and to present the above-mentioned evidentiary records.

Healthcare Technology

- **Information Blocking.** Hefty monetary penalties for information blocking have been proposed for all actors, including health information technology (IT) developers and healthcare providers, ensuring that information blocking will need to be a key focus area for compliance. With IT developers being required to incorporate the ability to export electronic health information (EHI) via their health IT as of January 2024, we expect issues surrounding the portability of such health information to be a major touchpoint in 2024.
- **Artificial Intelligence.** The excitement and concern continue to mount around use of AI in the healthcare industry, which is accelerating at pace. AI's impact could be a disruptor in the industry. The U.S. Department of Health and Human Services issued a proposed rule in December 2023 that seeks to set standards for use of AI by health IT developers. The White House also announced that 28 healthcare providers and payors have voluntarily committed to the safe, secure and trustworthy use and purchase of AI, which should help set the framework for the industry on its adoption and use of AI.
- **Telehealth.** Telehealth continues to be a significant modality of care that is now established as a permanent care delivery model in the healthcare landscape. Regulators continue to wrangle with balancing state licensure and reimbursement laws that act as a barrier to care with patient safety and ensuring that providers are taking adequate precautions to ensure telehealth is delivered in a secure manner that guards patient privacy now that the OCR's Notice of Enforcement Discretion is no longer in effect.
- **Data Rights/Ownership.** Who owns what data continues to serve as a major negotiation point in contracts between healthcare customers and their vendors. This includes issues surrounding deidentification of data and secondary use cases of data generated from use of technologies.

Janine Anthony Bowen

Vimy Devassy

Healthcare Antitrust

Marc Schildkraut

- **FTC Activity.** The FTC has been very active in the healthcare area. As a result, the BakerHostetler Antitrust team continues to pay close attention to antitrust developments affecting the healthcare industry. Take a look at BakerHostetler's antitrust blog site. For example, see our recent blog post that discusses how Louisiana Children's Medical Center (LCMC) is not required to file premerger notification pursuant to the HSR Act, as a court ruled that LCMC did not have to file such a

notification because LCMC's hospital acquisition was subject to state Certificate of Public Advantage authorization.

- **Policy Statement Withdrawal.** In keeping with a more active FTC under the Biden administration, both the FTC and the U.S. Department of Justice withdrew two antitrust policy statements related to enforcement in healthcare markets: Statements of Antitrust Enforcement Policy in Health Care (published in August 1996) and Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (published in October 2011). Additionally, the DOJ rescinded its 1992 statement relating to healthcare markets, Department of Justice and FTC Antitrust Enforcement Policy Statements in the Health Care Area (Sept. 15, 1993). No changes were made in the underlying laws; nevertheless, both the FTC and DOJ stated that these statements were outdated and no longer reflected healthcare market realities, and that competition would be better promoted without these statements, which led to this action by the FTC and DOJ. Thus, healthcare entities engaged in such areas as hospital mergers, joint ventures, sharing of information, joint purchasing arrangements, accountable care organization development and physician network joint ventures – which were covered by the statements – should continue to review, revisit and monitor processes and procedures in those arrangements to ensure they remain antitrust compliant.
- **HSR Filing.** In a Notice of Proposed Rulemaking in August 2023, the FTC proposed significant changes to the premerger notification process and a comprehensive redesign of the process. If adopted, these proposed rules will significantly impact the way the FTC and parties approach mergers and other such transactions under the HSR Act. The proposed rules will significantly change the magnitude of information and documents the parties would be required to provide in the HSR filing with the FTC. Additionally, the proposed rules are targeting private equity transactions in healthcare and would specifically require information on roll-ups (with a 10-year lookback period), interlocking directorates and identification of co-investors and minority partners.

Long-Term Care

- **SNF Reporting Obligations.** On Nov. 15, CMS released a final rule (the Rule) to increase reporting obligations for Medicare skilled nursing facilities and Medicaid nursing facilities (collectively, SNFs) in order to "give CMS and the states a more complete background on the organizations and individuals that own, oversee, and facilitate the operations of nursing homes." The Rule implements portions of Section 6101 of the Patient Protection and Affordable Care Act (ACA) and Section 1124(c) of the Social Security Act (the Act), which previously required the disclosure of certain ownership, managerial and other information regarding SNFs, and is a result of CMS' articulated concerns regarding private equity company-owned (PEC) and real estate investment trust-owned (REIT) ownership in SNFs.
- **New Disclosures.** Under the Rule, SNFs will be required to disclose the following:

  1. Each member of the governing body of the SNF, including the name, title and period of service for each such member.
  2. Each person or entity who is an officer, director, member, partner, trustee or managing employee of the SNF, including the name, title and period of service.
  3. Each additional disclosable party, including whether that party is a PEC or a REIT. "Additional disclosable parties" include any person or entity that does any of the following:
     a. Exercises operational, financial or managerial control over the SNF or a part thereof; provides policies and procedures for any of the SNF's operations; or provides financial or cash management services to the SNF.
     b. Leases or subleases real property to the SNF, or owns part of the real property equal to or exceeding 5 percent of the aggregate value of such real property.
     c. Provides management or administrative services, management or clinical consulting services, or accounting or financial services to the SNF.
  4. The organizational structure of additional disclosable parties as well as a description of the relationship of each such party both to the SNF and to one another. "Organizational structure" includes:
     a. For an LLC, all managers and all members (regardless of ownership percentage).
     b. For a corporation, all shareholders with a 5 percent ownership interest or greater.
     c. For a partnership, all general partners and all limited partners with a 10 percent ownership interest or greater.

Emily Crosby

- **PECs and REITs.** PECs are defined broadly in the Rule and include indirect ownership holders as follows: "a publicly traded or non-publicly traded company that collects capital investments from individuals or entities and purchases a direct or indirect ownership share of a provider." Unlike PECs, REITs are defined by the Rule simply by reference to the definition contained in the Internal Revenue Code of 1986, as amended, 26 U.S.C. 856.
- **Timing of New Disclosures.** SNFs will be required to report the above information upon initial enrollment, renewal, revalidation, reactivation, change of ownership and change of information. As required under Section 6101(b) of the ACA, CMS intends to make any information provided pursuant to Section 1124(c) of the Act publicly available within one year after the Rule is published in the Federal Register. The Rule was slated to become effective on Jan. 16, 2024, and provided that (i) Medicare SNFs would not be required to make the new disclosures until the Form CMS-855A is revised to collect this data and is publicly available for use; and (ii) Medicaid SNFs would not be required to make the new disclosures until the applicable state Medicaid agency has established the means to collect them. It should be noted that CMS published a revised CMS-855A on Nov. 17 and that the form has been updated to include PECs and REITs.

  SNF providers should review these important changes carefully and consider their plans for reporting alongside some other new reporting obligations that will take effect in January 2024 under the new CTA.

Licensure and Provider Enrollment

Ernessa Brawley

Charlotte Combre

- **Medicare Enrollment Updates.** Over the past year, CMS initiated many changes to the Medicare enrollment process. While some of the changes were designed to enhance the needs of the providers and suppliers to make enrollment easier, there were changes that also created backlogs.

  CMS moved more processes to the Medicare Administrative Contractors (MAC) and the State Survey Agencies (SSA). In a surprise move, CMS removed the Regional Offices from the tie-in review process for hospitals and other institutional providers, which is now the responsibility of the SSA. The tie-in review includes not only new facilities and change of ownership but also new locations. The MAC continues to review the enrollment application but now sends its recommendation to the SSA. The SSA has the option to perform a survey prior to approving the tie-in and send it back to the MAC to obtain CMS' approval.

  In late 2023, CMS made key changes that require all enrolling and currently enrolled institutional providers to submit information on PEC or REIT ownership. As with other ownership interests, PECs and REITs must be identified if these entities have a 5 percent or more (direct or indirect) (1) ownership of, (2) partnership interest in and/or (3) managing control of the provider. This change necessitated revisions to the 855A form.

  Medicare simplified the process for enrolling providers who reassign their benefits by merging the 855R into the 855I paper application. All data previously collected in the 855R is now captured on the 855I. CMS moved the reporting of physician assistant employer arrangements to the reassignment section of the 855I. There is no change, however, in how physicians, nonphysician practitioners or organizations/groups report reassignment in Medicare Provider Enrollment, Chain, and Ownership System (PECOS). With the new 855I, CMS also recognized acupuncture services and compact licenses, added two new physician specialties (Adult Congenital Disease and Micrographic Dermatologic Surgery), and expanded practice location types to include telehealth.

  Lastly, revalidations were top of mind in 2023, as both CMS and Georgia Medicaid had massive revalidation campaigns to catch up on provider revalidations postponed during the COVID-19 pandemic.

- **Validation Edits for Providers with Multiple Service Locations.** CMS finally implemented its validation edits for providers with multiple service locations. Initially set to go into effect Jan. 1, 2017, the activation of the requirement was delayed several times. CMS required the edits due to the increase in the number of off-campus, outpatient, provider-

based departments of hospitals, which may be operated in a different payment locality than the main provider. Thus, to ensure accuracy for Medicare Physician Fee Schedule and Outpatient Prospective Payment System payments, CMS now uses the service facility address of the off-campus, outpatient, provider-based department of a hospital facility to confirm the locality. Medicare then validates that the service facility location is enrolled as part of the provider and an exact match to the facility's PECOS record.

Clinical Research

- **Informed Consent Guidance.** The FDA issued long-awaited updated guidance on informed consent in clinical trials. The guidance outlines the primary components of informed consent and the roles and responsibilities of institutional review boards, investigators and sponsors in the informed consent process.

Payal Cramer

- **Underrepresented Populations.** To address underrepresentation of diverse patient populations in clinical research, the FDA issued guidance on collection of postmarketing data on underrepresented populations. The guidance provides recommendations to help sponsors obtain safety and effectiveness data on drugs in the postmarket setting for historically underrepresented populations in clinical trials.
- **Decentralized clinical trials.** The FDA issued draft guidance on decentralized clinical trials to support the development of drugs, biologics and devices. Decentralized clinical trials apply advances of technology and other innovations to the clinical trial space with the goal of increasing access to trial participation and diversity in trial populations.

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