American Health Law Association
The Year in Review Topic Team Outlines

The pace of developments in health care and health law accelerates each year. To help AHLA members keep up to date with these developments, AHLA is providing this paper as an extra resource to accompany the Year in Review slides.

We have assembled teams of outstanding lawyers for each health care topic, who have submitted outlines of the significant developments over the last year in their areas of expertise. We think this will be an outstanding resource for AHLA members.

As the Year in Review speakers, we greatly appreciate the Topic Teams' efforts to capture these recent developments, which were enormously helpful to us in preparing for this talk.

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I. ANTITRUST

(Updated January 2022)

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1. Provider Merger Enforcement

Authors: Michael Fischer and Najla Long, Bradley

a. Hackensack Meridian Health/Englewood Healthcare Foundation

- In December 2020, the FTC sued to block Hackensack Meridian Health's ("HMH") acquisition of Englewood Healthcare Foundation ("Englewood").[1]
    - HMH is the largest healthcare system in New Jersey, operating 12 general acute care ("GAC") hospitals, two children's hospitals, two rehabilitation hospitals, and one behavioral health hospital; and employing more than 7,000 physicians. In Bergen County, HMH operates two of the six hospitals located there, including a 781-bed flagship facility.
    - Englewood is one of very few remaining independent hospitals in Northern New Jersey. In addition to Englewood Hospital and Medical Center (531 licensed beds), it also operates Englewood Physician Network (over 500 physicians providing care at more than 100 locations across six counties in New Jersey and New York), and the Englewood Healthcare Foundation.
    - The FTC defined the relevant geographic market as no broader than Bergen County (the main area of competition for HMH, Englewood, and Pascack Valley Medical Center, which HMH partially owns).
    - Post-transaction, HMH would be one of only three GAC providers in Bergen County. The complaint alleges that the transaction would increase concentration in the relevant market to a presumptively unlawful level: post-transaction, the Herfindahl-Hirschman Index ("HHI") would increase by approximately 900 to almost 3,000, well beyond the post-acquisition market concentration level of 2,500 points and an increase of 200 points that is the threshold for presumptive illegality under the 2010 Horizontal Merger Guidelines.[2]
- In a sealed opinion, Judge John Michael Vazquez of the United States District Court for the District of New Jersey granted the FTC's request for a preliminary injunction on August 4, 2021. HMH and Englewood appealed the preliminary injunction to the

[1] Complaint, In the Matter of Hackensack Meridian Health, Inc./Englewood Healthcare Foundation, Docket No. 9399 (Dec. 3, 2020), *available at* https://www.ftc.gov/enforcement/cases-proceedings/2010044/hackensack-meridian-health-inc-englewood-healthcare-foundation.

[2] *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (2010), *available at* https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

Third Circuit Court of Appeals on August 26, 2021.

- On appeal, the merging parties advance a number of arguments in support of the transaction, including:

    - That Bergen County is an inappropriate geographic market due to robust evidence that commercial health plans and employers do not treat Bergen County as a distinct market, and do not view HUMC and Englewood as substitutable facilities for networks or plans.

    - That the FTC has not demonstrated "price discrimination" to customers as required to establish anticompetitive harm under the FTC's Horizontal Merger Guidelines. According to defendants, managed care plans negotiate their contracts on a regional basis (e.g., northeastern New Jersey), thereby disallowing the prospect of discriminatorily high rates for Bergen County subscribers. Because the FTC cannot establish price discrimination as the result of the transaction, the defendants argue, its prima facie case of anticompetitive effects fails.

    - That the lower court committed error by using patients' willingness to pay for the economic analysis, which allegedly has no bearing on insurers' willingness to pay and therefore is the incorrect metric to use.

- In its reply brief, the FTC argues:

    - That the element of price discrimination is applicable only in the context of a traditional supplier-customer relationship, whereas health care markets are multi-dimensional, involving suppliers (hospitals), insurers, and those covered by insurers.

    - That insurers would experience higher prices from HMH/Englewood, which in turn would be passed onto their members in the form of higher premiums – an indirect form of price discrimination for Bergen County residents who prefer to use local hospitals. In support of this argument, the FTC cites testimony and other evidence that insurers would be compelled to agree to post-merger price increases because they would not be able to offer a marketable network without the participation of HMH/Englewood.

    - That the FTC's economist expert analyzed the geographic market from a "hospital-based" perspective (i.e., the area where hospitals within Bergen County or contiguous counties derive their patients). Hospital-based methodology does not require a showing of price discrimination under the Guidelines (which the merging parties acknowledge in their own briefing).

- Nine amicus briefs have been filed by national trade organizations, including the American Hospital Association and Association of American Medical Colleges, in support of the transaction.

- A number of professors, economists, industry experts as well as twenty-six state attorneys general, including Pennsylvania, New York and California, have filed briefs in support of the FTC urging the Third Circuit to affirm the district court decision.

- In 2020, the state of New Jersey approved the disposition of Englewood's charitable assets pursuant to the transaction, but has not otherwise taken a stance for or against the transaction.

- Oral arguments related to the appeal took place on December 8, 2021 with a decision expected in early 2022.

b. Vazquez v. Indiana University Health Inc.

- In June 2021, an independent vascular surgeon practicing in southern Indiana ("Plaintiff") sued Indiana University Health, Inc., Indiana University Health Bloomington, Inc., IU Health Bloomington Hospital (collectively "IU Health"), and IU Health's Chief Medical Officer over allegations of monopolization, anticompetitive conduct and merging, breach of contract, and defamation.[3]

    - IU Health operates 14 hospitals throughout Indiana including Bloomington Hospital. Patients are often transferred to Bloomington Hospital because they retain the only Level III Trauma center, the only Level I Heart Attack center, and the only Stroke Center in the region.[4]

    - The Plaintiff is a vascular surgeon who previously retained admitting privileges at multiple IU Health facilities. As part of the recent acquisitions by IU Health, the plaintiff remained the only independent vascular surgeon in the area.[5]

    - IU Health is alleged to control 92.5% of inpatient discharges in the Bloomington area and 97% of primary care physicians because of anticompetitive acquisitions. As a result of these acquisitions, the Plaintiff alleges that this has led to localized healthcare costs and decreased quality of care.[6]

- In November 2021, the U.S. District Court for the Southern District of Indiana dismissed the Plaintiff's claims under Section 2 of the Sherman Act and Section 18 of the Clayton Act with prejudice. The state law claims for violations of Ind. Code § 24-1-2-2 and Ind. Code § 24-1-2-7, breach of contract, and defamation were dismissed

[3] Heebink, Kendall, *Surgeon Sues Indiana University Health, Alleging Monopolization*, News Health Healthcare (June 14, 2021).
[4] Order, *Vasquez v. Indiana University Health, Inc.*, Case No. 1:21-cv-01693-JMS-MG (S.D. Ind.) (Nov. 5, 2021).
[5] *Id*.
[6] Complaint, *Vasquez v. Indiana University Health, Inc.*, Case No. 1:21-cv-01693-JMS-MG (S.D. Ind.) (June 11, 2021).

without prejudice.[7]

- In granting the defendant's motion to dismiss, the Court considered several issues:
  - Plaintiff's geographic market definitions were viewed as "sufficiently contradictory to render them implausible" because he alleged patients traveled several hours to receive care in Bloomington and yet the geographic market should be limited to the immediate Bloomington area.
  - The Court also scrutinized when the Plaintiff's claim accrued and thus the statute of limitations began to run. Generally, there is a four-year statute of limitations on damages under the Clayton Act. The statute begins to run "as soon as the acquisition takes place." However, where a merger only produces anticompetitive effects post-merger, the statute begins to run at the time the injury occurred. The plaintiff alleged in his complaint that the injury took place in 2017, around the time that IU Health acquired Premier Healthcare; not two years later when his admitting privileges were revoked.
  - Finally, the Court considered whether it must exercise supplemental jurisdiction over the state law claims. The Court determined that judicial economy considerations, convenience, and fairness and comity warranted dismissal of the complaints without prejudice.

- In November 2021, the plaintiff filed an appeal to the U.S. Court of Appeals for the Seventh Circuit.

c. Marion HealthCare, LLC v. Southern Illinois Hospital Services

- In July 2021, Marion HealthCare ("Plaintiff"), a multispecialty surgery center, sued to enjoin the combination of Southern Illinois Hospital Services ("SIHS") and Harrisburg Medical Center ("Harrisburg") (collectively, the "Defendants") alleging that the transaction would "substantially reduce competition in an already highly concentrated market, would harm the public and would cause antitrust injury."[8]
  - SIHS is an Illinois not-for-profit corporation that owns and operates two acute care general hospitals, a critical access hospital, outpatient ambulatory surgery centers, and numerous physician practices and primary and specialty care clinics throughout southern Illinois.[9]
  - SIHS announced its intent to buy Harrisburg and create a four-hospital system serving a 16-county region. This purchase would leave only one non-SIHS

[7] *See*, Final Judgement Pursuant to Fed. R. Civ. P. 58, *Vasquez v. Indiana University Health, Inc.*, Case No. 1:21-cv-01693-JMS-MG (S.D. Ind.) (Nov. 5, 2021).
[8] Paavola, Alia, *Illinois hospitals sued over plan to create 4-hospital system*, Becker's Healthcare (Aug. 2, 2021).
[9] Complaint, *Marion HealthCare, LLC v. Southern Illinois Hospital Services et al*, Case No. 3:21-cv-00873 (S.D. Ill.) (July 7, 2021)

affiliated acute care general hospitals in the relevant market.

- Plaintiff alleges that this merger would violate Section 7 of the Clayton Act, Section 2 of the Sherman Act, and Sections 3(2) and (3) of the Illinois Antitrust Act (740 ILCS 3).[10] In doing so, Plaintiff invoked public policy promulgated by the Biden Administration which, in part, seeks to "enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony – especially as these issues arise in…healthcare markets…"[11]

    - Plaintiff also alleges that the relevant geographic market consists of a seven-county area including the Illinois counties of Jackson, Williamson, Franklin, Johnson, Perry, Saline, and Union. Currently, SIHS's pre-merger market share of inpatient acute care general hospital services is 71.1%, resulting in a "highly concentrated" market under the Herfindahl-Hirschman Index (HHI). The Plaintiff alleges that as a result of the merger, SIHS' HHI would increase 445 points, more than twice the amount necessary to presume anticompetitive effects.

- In October 2021, the Defendants filed a motion to dismiss for lack of subject matter jurisdiction and for failure to state a claim.[12] Broadly, the Defendant's argue that:

    - Plaintiff did not plausibly plead any injury in fact. Instead, the Plaintiff pled to speculative injury and not "actual or imminent" injury citing "potentially" raised costs to patients, preventing the "possibl[e] acquisition of Harrisburg by Plaintiff, future disruption of established referral patterns, and enhancement of Defendant's ability to attract and retain surgeons who might otherwise join Plaintiff.

    - Plaintiff did not allege any injury to itself or to competition.

    - Plaintiff failed to allege proximate cause. Instead, the Plaintiff's complaint alleges injury that is "too remote and too attenuated to support proximate cause."

    - Because no amendment can save the complaint, the Court should dismiss the complaint with prejudice.

d. Colucci v. Health First

- In April 2021, three plaintiffs alleged that Health First, Inc. engaged in "pervasive and long-term exclusionary conduct" as a means of maintaining a monopoly in the

[10] *Id*.
[11] Complaint, *Marion HealthCare, LLC v. Southern Illinois Hospital Services et al*, Case No. 3:21-cv-00873 (S.D. Ill.) (July 7, 2021).
[12] Defendant's Motion and Memorandum of Law in Support of Their Motion to Dismiss Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), *Marion HealthCare, LLC v. Southern Illinois Hospital Services et al*, Case No. 3:21-cv-00873 (S.D. Ill.) (Oct. 1, 2021).

market for acute care in Florida.[13]

- Health First was formed in 1995 by the joining of Holmes Regional Medical Center and Palm Bay Hospital and Cape Canaveral Hospital. At this time, Health First because the sole provider in Southern Brevard County because it controlled the only two acute care hospitals in the county. Since then, the only other acute care hospital to enter the market was Wuesthoff-Melbourne in 2002.

- Health First was initially sued for anticompetitive conduct in *Omni Healthcare Inc. v. Health First*, No. 6:13-cv-1509-Orl-37DAB (filed Sept. 27, 2013). Physician competitors of Health First sued the system for anticompetitive conduct. On August 16, 2016, Health First settled the case which was subsequently voluntarily dismissed.[14] The complaint alleges that Health First was "unchastised" by the settlement and continued efforts to maintain and strengthen its monopoly in violation of Sections 1 and 2 of the Sherman Act.

- The plaintiffs allege:

    - Monopolization of the acute care market in violation of Section 2 of the Sherman Act resulting in reduced competition and higher-than-competitive fees paid to Health First. Plaintiffs allege this has reduced quality of care to patients far below competitive standards.

    - Agreements in restraint of trade in violation of Section 1 of the Sherman Act by entering into exclusive-dealing agreements with physicians, and by organizing a group boycott of competing hospitals.

    - Violation of the Florida Antitrust Act through anticompetitive conduct. Specifically, Health First's alleged agreements with physicians and organization of a group boycott in violation of Fl. Stat. § 542.18 which prohibits "[e]very contract, combination, or conspiracy in restraint of trade or commerce in [the] state." Secondly, plaintiffs allege that Health First is in violation of Fl. Stat. § 542.19 which makes it "unlawful for any person to monopolize, attempt to monopolize, or combine or conspire with any other person or persons to monopolize…"

- Plaintiffs seek to enjoin the anticompetitive conduct and claim treble damages for the class.

- In August 2021, plaintiffs amended the complaint twice to include additional causes action including horizontal market division in restraint of trade and exclusive dealing in restraint of trade.[15] This was made necessary by the U.S. Dist. Ct. for the Middle

[13] Rizzi, Corrado, *Health First Hit with Antitrust Class Action in Florida*, Newswire (Apr. 20, 2021).
[14] Complaint, *Colucci v. Health First, Inc.,* Case No. 6:21-cv-00681 (M.D. Fla.) (Apr. 19, 2021).
[15] Second Amended Class Action Complaint, *Colucci v. Health First, Inc.,* Case No. 6:21-cv-00681 (M.D. Fla.) (Aug. 25, 2021).

Dist. of Florida dismissing the original complaint without prejudice for being a "shotgun" complaint containing multiple counts where each count adopts the allegations of all preceding counts.

e. Board of Dental Examiners of Alabama Settles Teledentistry Charges

- In October 2021, the Federal Trade Commission ("FTC") filed a complaint alleging the Board of Dental Examiners of Alabama ("Dental Board") excluded emerging competition from new and innovative teledentistry platforms.[16] As a result of this complaint, the Dental Board agreed to stop requiring on-site supervision by licensed dentists of alignment scans of prospective patients' mouths seeking to address misaligned teeth or gaps between teeth.[17]

- The Dental Board consists of six licensed dentists and one licensed dental hygienist who administer dental licensing in Alabama. In September 2018, the Dental Board sent a letter to new companies such as SmileDirectClub, Candid Co., and SmileLove, LLC (collectively, the "Companies") demanding they stop using non-dentist personnel to take scans of patients' mouths. As a result, SmileDirectClub abandoned plans to open additional locations in Alabama.

- The Companies created a new treatment model in which patients are fitted for clear aligners following a visit to a storefront location where a digital scan is performed by a dental assistant. The scan is reviewed by a dentist working remotely and is "substantially less expensive than traditional treatments."[18] In response, the Dental Board amended Alabama Admin. Code 270-X-3.10(o)(2) to prohibit non-dentists from performing digital scans without on-site dentist supervision.

- The complaint alleges that the Dental Board's actions have "unreasonably restrained competition for the treatment of malocclusion in Alabama."[19]

    - Additionally, the complaint alleges that the amendment offers no procompetitive benefits sufficient to justify the harmful effect on competition. As a result, the alleged acts by the Dental Board "constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

    - According to the complaint, state regulatory boards comprised of active market participants (such as licensed dentists continuing to practice as is the case here)

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[16] *See,* Complaint, In the Matter of Board of Dental Examiners of Alabama, *available at* https://www.ftc.gov/system/files/documents/cases/1910153_alabama_bd_dental_examiners_complaint.pdf

[17] *Alabama Board of Dental Examiners Agrees to Settle FTC Charges that it Unreasonably Excluded Lower Cost Online and Teledentistry Providers from Competition,* Federal Trade Commission (Sept. 28, 2021), *available at* https://www.ftc.gov/news-events/press-releases/2021/09/alabama-board-dental-examiners-agrees-settle-ftc-charges-it?utm_source=govdelivery

[18] *See,* Complaint, In the Matter of Board of Dental Examiners of Alabama, *available at* https://www.ftc.gov/system/files/documents/cases/1910153_alabama_bd_dental_examiners_complaint.pdf

[19] *Id*.

can violate antitrust law by publicizing and enforcing rules that harm competition in the industry in which board members participate.[20]

- The FTC voted 5-0 to issue the complaint and accept the proposed consent order for public comment. The consent order requires the Dental Board to:
    - Cease and desist from requiring on-site supervision by dentists when non-dentists perform intraoral scans on prospective patients
    - Cease and desist from requiring non-dentists affiliated with clear aligner platforms to maintain on-site dentist supervision when performing intraoral scanning
    - Provide notice of the proposed order to board members and employees, and to certain dentists and clear aligner platforms
    - Notify the commission of any changes to its rules related to intraoral scanning or clear aligner platforms.

f. Taro, Sandoz, and Apotex DOJ Civil Settlements

- In October 2021, Taro Pharmaceuticals USA, Inc. ("Taro"), Sandoz Inc. ("Sandoz") and Apotex Corporation ("Apotex"), three generic pharmaceutical manufacturers, agreed to pay a total of $447.2 million to resolve alleged violations of the False Claims Act.[21]

- The Anti-Kickback Statute ("AKS") prohibits companies from receiving or making payments in return for arranging the sale or purchase of items for which payment may be made by a federal health care program. The False Claims Act ensures that the United States is fully compensated when it is the victim of kickbacks paid to further anticompetitive conduct.

- The Department of Justice alleged that between 2013 and 2015, all three companies paid and received compensation prohibited by the AKS by making arrangements with other pharmaceutical manufacturers to control price, supply, and allocation of generic drugs. The result of such a scheme was to "increase costs both to federal health care programs and beneficiaries."[22]

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[20] *Alabama Board of Dental Examiners Agrees to Settle FTC Charges that it Unreasonably Excluded Lower Cost Online and Teledentistry Providers from Competition,* Federal Trade Commission (Sept. 28, 2021), *available at* https://www.ftc.gov/news-events/press-releases/2021/09/alabama-board-dental-examiners-agrees-settle-ftc-charges-it?utm_source=govdelivery

[21] *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs,* Department of Justice Office of Public Affairs (Oct. 1, 2021) *available at* https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability

[22] *Id*.

- Taro manufactures etodolac, a NSAID, and nystatin-triamcinolone cream, an antifungal medicine. As a result of the allegations and settlement, Taro agreed to pay $213.2 million.

- Sandoz manufactures benazepril, used to treat hypertension, and clobetasol, a corticosteroid. As a result of the allegations and settlement, Sandoz agreed to pay $185 million.

- Apotex manufactures pravastatin, a drug used to treat high cholesterol. As a result of the allegations and settlement, Apotex agreed to pay $49 million.

- Each company is also subject to a 5-year Corporate Integrity Agreement ("CIA") in order to "promote transparency and accountability by requiring the companies to report price-related information to OIG and mandating individual certifications by key executives involved in pricing and contracting functions."[23] In addition to the internal monitoring and price transparency provisions, the CIAs "also require the companies to implement compliance measures including risk assessment programs, executive recoupment provisions and compliance-related certifications from company executives and board members."[24]

- Prior to the payment of civil penalties and implementation of CIAs, each company entered into deferred prosecution agreements with the Antitrust Division to resolve corresponding criminal charges. Taro paid an additional criminal penalty of $205.6 million, Sandoz paid $195 million, and Apotex paid $24.1 million. Each of these deferred prosecution agreements also included an admission of guilt for price fixing.

- In a press release, the United States Attorney for the Eastern District of Pennsylvania made clear that the office "will continue to aggressively pursue these violations of the Anti-Kickback Statute and the False Claims Act and obtain significant recoveries."[25]

B. Pharmaceutical and Medical Device Merger Enforcement

Authors: Katharine O'Connor and Alexandra Lewis, McDermott Will & Emery
(As of June 2021)

1. Ossur/College Park and Otto Bock Healthcare/Freedom Innovations Approved with Divestitures

a. Ossur/College Park

- Ossur Hf and College Park Industries, Inc., are manufacturers of prosthetic limbs.

[23] *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs,* Department of Justice Office of Public Affairs (Oct. 1, 2021) *available at* https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability
[24] *Id*.
[25] *Id*.

Ossur agreed to purchase College Park in July 2019. On April 6, 2020, the FTC filed a complaint alleging that the acquisition would harm competition in the market for myoelectric elbows (prosthetics that are controlled with the electrical signals generated naturally by your own muscles).

- The transaction was not reportable under the Hart-Scott-Rodino Act, but still caught the attention of the FTC.

- At the time the complaint was filed, College Park was the leading supplier of myoelectric elbows. Ossur Hf was in the process of developing its own, competing line of myoelectric elbows. The FTC alleged that the only competitors for the manufacture and supply of myoelectric elbows in the U.S. were College Park, Otto Bock HealthCare North America, and Fillauer LLC.

- The FTC argued that the acquisition would have the effect of eliminating Ossur Hf as a competitor, thereby reducing the number of competitors in the myoelectric elbow market from 4 to 3.

- The Commission vote to issue the complaint was 5-0.

- On April 7, 2020, the FTC announced a consent agreement with the companies. Under the agreement, College Park agreed to divest its myoelectric elbow business to Hugh Steeper Ltd., a UK-based prosthetic maker.

- On May 28, 2020, the FTC approved the final order 4-0-1, with Rebecca Kelly Slaughter not participating.

b. Otto Block/Freedom Innovations

- Otto Bock HealthCare North America Inc. and Freedom Innovations are prosthetics manufacturers. In September 2017, the companies announced that Otto Bock would be acquiring Freedom Innovations. In December 2017, the FTC issued an administrative complaint arguing that the transaction would harm competition in the market for microprocessor prosthetic knees.

  - Like Ossur/College Park, the acquisition was not reportable under the Hart-Scott-Rodino Act, but was nonetheless investigated by the FTC.

  - At the time the complaint was filed, Otto Bock was the leading manufacturer and supplier of microprocessor prosthetic knees in the U.S. Freedom Innovations was the second-largest manufacturer and supplier. The FTC argued that competition between the two companies resulted in substantially lower prices to prosthetic clinics, and provided significant design improvements.

- In May 2019, Chief Administrative Law Judge D. Michael Chappell upheld the FTC's complaint, finding that competition between the two companies spurred

innovation and enabled customers to negotiate lower prices, giving rise to a presumption that the acquisition may substantially lessen competition. Judge Chappell ordered Otto Bock to divest the assets of Freedom Innovations to an FTC-approved buyer.

  - Otto Bock appealed the decision to the full panel of FTC Commissioners.

- In November 2019, the Commissioners issued an Opinion and Final Order upholding Judge Chappell's decision, requiring the two companies to unwind the acquisition and for Otto Bock to divest Freedom Innovation's business with limited exceptions.

  - The Commission voted 5-0 to unwind the acquisition. **It marked the first time that group of Commissioners ordered a consummated acquisition unwound.**

- Otto Bock appealed the decision to the D.C. Circuit, but eventually asked the Court to stay its review pending settlement negotiations with the FTC.

  - In October 2020, Otto Bock filed a divestiture application, offering to divest certain assets including all microprocessor prosthetic knee products and technology to Proteor, Inc., an established global manufacturer and supplier of lower-limb prosthetic devices.

- The FTC approved Otto Bock's divestiture application in December 2020, after a public comment period, with a vote of 5-0.

2. Abbvie/AlleZrgan Approved with Divestitures (3 to 2 Vote with Strong Dissents)

- AbbVie announced it was acquiring Allergan for $63 billion in June 2019.

- The FTC filed a complaint and announced a consent agreement with the companies on May 5, 2020.

  - The FTC's investigation spanned ten months, and included cooperation with antitrust agencies in Canada, the EU, Mexico and South Africa, as well as several state Attorneys General.

  - The Complaint alleged that the transaction would harm current competition in the market for exocrine pancreatic insufficiency (EPI) drugs, and future competition in the market for an IL-23 inhibitor in late-stage development, which is used to treat ulcerative colitis and Crohn's disease.

  - The FTC alleged that four companies sell prescription drugs to treat EPI in the U.S. At the time the complaint was filed, AbbVie was the largest supplier, and Allergan was the second-largest supplier. Together, they accounted for more than 95% of the market.

- The FTC alleged that Johnson & Johnson was the only company with an FDA-approved IL-23 inhibitor at the time the complaint was filed. AbbVie and Allergan each had IL-23 inhibitors in late-stage development.

- Allergan shareholders also brought a class action lawsuit to slow the deal, arguing that AbbVie did not disclose material information in the deal's proxy statement. The lawsuit was dismissed around the time that AbbVie and Allergan reached their consent agreement with the FTC.

- The consent agreement required Allergan to divest its assets related to EPI drugs Zenpep and Viokace to Nestle, S.A. The agreement further required Allergan to transfer Allergan's rights and assets related to its in-development IL-23 inhibitor, called brazikumab, to AstraZeneca.

- The FTC vote to issue the complaint and accept the proposed consent order for public comment was 3-2, with Rohit Chopra and Rebecca Kelly-Slaughter dissenting.

  - The majority stated that the companies' product portfolios were "largely complementary," and that the divestitures outlined in the consent agreement sufficiently addressed concerns over potential price hikes or stifled innovation as a result of the merger.

  - The dissent was concerned over divesting drugs to Nestle SA, a company that did not sell pharmaceuticals at the time. The dissent also expressed concern that AstraZeneca would have no incentive to continue developing the IL-23 inhibitor because it paid nothing for the drug development project, and would be free to re-license the business to another company.

- In September 2020, the FTC approved the transaction and consent agreement. The vote was 3-1-1, with Commissioner Rohit Chopra voting no and Commissioner Rebecca Kelly Slaughter not participating.

3. Stryker/Wright Medical Group Approved with Divestiture

- Stryker Corporation and Wright Medical Group N.V. are medical device companies. In 2019, Stryker announced it was acquiring Wright for $4 billion. On November 3, 2020, the FTC filed a complaint, alleging that the merger would have anticompetitive effects in two product markets: total ankle replacements and finger joint arthroplasty implants. At the time the complaint was filed:

  - Wright was the largest supplier of total ankle replacements and Stryker was third-largest supplier. Together, they accounted for approximately 75% of the U.S. market.

  - Stryker was the second-largest supplier of finger joint arthroplasty implants and

Wright was the third-largest supplier. Together, the companies had over 50% market share of the U.S. market.

- The FTC also filed a proposed consent agreement on November 3, 2020. The agreement required the companies to divest all assets related to Stryker's total ankle replacements and finger joint implant products to DJO Global.

- On December 17, 2020, the FTC approved the consent agreement with a Commission vote of 5-0. The FTC worked cooperatively with the UK Competition and Markets Authority.

4. DOJ/FTC Issue New Vertical Merger Guidelines

Authors: Katharine O'Connor and Alexandra Lewis, McDermott Will & Emery
(As of June 2021)

- The FTC and DOJ released their final Vertical Merger Guidelines in June 2020. These Guidelines address mergers between different firms along the supply chain. The guidelines codify existing theories of potential harm and identify potential efficiencies and price benefits from vertical integration.

- According to the Vertical Merger Guidelines, in analyzing the potential harm of a vertical transaction the antitrust enforcement agencies will ask whether the parties, after they have merged, will have the ability or incentive to foreclose rivals.

    - For example, if a hospital system acquires an ambulatory care provider in the same geographic area, will the merged entity have the ability to force payors into an exclusive arrangement that limits the payors' ability to contract with other hospitals or ambulatory care providers? Or, will the merged entity have the ability to cherry-pick profitable cases and refer less profitable cases to other entities?

    - In a vertical merger between an insurer and a pharmacy, the concern is that insurer enrollees could use only the payor's pharmacy or have to pay higher fees to use a different pharmacy. Either result forecloses retail pharmacy competition.
- Commissioners Chopra and Slaughter dissented from final guidelines, with criticism that the Guidelines incorrectly view vertical mergers as "often procompetitive."

    - Commissioner Chopra is nominated to head the Consumer Financial Protection Bureau. Commissioner Slaughter now is acting FTC Chair, and is in the running for nomination to become Chair.

- There is a strong likelihood of increased enforcement in vertical merger space under the Biden administration.

5. Multi-jurisdictional working group aimed at building a new approach to pharmaceutical mergers.

Authors: Katharine O'Connor and Alexandra Lewis, McDermott Will & Emery
(As of June 2021)

- In March 2021, the antitrust agencies and state Attorneys General announced their participation in a cross-border working group aimed at building a new approach to pharmaceutical mergers. The working group is spearheaded by the FTC and will include the DOJ Antitrust Division, state Attorneys General, the Canadian Competition Bureau, the European Commission and the U.K. Competition and Markets Authority.

- Among other issues, the working group plans to update theories of harm, assess characteristics of a successful divestiture buyer, and consider price-fixing and other "regulatory abuses" in merger review.

- One consideration that is likely to be part of this review is whether the traditional approach of evaluating transactions based on narrow product overlaps is the proper framework, or whether regulators should evaluate these transactions using a broader perspective.

C. Non-Merger Federal and State Enforcement

1. Provider Enforcement

Authors: Michael Fischer and Najla Long, Bradley
(Updated June 2021)

a. DOJ challenge of Geisinger's minority interest in Evangelical Community Hospital

- In August 2020, the Department of Justice Antitrust Division ("DOJ") filed a lawsuit in the United States District Court for the Middle District of Pennsylvania challenging Geisinger Health System's recent transaction with a competing hospital, Evangelical Community Hospital.[26]

    - During the pendency of the lawsuit, Geisinger and Evangelical are subject to a hold-separate agreement entered into in October 2019.

- Pursuant to the self-styled "Collaboration Agreement" executed in February 2019, Geisinger acquired a 30% interest in Evangelical while committing to invest $100 million in that hospital. In return, Geisinger received rights of first offer and first refusal with respect to Evangelical's future competitive initiatives. Geisinger also

[26] *See* Complaint, *United States v. Geisinger Health et al.* (M.D. Pa.) (Aug. 5, 2020), *available at* https://www.justice.gov/opa/press-release/file/1301656/download.

secured power over Evangelical's use of such funds.

  - Post-transaction, the parties would operate five of the eight hospitals in a six-county area in central Pennsylvania and, combined, would account for 71% of inpatient general acute care discharges in that area.

- According to the DOJ's complaint, Geisinger's partial acquisition of Evangelical was undertaken in lieu of a full acquisition because the parties recognized that a full acquisition would pose a substantial antitrust risk.

  - After the letter of intent was originally signed in 2018, a senior Geisinger employee allegedly wrote that the partial acquisition agreement was "[k]inda smart really" because it "[d]oes not require AG approval," in an acknowledgement of the significant antitrust risk posed by a full acquisition and an effort to avoid antitrust review.

  - Moreover, in structuring the transaction, the parties sought to mitigate any concerns about potential competitive harm by agreeing to negotiate separately with commercial health plans.

- The DOJ concluded that the transaction was, on balance, anticompetitive because it reduced the parties' incentive to compete going forward as well as facilitated collusion through the sharing of competitively sensitive information between them.

  - Geisinger and Evangelical have a history of coordinating with each other in the past via no-poach agreements, lending credence to DOJ's principal concern: that Geisinger could raise prices at its hospital, causing patients to divert to Evangelical, which would increase the value of its investment in Evangelical. In that sense, Geisinger would gain market power to profitably raise prices at its own hospitals.

  - Geisinger may also be viewed by DOJ as somewhat of "bad actor" from an antitrust standpoint. The complaint notes that Geisinger has had multiple transactions challenged in the past.

- In March 2021, DOJ announced that the parties reached a settlement to resolve the competition concerns.[27] Under the terms of the settlement:

  - Geisinger's ownership interest in Evangelical is limited to a 7.5% passive investment (Geisinger originally sought a 30% interest in Evangelical).

  - Geisinger is prohibited from exercising any control or influence over Evangelical,

[27] *See* Press Release, Justice Department Resolves Antitrust Case Against Leading Central Pennsylvania Health Care Providers (March 3, 2021), *available at* https://www.justice.gov/opa/pr/justice-department-resolves-antitrust-case-against-leading-central-pennsylvania-health-care.

including rights of first offer or first refusal.

- This case represents a departure from traditional antitrust enforcement in that it focuses on the alleged dampening of competition from a partial acquisition, notwithstanding a transactional structure that does not combine the price-setting function, which traditionally has been the primary determinant of accretive market power.

b. $100M criminal market allocation settlement against Florida Cancer Specialists & Research Institute

- In April 2020, the Department of Justice Antitrust Division ("DOJ") announced that it had brought a one-count felony charge against Florida Cancer Specialists & Research Institute, LLC ("FCS"), an oncology group headquartered in Fort Myers, Florida, for conspiring with another provider group – "Oncology Company A" – to suppress competition by allocating cancer patients in Southwest Florida.[28] DOJ signaled that this action is the first in a broader investigation of market allocation in the oncology industry.

- The charge alleged that the parties, among other things, agreed through "conversations and communications" that FCS would provide medical oncology services but not radiation oncology services and that Oncology Company A would provide radiation oncology services to the exclusion of medical oncology services.[29]

- The conspiracy was alleged to have dated back to as early as 1999 and was in effect until at least September 2016. During the relevant time period, FCS – one of the largest private oncology practices in the country – generated more than $950 million in revenue. The DOJ alleged that the conspiracy to allocate services was a *per se* violation of the Sherman Act, meaning that the conduct at issue was conclusively presumed to harm competition.

- DOJ and FCS entered into a Deferred Prosecution Agreement ("DPA") that includes, in part, FCS's agreement to pay a $100 million criminal penalty, the maximum allowable for violations of Section 1 of the Sherman Act. In addition, FCS agreed to pay the State of Florida more than $20 million in disgorgement of profits and abide by other terms of relief to resolve the State's investigation. DOJ indicated that it entered into the DPA as a means of lessening the disruption to FCS's patients and employees and in recognition of FCS's willingness to cooperate with the DOJ's pending investigation.

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[28] *See* Press Release, Leading Cancer Treatment Center Admits to Antitrust Crime and Agrees to Pay $100 Million Criminal Penalty (Apr. 30, 2020), *available at* https://www.justice.gov/opa/pr/leading-cancer-treatment-center-admits-antitrust-crime-and-agrees-pay-100-million-criminal.

[29] *See* Information, *United States v. Florida Cancer Specialists & Research Institute, LLC* (M.D. Fla.) (Apr. 30, 2020), *available at* https://www.justice.gov/opa/press-release/file/1272551/download.

c. DOJ criminal indictment of Surgical Care Affiliates for alleged no-poach agreement

- In January 2021, the Antitrust Division of the Department of Justice ("DOJ") announced that it had brought a two-count felony charge against Surgical Care Affiliates, LLC and its related entity (collectively, "SCA"), a company which owns and operates outpatient medical care centers across the country, for allegedly agreeing with competitors not to solicit senior-level employees.[30]
    - The charge alleges that SCA through separate agreements with other companies and individuals that participated as co-conspirators agreed, among other things, that they would not solicit each other's senior-level employees.[31]
    - The indictment specifically cites communications between competitors of SCA and recruiters.
    - The conspiracy allegedly dates back to as early as May 2010 and was in effect until at least July 2017.
    - The DOJ alleged that the conspiracy to allocate employees was a *per se* violation of the Sherman Act, meaning that the conduct at issue would be presumed to harm competition.
    - The DOJ has signaled that this action is the first in an ongoing investigation into employee allocation agreements and employer collusion.
- In October 2016, the DOJ and the Federal Trade Commission issued guidance regarding no-poach agreements, indicating that they plan to pursue these cases criminally and stating that no-poach agreements "eliminate competition in the same irredeemable way as agreements to fix product prices or allocate customers, which have traditionally been criminally investigated and prosecuted as hardcore cartel conduct."[32]
- Such violations of the Sherman Act carry a maximum penalty of a $100 million fine for corporations. The fine may be increased to twice the gain derived from the crime or twice the loss suffered by victims if either amount is greater than the statutory maximum.

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[30] *See* Press Release, Health Care Company Indicted for Labor Market Collusion (Jan. 7, 2021), *available at* https://www.justice.gov/opa/pr/leading-cancer-treatment-center-admits-antitrust-crime-and-agrees-pay-100-million-criminal.

[31] *See* Indictment, *United States v. Surgical Care Affiliates, LLC et al.* (N.D. Texas) (Jan. 5, 2021), *available at* https://www.justice.gov/opa/press-release/file/1351266/download.

[32] *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDANCE FOR HUMAN RESOURCE PROFESSIONALS (2016), *available at* https://www.justice.gov/atr/file/903511/download.

D. Pharmaceutical Enforcement

Authors: Katharine O'Connor and Alexandra Lewis, McDermott Will & Emery
(As of June 2021)

1. DOJ generic pharmaceutical investigation led to deferred prosecution agreements and fines for Heritage, Rising, Sandoz, Apotex, and Taro, and indictments for executives from Heritage, Taro and Sandoz.

- The Antitrust Division filed ten cases in its ongoing investigation into the generic pharmaceutical industry. Charges were brought against six companies and four individual executives for their roles in fixing prices of generic drugs.
    - The cases against the companies and the individuals are built on hard market evidence of price fixing, as well as damning communications between and amongst representatives of the companies. For example, in one text exchange the CEO of Heritage told the president of Heritage that their scheme had yielded $466,000 in profits in one day.
- From June 2019 through July 2020, the Justice Department entered into five deferred prosecution agreements ("DPA's") with five generic drug manufacturers. The generic manufacturers were Heritage Pharmaceuticals Inc. (DPA entered June 2019), Rising Pharmaceuticals Inc. (DPA entered December 2019), Sandoz Inc. (DPA entered March 2020), Apotex Corporation (DPA entered May 2020), and Taro Pharmaceutical (DPA entered July 2020).
- The agreements were the result of a large-scale price fixing investigation in a variety of generic drug product markets.
    - Heritage Pharmaceuticals was required to pay more than $7 million in criminal penalty and civil damages and cooperate with ongoing parallel investigations in the generics industry.
    - Rising Pharmaceuticals was required to pay over $3 million in criminal penalty, restitution and civil damages and cooperate fully with the Antitrust Division's ongoing criminal investigation.
    - Sandoz agreed to pay a $195 million criminal penalty. The company also admitted that its sales affected by the charged conspiracies exceeded $500 million. Sandoz also agreed to cooperate fully with the ongoing criminal investigation.
    - Apotex agreed to pay a $24.1 million criminal penalty and agreed to cooperate fully with the ongoing criminal investigation.
    - **Taro agreed to pay a $205.7 million criminal penalty, the largest ever for a domestic antitrust case.** Taro also admitted to securing more than $500 million

in sales connected to the illegal conspiracy and to cooperate fully with the ongoing criminal investigation.

- In June 2020, Teva Pharmaceuticals USA Inc. and Glenmark Pharmaceuticals Inc. were charged for their roles in the illegal conspiracy. The Division alleged that Glenmark secured a minimum of $200 million from the conspiracy and Teva secured at least $350 million.

- Four executives were also charged for their role in the conspiracy.

    - In January 2017, former Heritage CEO Jeffrey Glazer and former Heritage president Jason Malek pled guilty to two counts of felony charges of conspiracy.

    - In February 2020, Hector Armando Kellum, a former Sandoz executive, pled guilty to a single count of conspiracy to restrain trade through price fixing.

    - In February 2020, Ara Aprahamian, a former top executive at Taro Pharmaceutical, was indicted for his role in the conspiracy.

2. FTC/state AGs' complaint against Vyera related to Daraprim

- In April 2020, the FTC and NY Attorney General's office, joined by state Attorneys General in Illinois, Ohio, California, North Carolina, Virginia and Pennsylvania, sued Vyera Pharmaceuticals LLC, alleging that Vyera engaged in an "elaborate anticompetitive scheme" to maintain its monopoly for the life-saving drug Daraprim. Daraprim treats toxoplasmosis, a parasitic infection that is particularly fatal to the immunocompromised, such as people living with HIV/AIDs or undergoing cancer treatment. This is one of the cases brought against now-famous "pharma bro" Martin Shkreli and his pharmaceutical companies.

    - Pyrimethamine is on the WHO's Model List of Essential Medicines, and for those living with HIV/AIDs and other immunocompromised persons, the drug remains the "gold standard" for treating toxoplasmosis.

    - Daraprim was approved by the FDA in 1953; it lost patent protection or regulatory exclusivity a long time ago. It was the only FDA-approved pyrimethamine until a generic was approved in February 2020.

    - In 2010, GlaxoSmithKline (GSK) charged $1 per tablet. GSK sold the U.S. rights to CorePharma/Amedra in 2010. From 2010 to 2015, Amedra gradually raised the price to $13.50/tablet. Impax acquired Daraprim in 2015, increasing the price-per-tablet to $17.50 (by 30%) and implemented a restricted distribution system.

    - In August 2015, Vyera bought the U.S. rights from Impax for $55 million. The day after the deal was finalized, Vyera raised the price from $17.50 to $750 per

tablet—a more than 4,000% increase. Vyera also entered into agreements:

- prohibiting distributors and purchasers from reselling Daraprim to potential generic competitors or their agents;
- prohibiting manufacturers from supplying Daraprim to potential generic competitors; and
- entered into data-blocking agreements to prevent distributors from selling sales data, effectively masking the true size of the Daraprim market to deter generic competitors.

- The plaintiffs alleged that Vyera successfully foreclosed generic competition resulting in increased prices to consumers. The case is ongoing. On March 30, 2021, Shkreli and Vyera dropped demands for a jury trial. In exchange, the seven states that joined the FTC's lawsuit agreed not to seek civil penalties or forfeitures.

- The Supreme Court's ruling in *AMG Capital v. FTC*, issued in April 2021, dealt a major blow to the FTC's ability to recoup money from defendants in federal court under section 13(b) of the FTC Act. It remains to be seen how the AMG decision will affect the FTC's efforts to recoup money from Shkreli and Vyera.

3. FTC announced settlement with Indivior related to product hopping of Suboxone

- In July 2020, the FTC filed a complaint against Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals), a pharmaceutical producer of the branded drug Suboxone, used to minimize withdrawal symptoms in patients recovering from opioid addiction in what is known as "opioid replacement therapy."
- In 2009, Indivior's patents for Suboxone were set to expire, giving way to potential entry of competing generic versions of Suboxone. The FTC alleged that Indivior developed a "product hopping scheme" by introducing a dissolvable oral version of Suboxone before the generic version of Suboxone tablets became available, in an effort to shift prescriptions to the patent-protected dissolvable version.
    - The complaint also alleged that Indivior filed a meritless petition over safety claims with the FDA asking that the agency reject generic tablet applications, in an effort to buy more time to move patients to the patent-protected dissolvable version of Suboxone.
    - The FTC Commission vote authorizing the complaint and proposed settlement order was 3-0-2, with Rebecca Kelly Slaughter not participating and Christine Wilson recused.

- Under the settlement, Indivior agreed to pay $10 million in fines to a fund that will be used to provide payments to people who purchased the dissolvable oral branded

version of Suboxone. The settlement also contains a permanent injunction barring Indivior from similar future conduct.

- The settlement follows the FTC's 2019 settlement with Indivior's former parent company, Reckitt Benckiser Group plc. Under that settlement agreement, Reckitt was required to pay $50 million in fines to the same consumer payment fund.

E. DOJ/FTC Joint Statement regarding collaborations intended to fight COVID-19 pandemic

Authors: Katharine O'Connor and Alexandra Lewis, McDermott Will & Emery
(As of June 2021)

- On March 24, 2020, the U.S. Federal Trade Commission (FTC) and U.S. Department of Justice (DOJ) issued a Joint Antitrust Statement Regarding COVID-19 (Statement).
    - In this Statement, the FTC/DOJ recognize that public health efforts in response to COVID-19 will require government and private cooperation.
    - Many forms of pro-competitive collaborations do not violate the antitrust laws, as recognized in existing FTC/DOJ guidance such as the Antitrust Guidelines for Collaborations Among Competitors and the Statements of Antitrust Enforcement Policy in Health Care (Health Care Statements).
    - However, the FTC/DOJ state that they are prepared to pursue civil violations of the antitrust laws for agreements "between individuals and business to restrain competition through increased prices, lower wages, decreased output, or reduced quality as well as efforts by monopolists to use their market power to engage in exclusionary conduct."
    - DOJ also has the power to prosecute criminal violations of the antitrust laws.
- The Joint Statement contains guidance on joint activity unlikely to raise antitrust concerns. The following address the antitrust framework for several types of joint activities that individuals and business may undertake in response to COVID-19
    - Petitioning the Government
        - Under *Noerr-Pennington*, parties may petition the government or jointly engage in lobbying efforts. These rights remain untouched in the current circumstances.
    - NCRPA
        - The Statement also encourages parties to notify joint ventures under the **National Cooperative Research and Production Act**, which provides for

flexible treatment under the antitrust laws for certain joint ventures. Parties considering joint ventures should consider whether it is appropriate to notify the DOJ under the NCRPA.

- Research and Development
  - The agencies reiterate their guidance that "when firms collaborate on research and development this 'efficiency-enhancing integration of economic activity' is typically procompetitive."
- Sharing General "Know-How" and Clinical Best Practices
  - Parties may continue to share technical "know-how," clinical best practices, or other similar information to combat COVID-19. Parties may do so, for example, to strategize about how to deliver products to healthcare providers in need or deliver critical services to patients.
- Joint Purchasing Arrangements
  - Statement 7 of the Health Care Statements addresses joint purchasing arrangements, the FTC/DOJ recognize that many joint purchasing arrangements among hospitals or other healthcare providers do not raise antitrust concerns as they are designed to achieve efficiencies – cost-savings – that should benefit consumers.

- Emergency measures and government collaboration.
  - If competitors are contemplating measures that may involve conduct that would be viewed as anticompetitive under normal circumstances but they believe is necessary to support the government's COVID-19 efforts—for example, to help healthcare providers receive critical supplies—this still may be possible under certain emergency government powers. For example, both the **Defense Production Act of 1950** and the **Pandemic and All-Hazards Preparedness Act (PAHPA)** have provisions for antitrust immunity for agreements made under the supervision and in cooperation with the federal government.

F. Civil Litigation

1. BCBS MDL Proposed Settlement

Authors: Michael Fischer and Najla Long, Bradley
(As of June 2021)

- In October 2020, a proposed Settlement Agreement was reached in a class action suit against the Blue Cross and Blue Shield Association ("BCBSA") and its individual

member plans ("Member Plans") (collectively, the "Defendants" or "Blues").[33] This litigation began as a single case in 2012 and subsequently converted into a multi-district proceeding in the Northern District of Alabama involving the consolidation of more than 40 actions filed by subscriber plaintiffs against the Defendants.[34]

- The subscriber plaintiffs allege, among other things, that Defendants violated Sections 1, 2, and 3 of the Sherman Antitrust Act, 15 U.S.C. §§ 1-3, by entering into an unlawful agreement that restrained competition between them in the markets for health insurance and for the administration of commercial health benefit products in the United States and its territories.

- On October 16, 2020, a proposed Settlement Agreement was entered into by and among Defendants and class representatives.[35] The Settlement Agreement was preliminarily approved by the U.S. District Court for the Northern District of Alabama Southern Division on November 30, 2020.[36]

    - Prior to the subscriber settlement, the court ruled that the per se rule applies in this litigation, meaning that the plaintiffs need only prove an anticompetitive market allocation/price fixing agreement, without having the additional burden to prove anticompetitive harm on a specific market. Per se illegal agreements are those that are so inherently anticompetitive on their face that no further analysis of their effect on markets is necessary.

    - The subscriber settlement includes a $2.67 billion damages award and certain injunctive relief, including the abolition of Blue's "National Best Efforts" pact, which required members to derive a minimum of two-thirds of their revenue from Blue-branded services. The settlement also eliminates the Blue Card program, which required states to treat members of another state's program as in-network, eliminating incentives to compete for those members. Provider plaintiffs are still seeking class certification from the court.

- An ongoing class action against Delta Dental in the US District Court for the Northern District of Illinois in large part mirrors the allegations in the Blue Cross litigation. The plaintiff class of providers allege that Delta Dental Association and its state entities divided markets and fixed reimbursement rates to dentists below competitive levels. The Delta Dental court has likewise ruled that the per se rule applies.

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[33] *See generally* Settlement Agreement, *In Re: Blue Cross Blue Shield Antitrust Litigation* (MDL No. 2406) (N.D. Ala.) (Oct. 30, 2020).
[34] *See* Memorandum Opinion and Order Preliminarily Approving Settlement, Plan of Distribution, and Notice Plan, and Directing Notice to the Class, page 3, *In Re: Blue Cross Blue Shield Antitrust Litigation* (MDL No. 2406) (N.D. Ala.) (Nov. 30, 2020).
[35] *See* Settlement Agreement, *In Re: Blue Cross Blue Shield Antitrust Litigation* (MDL No. 2406) (N.D. Ala.) (Oct. 30, 2020).
[36] *See generally* Memorandum Opinion and Order Preliminarily Approving Settlement, Plan of Distribution, and Notice Plan, and Directing Notice to the Class, page 4, *In Re: Blue Cross Blue Shield Antitrust Litigation* (MDL No. 2406) (N.D. Ala.) (Nov. 30, 2020).

- At $2.67 billion, the settlement represents one of the largest antitrust class settlements in history. The court notes that, although the monetary benefit when distributed between settlement class members may not be the amount a lay observer would expect, the structural relief that the plaintiffs have obtained is more important that the dollar amount of the settlement. The injunctive aspects of the settlement significantly alter the Blues' business practices and substantially increase the value of the settlement to the class members.[37]

- A Final Approval Hearing for the settlement is scheduled for October 20, 2021.[38]

G. EpiPen Litigation Classes Certified

Authors: Michael Fischer and Najla Long, Bradley
(As of June 2021)

- In August 2017, the Judicial Panel on Multidistrict Litigation consolidated several actions alleging claims of anticompetitive conduct related to the marketing of EpiPens.[39]

    - The Multidistrict Litigation ("MDL") was assigned to the U.S. District Court for the District of Kansas, which subsequently divided the MDL into two separate litigation tracks:

        - (1) a "consumer class cases" track consisting of individual consumers or third-party payor who purchased EpiPens for consumption, and

        - (2) a "Sanofi case track" consisting of case filed by Sanofi-Aventis U.S., LLC ("Sanofi") against Mylan, Inc. and Mylan Specialty, L.P. ("Mylan") alleging that Mylan, as distributor of the EpiPen, engaged in anticompetitive conduct to prevent Sanofi's rival product Auvi-Q from accessing the epinephrine autoinjector market ("EAI") and prevent consumers from purchasing Auvi-Q.[40]

- In February 2020, the U.S. District Court for the District of Kansas, considering the Consumer Class Cases, certified two classes: (1) a Nationwide RICO Damages Class

[37] *See* Memorandum Opinion and Order Preliminarily Approving Settlement, Plan of Distribution, and Notice Plan, and Directing Notice to the Class, page 32, *In Re: Blue Cross Blue Shield Antitrust Litigation* (MDL No. 2406) (N.D. Ala.) (Nov. 30, 2020).
[38] *See* Memorandum Opinion and Order Preliminarily Approving Settlement, Plan of Distribution, and Notice Plan, and Directing Notice to the Class, page 66, *In Re: Blue Cross Blue Shield Antitrust Litigation* (MDL No. 2406) (N.D. Ala.) (Nov. 30, 2020).
[39] Transfer Order, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, MDL No. 2785 (J.P.M.L. Aug. 4, 2017).
[40] Order Designating A Separate Track For The Sanofi Case, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, (D. Kan. Sept. 14, 2017).

and (2) a State Antitrust Damages Class.[41]

- The plaintiffs' theories of antitrust liability are premised upon allegations that (1) Mylan unlawfully entered into exclusive dealing arrangements with pharmacy benefit managers ("PBMs") "who drove and kept EpiPen prices above competitive levels and (2) the defendants entered into "reverse payment patent litigation settlements" to delay the entry of generic competitors into the EAI market.

- In certifying the State Antitrust Class, the Court concluded the plaintiffs plausibly alleged they can show market power in a relevant market with common evidence by relying on an expert's report and opinions. Similarly, the Court concluded that plaintiffs' experts' opinions "satisfied the predominance requirement, as used to support their exclusive dealing claim" premised upon a theory that Mylan's "conditional rebating strategy managed to restrict a substantial portion of the market" and "Mylan's actions raised baseline prices for all payors, even those on non-foreclosed formularies and despite the presence of prices negotiated from that baseline."

- The Court also found that "plaintiffs' theory that defendants used a reverse payment to delay entry of a generic EAI competitor" could be plausibly proved by plaintiffs' experts' analysis "with evidence that applies on a classwide basis."

- In December 2020, the U.S. District Court for the District of Kansas granted summary judgment in favor of Mylan against Sherman Act claims brought by Sanofi.[42]

  - Sanofi alleged Mylan engaged in anticompetitive monopolization practices to shut out Sanofi's Auvi-Q—a rival to Mylan's EpiPen—from the EAI market and block consumer purchases of Auvi-Q.

  - For its part, Mylan contended that its conduct was not anticompetitive because (a) Mylan's rebate agreements with payors passed the price-cost test and therefore did not violate antitrust laws; (b) based on a rule of reason analysis, Mylan's rebate agreements were not unlawful exclusionary contracts; (c) Sanofi's theory of antitrust liability "premised on Mylan leveraging its non-contestable demand to force payors into agreeing to exclusive contracts" should be rejected; and (d) Mylan's EpiPen marketing and EpiPen4Schools® program did not violate antitrust laws.

  - Following the Third Circuit's reasoning in *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, the Court declined to decide whether the price-cost test applied to Sanofi's claim

[41] *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2020 WL 1873989 (D. Kan. Feb. 27, 2020).
[42] *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2020 WL 8374137 (D. Kan. Dec. 17, 2020).

based on rebate agreements between Mylan and payors because it concluded, under its rule of reason analysis, that Sanofi "failed to present a triable issue that Mylan's rebate contracts foreclosed Sanofi from a substantial share of the market."

- The Court agreed with Mylan's arguments that: (1) there was no factual dispute whether Mylan engaged in anticompetitive conduct and (2) no reasonable jury could find that Sanofi sustained an antitrust injury.
  - Because summary judgment was granted in favor of Mylan based on Mylan's two other arguments, the Court declined to consider Mylan's contention that Sanofi failed to present sufficient evidence to support a claim for antitrust damages.

- In January 2021, the U.S. District Court for the District of Minnesota denied motions to dismiss Sherman Act claims raised by drug wholesalers against Mylan and co-defendant PBMs, alleging that Mylan unlawfully maintained a monopoly share of the EAI market by paying bribes and kickbacks to the PBMs.[43]
  - The Court reasoned that the plaintiffs sufficiently alleged a relevant product market of EAIs and an antitrust injury of inflated EpiPen prices.
  - The Court also rejected Mylan's argument that bribery allegations cannot support a claim under Section 2 of the Sherman Act, reasoning that plaintiffs' plausibly alleged anticompetitive conduct by alleging that Mylan paid rebates not only for favorable formulary placement but also "to induce PBMs to abandon their role as a price disciplinarian in the market."

H. Restasis Litigation Class Certified

Authors: Michael Fischer and Najla Long, Bradley
(As of June 2021)

- On February 11, 2019, a group of Direct Purchase Class Plaintiffs ("DPPs") filed a class action lawsuit against Allergan, Inc. ("Allergan") in the United States District Court for the Eastern District of New York, alleging that Allergan violated certain provisions of the Sherman Act by taking several unlawful actions to delay the market entry of generic versions of its product Restasis.[44]

- A year later, on February 16, 2020, the DPPs and Allergan entered into a settlement agreement the "Settlement Agreement"), pursuant to which Allergen agreed to pay the class $51,250,000.[45]

[43] *In re EpiPen Direct Purchaser Litig.*, No. 20-CV-0827 (ECT/TNL), 2021 WL 147166 (D. Minn. Jan. 15, 2021).
[44] Direct Purchaser Class Plaintiffs' First Amended Consolidated Class Action Complaint, *In Re Restasis (Cyclosporine Opthalmic Emulsion) Antitrust Litigation,* Case:1:17-cv-06684-NG-LB (Document 245).
[45] Opinion and Order, *In Re Restasis (Cyclosporine Opthalmic Emulsion) Antitrust Litigation,* Case:1:17-cv-06684-NG-LB (Document 562).

- On May 15, 2020, the court granted preliminary approval of the settlement and set a final date for a hearing on the fairness of the Settlement Agreement.

    - The preliminary approval order defined the members of the class as all persons or entities that purchases Restasis in the US or its territories directly from Allergan at any time after May 2014 through and including February 16, 2020.

    - The preliminary approval order excluded CVS Pharmacy, Inc., Rite Aid Crop., Rite Aid Hdqtrs. Corp., Walgreen Co., The Kroger Co., Albertsons Companies, Inc., and HEB Grocery Company L.P. Each of these entities separately settled their claims against Allergan.

- The court approved the Settlement Agreement on October 7, 2020.

    - The court also approved $16.4 million in attorneys' fees and almost $2 million dollars in litigation costs for class counsel.[46]

I. Active Civil Pay-For-Delay Litigation

Authors: Katharine O'Connor and Alexandra Lewis, McDermott Will & Emery
(As of June 2021)

1. Glumetza Antitrust Litigation (MTD denied in 2020, set for trial in October 2021)

- Direct purchasers of Glumetza, a brand-name anti-diabetic medication, sued drug companies Bausch Health Companies Inc. (formerly Valeant), Santarus Inc. (Bausch subsidiary), Lupin Pharmaceuticals Inc., and Assertio Therapeutics Inc.

    - Lupin is the generic manufacturer (metformin is the name of the generic drug). Assertio is the patent holder for Glumetza, and Santarus had commercialization rights for Glumetza.

- Pharmaceutical drugs require FDA approval and the Abbreviated New Drug Application ("ANDA") process is designed to encourage generic drugs by easing the approval process.

    - A company is eligible to file an ANDA when it has a generic drug product, which is a drug that is comparable to an innovator (or brand-name) drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. The applications need only scientifically establish that the generic product perform in the same manner as the innovator drug.

[46] *Id.*

- Generic applicants must also certify to the FDA either that no patents cover the comparable brand-name drug, that the relevant patents have expired, or that such patents are invalid or will not be infringed by the new drug.

- A certification of invalidity or noninfringement is deemed a statutory act of patent infringement. The brand manufacturer can bring a patent infringement lawsuit, and if it is brought within 45 days the FDA must stay the generic's approval until the resolution of the lawsuit or for 30 months, whichever comes first.

- In July 2009, Lupin filed an ANDA to market generic versions of Glumetza, and filed for a certification of noninfringement or invalidity. In November 2009, Assertio sued Lupin, triggering the 30-month stay. In January 2012, while the lawsuit was ongoing and 26 months into the 30 month stay, the FDA tentatively approved Lupin's ANDA making their generic form of Glumetza approvable but for the 30-month stay or resolution of the lawsuit.

- In February 2012, Assertio and Santarus, Inc. which now owned the commercialization rights to Glumetza, settled with Lupin. The lawsuit was terminated before the 30-month stay, and with the ANDA approval in place Lupin would have had the green light to market its generic.

  - Instead, Lupin promised to terminate the lawsuit, not to challenge the patents' validity, and not to market a generic version of Glumetza for four years. In return, Assertio and Santarus promised to not market or permit another manufacturer to market an authorized generic for at least 180 days following Lupin's generic entry in February 2016 (after the four-year period expired).

    - The agreement further provided that if any other generic succeeded in marketing a generic Glumetza before February 2016, Lupin could market immediately; and that Assertio and Santarus would not license any other generic manufacturers until 180 days after Lupin's market entry.

- According to the complaint, the deal maintained Assertio's monopoly for brand-name Glumetza and gave Lupin a monopoly for generic Glumetza. The value of the settlement to Lupin was over fifty million dollars.

  - No generic manufacturers entered the market before Lupin. Sun Pharmaceuticals and Watson Pharmaceuticals (now Teva) each filed ANDA's in 2011 and 2012, respectively. Assertio and Santarus entered settlements with both companies, and neither companies' generic Glumetza product entered the market until mid-2017.

- According to the complaint, the monopoly yielded $150 million in sales to Assertio and Santarus in 2012 alone. In February 2015, a 500mg tablet cost $5.72. By July 2015, a single tablet cost more than $51 –an 800% increase.

- Lawsuits were filed in the double-digits beginning in 2019 and were eventually

consolidated in the Northern District of California.

- In response to the defendants' statute of limitations defense, Judge Alsup found that the claims were within statute of limitations because recent drug sales constituted a continuation of the alleged price-fixing conspiracy.

- Members of the approved plaintiff class were pared down based on whether they sufficiently alleged they were direct purchasers. Any potential plaintiff that failed to allege they were a direct purchaser was dismissed.

- On May 6, 2021, Judge Alsup denied defendants' motion for summary judgment, finding that a reasonable trier of fact could conclude that the cross-covenants not to compete exceeded the scope of defendants' patent rights. The court further held that a reasonable trier of fact could conclude that defendants' restraints delayed generic entry, stifled competition, and caused plaintiffs to pay more for brand and generic Glumetza than they otherwise would have.

    - The judge also denied plaintiffs' motion for summary judgment on the issue of whether defendants had market power, finding there was a question of fact as to whether the relevant market included other products.

2. Staley et al v. Gilead Sciences Inc. et al

- In May 2019, a class action brought on behalf of purchasers of HIV medications in the United States was filed against Gilead Sciences, Bristol-Myers Squibb Co. (BMS), Janssen Pharmaceuticals (a subsidiary of Johnson and Johnson), and Japan Tobacco (JT).

    - Class representatives included individual consumers, union and welfare funds, and individual AIDS activists.

- Combination antiretroviral therapy (cART) regimens are an effective form of HIV management and AIDS prevention. NRTI's are a class of drugs that are a critical input for cART regimens. Tenofovir is the most commonly used NRTI in the U.S. and comes in two forms: TDF and TAF.

- TDF and TAF are almost always used in conjunction with another NRTI—usually either 3TC or FTC, which are interchangeable. Fixed dose combination drugs (FDC's) combine cART regimen drugs into one dose.

    - At the time the lawsuit was filed, defendant Gilead held patents for FTC and TDF. A generic version of 3TC was already in the market.

- Gilead allegedly entered into separate anticompetitive agreements with BMS, Janssen and JT to create and market FDC's that combined Gilead's patented NRTI's with the other companies' third agents.

- Each agreement included a clause—labeled a "no generics provision"—which prevented BMS, Janssen and JT from creating or marketing a competing FDC made with generic or substitutable versions of TDF or FTC (Gilead's patented NRTI's), even after the patents had expired.

- In exchange, Gilead paid royalties to the other defendants and bore some or all of the responsibility for seeking regulatory approval and commercialization in the U.S.

- On October 15, 2019, the FTC filed an amicus brief on the narrow issue of market definition, arguing that more than one relevant market or submarket is cognizable for a single class of products or services, depending on the alleged anticompetitive harm.

- On March 3, 2020, Judge Edward M. Chen (N.D. Cal) granted in part and denied in part defendants' motion to dismiss and granted the plaintiff class leave to amend their complaint.

  - The claims against Japan Tobacco were dismissed with prejudice after a finding that the alleged agreement with JT did not contain an express no-generics provision.

- On July 29, 2020, Judge Chen granted in part and denied in part defendants' motion to dismiss the plaintiffs' first amended complaint. Discovery is ongoing.

  - The court dismissed plaintiffs' overarching conspiracy claims; claims based on defendants' alleged payment of royalties after patent expiration; and claims based on patent term extension for Gilead's TAF-related patent.

  - The court upheld plaintiffs' claims of bilateral conspiracy. The court found that the proposed market could include multiple cART drug regiments, and that the question of market definition was proper for a jury.

3. AbbVie Humira Litigation (District Court held for AbbVie, appealed to 7th Cir.)

- In May 2019, a class action was brought on behalf of indirect purchasers of Humira, alleging that AbbVie built a "patent thicket" around Humira, its immunosuppressant biologic medication, for the purpose of preventing cheaper biosimilars from coming to market.

  - The lawsuit is considered the first pay-to-delay decision in a biosimilar market.

  - A biosimilar is a biologic medical product highly similar to another, already approved biological medicine. Conceptually, the relationship between biologics and biosimilars is akin to branded drugs and generics, though the law does not

treat them as equivalents. It remains unsettled how the law will treat biosimilars, and cases like the Humira litigation may have a significant impact in that way.

- The class members accuse AbbVie of repeatedly asserting over 100 invalid, unenforceable or noninfringed patents for the purpose of preventing biosimilars from entering the market, and to maintain its monopoly on Humira.
    - The class members have asserted that AbbVie established a *quid pro quo* with biosimilar makers Samsung Bioepis Co., Amgen Inc., and Sandoz Inc., whereby the biosimilars would delay entry of their biosimilars into U.S. markets until 2023 and in exchange would be able to enter the U.K. market in 2018, before AbbVie's patent expired.
    - They argue that AbbVie's patents are weak, and that the *quid pro quo* was designed to eliminate the biosimilar manufacturers' incentive to challenge the patents.
- In June 2020, Judge Manish Shah (N.D. IL) granted AbbVie's motion to dismiss.
    - Judge Shah acknowledged that the cost of Humira is exponentially higher in the U.S. than in European markets.
    - Nonetheless, the court held that AbbVie's patents were not "sham" patents, and that the effect of the agreements were to increase competition by bringing competitors into the market when the patents would otherwise have prevented entry.
    - The court's decision is seen by many as a precedent that would make it even more difficult for biosimilars to bring competing products to market.
- In February 2021, the plaintiff class appealed the court's ruling to the Seventh Circuit.
    - Whoever loses the circuit appeal is expected to bring the case to the Supreme Court.
- As of May 2021, Alvotech, a biosimilar manufacturer, filed a complaint in the Eastern District of Virginia seeking declaratory judgments that several of AbbVie's patents for Humira are invalid and not being infringed.
    - The complaint does not contain antitrust claims but does seek declarations that the patents are unenforceable due to AbbVie's efforts to keep biosimilars off the market.
    - The suit alleges that the original Humira patents expired in 2016, but AbbVie has since acquired over 100 related patents—a "patent minefield"—to maintain its

monopoly. The suit echoes the "patent thicket" arguments made by the class of plaintiffs in the ongoing AbbVie Humira antitrust litigation.

J. McLaren/ProMedica Refusal to Deal Case

- In November 2020, St. Luke's Hospital sued ProMedica Health System Inc., over ProMedica's termination of its health plan contracts with St. Luke's. St. Luke's claimed the terminations and ProMedica's related actions would significantly injure St. Luke's and further ProMedica's campaign to monopolize the market.

- ProMedica sought to acquire St. Luke's, but the acquisition was challenged by the FTC. ProMedica was ultimately required to divest St. Luke's in 2014.

    - McLaren Hospital later acquired St. Luke's Hospital.

- On the same day that the McLaren acquisition of St. Luke's went into effect, ProMedica terminated eight contracts to provide services on St. Luke's campus. St. Luke's sued ProMedica, alleging that it terminated the eight contracts, cancelled commercial insurance contracts, and pressured physicians to stop practicing at St. Luke's.

    - Judge Zouhary (N.D. Ohio) enjoined ProMedica from terminating its commercial and Medicare insurance contracts with St. Luke's. "If the motives behind defendants' actions were not clear based on their actions alone, ProMedica executives themselves admitted the motivation behind their decision to cancel the agreements was the presence of a more formidable St. Luke's in the market."

- ProMedica appealed to the 6th Circuit in January 2021.

K. Tech Enforcement and Potential Application to Health Care Entities

Authors: Katharine O'Connor and Alexandra Lewis, McDermott Will & Emery
(As of June 2021)

- Expect technology companies to remain under heavy scrutiny during the Biden administration.

    - The Biden Administration is rumored to be encouraging the enforcement agencies to bring cases even if they are going to lose.

    - President Biden has nominated Lina Khan to fill one of the vacant FTC commissioner seats. An outspoken critic of "Big Tech," Khan is well known for advocating that leading technology firms should be scrutinized for the alleged effect their conduct has on competitors. Khan has repeatedly argued for a departure from the consumer welfare standard, which is focused largely on prices to end consumers, and instead suggests that a broader framework of potential harms should be considered.

- On March 5, 2021, progressive antitrust author and law professor Tim Wu was named to the National Economic Council as a special assistant to President Biden on technology and competition policy. Wu is known as an outspoken critic of Big Tech and is an advocate for using enforcement power to break up monopolist firms.

- Amy Klobuchar has also made headlines recently with her push to cement a more aggressive approach to antitrust through increased oversight and proposed legislation.

  - Senator Klobuchar (D-MN) is leading an antitrust policy ramp-up that includes legislative proposals across the antitrust spectrum, including making it easier for the federal antitrust agencies to challenge transactions.

  - For fiscal year 2021, Congress has approved a budget increase of $20 million for the FTC and $18 million for the DOJ Antitrust Division. The budget increase provides welcome relief to the antitrust agencies, whose resources have been taxed by aggressive merger enforcement, including several ongoing litigations.

  - The Competition and Antitrust Law Enforcement Reform Act of 2021, introduced on February 4, would increase the FTC and Antitrust Division budgets by more than $300 million each for fiscal year 2022. Among many proposed changes, the bill would lower the standard of proof for government enforcement actions by prohibiting mergers that "create an appreciable risk of materially lessening competition." The current standard prohibits mergers where the effect "may be substantially to lessen competition." The bill would also shift the burden of proof in certain enforcement actions from the government to the merging parties to show that the merger is not likely to materially lessen competition. Mergers or acquisitions subject to burden shifting include:

    - Acquisitions that significantly increase market concentration;

    - Acquisitions by an acquirer with at least 50% market share;

    - Acquisitions of a "disruptive" firm by a competitor;

    - Acquisitions that would enable the acquiring firm to unilaterally exercise market power as a buyer or seller; and

    - Mergers valued at greater than $5 billion, or involving acquirers with assets, net revenue or market capitalization greater than $100 billion.

  - These proposals, if ultimately enacted, would enhance the enforcement agencies' ability to challenge and block large-firm transactions.

- Key decisions in the tech sector could impact antitrust jurisprudence more broadly,

particularly in M&A.

- Retrospective scrutiny of mergers in the Facebook and Google antitrust lawsuits may be the "canary in the coal mine" signaling the enforcement agencies willingness to review prior approved transactions in other sectors, including healthcare.

  - In December 2020, The FTC, in cooperation with attorneys general from 46 states, D.C. and Guam, sued Facebook for illegal monopolization. The complaint alleged that Facebook has illegally maintained its monopoly through a years-long strategy of acquiring nascent competitors and imposing anticompetitive conditions on software developers. The FTC is seeking divestiture of assets including Instagram and WhatsApp, a prohibition from imposing anticompetitive conditions on software developers, and a requirement that Facebook seek prior notice and approval for future mergers and acquisitions.

    - The anticompetitive acquisition aspect of the FTC's case is significant because it employs the nascent competitor theory to attack three mergers that were previously reviewed and approved by the Commission itself. The nascent competitor theory is based on the idea of a firm's potential to become a competitive threat, as opposed to the more common challenges brought against established competitors. The theory has remained dormant for the last few decades, but the Facebook case signals a revival of the theory that could spill over into enforcement efforts in other sectors, including healthcare.

      - The FTC points to a trove of internal emails from Mark Zuckerberg and other Facebook executives describing social product network effects, potential competitive threats posed by the apps, and the insight the apps could give Facebook for future strategic acquisitions.

  - In October 2020, the Justice Department, along with eleven state Attorneys General, filed a civil suit against Google has employed illegal tactics to maintain its monopoly in search and advertising markets.

    - The complaint alleges that Google has entered into exclusionary agreements that collectively lock up the primary avenues through which users access search engines, by requiring that Google be set as the preset default search engine on mobile devices and computers, and in some cases prohibiting the pre-installation of a competitor search engine.

    - The complaint also alleges that Google has used monopoly profits from its agreements and advertising revenues to buy preferential treatment for its search engines.

- The Department has asked for an adjudication and decree that Google acted unlawfully to maintain general search services, search advertising, and general search text advertising monopolies, and for Google to be enjoined from continuing to engage in the alleged anticompetitive practices and from engaging in future practices.

- The Justice Department's arguments echo the arguments made in the Department's case against Microsoft in the early 2000's. Microsoft ultimately lost, in part because of statements made by Bill Gates and other executives that Microsoft set out to eliminate new competitors.

▪ These cases signal enforcement agencies' increased willingness to review prior acquisitions and to employ the nascent competitor theory of harm. They also incorporate market-based evidence of monopolization, and rely on circumstantial evidence from memorialized conversations by and among executives that strongly suggest predatory conduct.

o The pandemic also provided opportunities for collusion among competing and vertical firms, particularly in healthcare. The FTC has signaled a willingness to challenge vertical transactions under the new vertical merger guidelines with its challenge to the Illumina/Grail biotech acquisition.

▪ The FTC filed an administrative complaint to block Illumina's $7.1 billion proposed acquisition of GRAIL. GRAIL makes non-invasive MCED tests. The FTC alleges that Illumina is the only provider of the DNA sequencing that MCED competitors, including all of GRAIL's rivals, require. Illumina formed GRAIL in 2015 but has since reduced its ownership interest to 14.5% of GRAIL's voting shares.

▪ The FTC Commissioners voted 4-0 to issue the complaint. FTC Acting Chair Rebecca Kelly Slaughter said that the acquisition would "likely reduce innovation in [MCED testing], diminish the quality of MCED tests, and make them more expensive."

▪ This is the FTC's first vertical merger challenge in decades, signaling follow-through on the Democratic FTC commissioners' approach to increase vertical transaction scrutiny. It also follows on the heels of the release of the vertical merger guidelines in 2020.

▪ The FTC argues that because Illumina is the only viable supplier of a critical input—DNA sequencing—Illumina will be in a position to raise prices charged to GRAIL's competitors. According to the complaint, Illumina's post-acquisition position would allow it to impede competitor research and development, and/or refuse or delay executing critical licensing agreements for MCED lab testing. The FTC also said that Illumina's dominant market position in critical inputs means it would take years for MCED test developers

to switch to a competing DNA sequencing supplier, if one was later developed, and in some situations would require the developer to conduct new clinical trials.

- There is also increased crossover between healthcare and technology, particularly with biotech products and the rise of telehealth as a result of the pandemic.

II. BUSINESS LAW, TRANSACTIONS AND GOVERNANCE

(As of January 2022)

A. Significant Transactions

Oracle announces acquisition of Cerner
Author: Kim Ruark, Baker & Hostetler

- Oracle is moving into the healthcare space with the acquisition of electronic health records company Cerner. With this combination, the companies anticipate leveraging Oracle's voice and cloud technologies to improve Cerner's products.

- The all-cash deal is valued at approximately $28.3 billion.

Source: https://www.prnewswire.com/news-releases/oracle-buys-cerner-301448252.html

Bain and other investors buying athenahealth
Author: Kim Ruark, Baker & Hostetler

- Bain Capital and Hellman & Friedman will pay $17 billion to become majority owners of the cloud-based EHR/physician practice support company.

- Second acquisition of athenahealth in the last three years.

- Anticipated to close in the first quarter of 2022.

Source: https://www.healthcareitnews.com/news/athenahealth-bought-private-equity-firms-hellman-friedman-bain-capital; https://www.baincapital.com/news/athenahealth-healthcare-technology-leader-be-acquired-hellman-friedman-and-bain-capital-17

Intermountain Healthcare and SCL Health announce merger plans
Author: Kim Ruark, Baker & Hostetler

- Utah-based Intermountain and Colorado-based SCL signed a definitive agreement in December.

- The combined system will be based in Salt Lake City and include hospitals, clinics and employees in Utah, Idaho, Nevada, Colorado, Montana and Kansas. The seven Catholic hospitals operated by SCL will retain their names and religious affiliations.

- The deal is expected to close in April 2022.

Sources: https://www.healthcaredive.com/news/intermountain-scl-health-merger-plans/611636/; https://www.sclhealth.org/news/2021/09/intermountain-healthcare-and-scl-health-announce-intent-to-merge/

Quidel to acquire Ortho Clinical Diagnostics
Author: Kim Ruark, Baker & Hostetler

- Quidel Diagnostics, a producer of point-of-care testing including at-home COVID-19 tests, will spend $6 billion to acquire Ortho Clinical Diagnostics.

- Ortho has international operations and its business is focused on lab testing. Quidel expects the combination to allow it to expand globally and to "meet patient testing needs at all points of the care continuum."

- Anticipated to close in the first half of 2022.

Source: https://ir.quidel.com/news/news-release-details/2021/Quidel-Corporation-Signs-Definitive-Agreement-to-Acquire-Ortho-Clinical-Diagnostics/default.aspx

Thermo Fisher Scientific Inc. acquires PPD, Inc.
By: Torrey McClary, Ropes & Gray, Kim Ruark and Victoria Stephenson, Baker & Hostetler

- Thermo Fisher Scientific Inc. acquired PPD, Inc., a leading clinical research organization for $17.4 billion after the transaction was cleared by US and European regulators.

- Thermo Fisher sells laboratory equipment and provides pharmaceutical manufacturing and other services to clients around the world. The PPD acquisition allows the company to expand into clinical trial services.

Sources: https://thermofisher.mediaroom.com/2021-04-15-Thermo-Fisher-Scientific-to-Acquire-PPD-Inc-a-Leading-Clinical-Research-Organization; https://thermofisher.mediaroom.com/2021-12-08-Thermo-Fisher-Scientific-Completes-Acquisition-of-PPD,-Inc.; https://www.law360.com/articles/1445501/uk-watchdog-clears-thermo-fisher-s-21b-ppd-deal

LifePoint acquires Kindred, launches ScionHealth
Author: Kim Ruark, Baker & Hostetler

- LifePoint Health paid an undisclosed amount for Kindred in a transaction that closed in December 2021. After the transaction, LifePoint now operates in 29 states with

more than 65 community hospitals, 30 rehab and behavioral health facilities and 170 additional care sites
- In connection with the transaction, LifePoint announced the launch of ScionHealth.

- ScionHealth is a separate company that includes 79 hospitals (Kindred's 61 long-term acute care hospitals, plus 18 of LifePoint's community hospitals).

- LifePoint committed to spend $1.5 billion over the next three years for capital improvements, staffing and technology.

Source: https://www.lifepointhealth.net/news/2021/12/23/lifepoint-health-completes-kindred-healthcare-transaction

Tenet/USPI acquires ambulatory surgery centers from SurgCenter Development
Author: Kim Ruark and Victoria Stephenson, Baker & Hostetler

- Tenet Healthcare Corporation and United Surgical Partners International acquired SCD's interest in 86 ASCs for approximately $1.1 billion and enter into a multi-year agreement with SCD's principals for further development projects.

- Tenet/USPI anticipates buying a portion of the equity interests in those ASCs from physicians for an additional $250 million.

Sources: https://investor.tenethealth.com/press-releases/press-release-details/2021/Tenet-and-USPI-to-Acquire-SurgCenter-Development-and-Establish-Long-Term-Development-Partnership/default.aspx; https://investor.tenethealth.com/press-releases/press-release-details/2021/Tenet-and-USPI-Complete-Transaction-to-Acquire-SCD/default.aspx

Tenet sells five hospitals in South Florida
Author: Kim Ruark, Baker & Hostetler

- Steward Health Care System purchased five hospitals and their affiliated physician practices in Miami-Dade and Southern Broward County from Tenet for approximately $1.1 billion.

- After the transaction, physician-owned Steward operates 44 hospitals in nine states, Colombia and Malta.

- The transaction **closed in August 2021**.

Sources: https://investor.tenethealth.com/press-releases/press-release-details/2021/Steward-Health-Care-to-Acquire-Five-Hospitals-in-the-Miami-DadeSouthern-Broward-Area-From-Tenet-Healthcare/default.aspx; https://investor.tenethealth.com/press-releases/press-release-details/2021/Tenet-Completes-Sale-of-Five-Hospitals-in-the-Miami-DadeSouthern-Broward-Area/default.aspx

Aytu BioScience and Neos Therapeutics announce merger
Authors: Peter Greenbaum, Wilentz, Goldman & Spitzer, and Kim Ruark, Baker & Hostetler

- In their creation of such they mean to focus further on patient support program integration of Aytu's prescription therapeutics. Their merge creates an estimated $100M revenue specialty pharmaceutical company.

- They will target the ADHD market specifically

- The transaction **closed in February 2021**

Sources: https://www.benzinga.com/pressreleases/20/12/g18730735/aytu-bioscience-and-neos-therapeutics-announce-definitive-merger-agreement-creating-a-combined-100; https://www.firstwordpharma.com/node/1799766?tsid=17.

Humana purchases remaining shares of Kindred at Home for $5.7 billion
Authors: Torrey McClary, Ropes & Gray, and Rachel Ludwig, Jones Day

- The deal signals a growth in Humana's home-based health services and will leave Humana with $8.1 billion of value formerly held by Kindred.

- Humana will integrate Kindred's home health operations with its own Home Solutions business under the CenterWell Home Health brand.

Status as of December 2021: This transaction **closed in August 2021**.

Sources: https://www.healthcarefinancenews.com/news/humana-purchases-remaining-share-kindred-home-57b; https://press.humana.com/news/news-details/2021/Humana-Completes-Acquisition-of-Kindred-at-Home/default.aspx#gsc.tab=0

Molina agrees to purchase Cigna's Medicaid business in Texas for $60 million
Authors: Torrey McClary, Ropes & Gray, and Rachel Ludwig, Jones Day

- The deal signals a growth in Molina's existing services in Texas as it includes Cigna's Medicare-Medicaid Plan contracts in Texas, as well as select operating assets. The deal will provide Molina with about 50,000 enrolled members across Texas.

- Molina projects an additional $1 billion in annual revenue after the closing of the transaction.

- The transaction is subject to state and federal approval and is expected to close in the second half of 2021.

Sources: https://www.healthcarefinancenews.com/news/molina-buys-cignas-medicaid-business-texas-60m; https://www.cigna.com/about-us/newsroom/news-and-views/press-releases/2021/molina-healthcare-to-acquire-cignas-texas-medicaid-contracts.

B. Canceled or Delayed Deals

Tower Health/Canyon Atlantic Partners
Authors: Torrey McClary, Ropes & Gray, and Nathan Money

Tower Health, a Reading, PA based system, terminated a deal to sell two hospitals to Canyon Atlantic Partners, an Austin-based firm focused on hospital turnarounds.

- Tower Health leaders cited Canyon Atlantic's inability to demonstrate "the necessary regulatory and operational preparedness…[and] financial ability" to operate the hospitals post-closing as the rationale for the termination.

- As a result of the termination, Tower Health is permanently closing the two hospitals which were to be sold to Canyon Atlantic.

- After several failed mergers and sales, Tower Health signed a letter of intent to establish an alliance with Penn Medicine. The scope of the alliance remains to be determined, but a steering committee was established to "evaluate potential areas of collaboration".

Additional Source: https://www.inquirer.com/business/health/tower-health-closing-brandywine-jennersville-hospital-20211209.html

Article on Penn Medicine Alliance: https://www.beckershospitalreview.com/hospital-transactions-and-valuation/tower-health-won-t-sell-hospitals-pursues-alliance-with-penn-medicine.html

Tower Health statement on Penn Medicine Alliance:
https://towerhealth.org/articles/tower-health-board-charts-path-forward-including-plan-develop-strategic-alliance-penn

SSM Health/Quorum
Authors: Torrey McClary, Ropes & Gray, and Nathan Money

SSM Health, the St. Louis based owner of St. Mary's Hospital in Jefferson City, MO ended talks to sell the hospital to Quorum Health, a Tennessee based group.

- Instead of selling St. Mary's to Quorum Health, SSM announced new leadership and expressed an intent to make new investments in care and services

- The letter of intent between the parties was initially signed in November 2020

- SSM announced an end to talks in a letter to SSM board members on October 11, 2021

Additional Source: https://www.beckershospitalreview.com/hospital-transactions-and-valuation/ssm-health-ditches-deal-to-sell-hospital-to-quorum.html

Cone Health and Sentara were set to merge in early 2021
Authors: Torrey McClary, Ropes & Gray, and Rachel Ludwig, Jones Day

- However, the deal has not closed yet and is pending public comment and regulatory review.

- The merger would create a nonprofit hospital system consisting of 17 hospitals and is projected to generate $11.5 billion in annual receipts.

- The AG has extended the deadline for the merger, and the transaction is set to close "mid 2021."

- Source: https://www.northcarolinahealthnews.org/2021/04/23/attorney-general-stein-extends-deadline-for-cone-health-merger-comments/.

  [See attached June 2021 press release re decision to end affiliation plans. https://www.conehealth.com/news/news-search/2021-news-releases/cone-health-sentara-healthcare-decide-to-end-affiliation-plans/]

CommonSpirit / Essentia
Authors: Torrey McClary, Ropes & Gray, and Nathan Money

After signing a letter of intent in January 2021, Minnesota based Essentia Health and Chicago-based CommonSpirit Health abandoned a deal for Essentia to acquire 14 hospitals and three clinics.

- The abandonment was announced via joint statement on May 18, 2021

- The abandonment came only two weeks after 700 nurses and healthcare workers published a petition expressing concern about the deal.

- The MN Nurses Association also expressed concerns, citing worries that the acquisition would lead to layoffs and reduced access to care for patients. (link)

- The joint statement said that both sides "were unable to come to an agreement that would serve the best interests of both organizations, the people we employ, and the patients we serve."

- Notice the specific mention of employees – adding merit to the suspicion that the abandonment was spurred, at least in part, by the actions of nurses and other workers.

Joint Statement: https://wwhttps://www.essentiahealth.org/about/media-article-library/2021/update-on-negotiations-between-commonspirit-health-and-essentia/w.essentiahealth.org/about/media-article-library/2021/update-on-negotiations-between-commonspirit-health-and-essentia/

LifePoint / Prisma
Authors: Torrey McClary, Ropes & Gray, and Nathan Money

After entering an agreement in March 2020, Tennessee based, LifePoint Health and Greenville, SC based Prisma Health abandoned a deal to jointly acquire KershawHealth, a single-hospital system in Camden, SC and Providence Health, a two-hospital system in Columbia, SC.

- In a joint statement the two parties cited inquiries by the FTC and state regulators as making it "prohibitive to move forward" on the deal.

  Joint Statement: https://prismahealth.org/patients-and-guests/news/agreement-for-prisma-health-to-acquire-kershawhealth-and%C2%A0providence-health-terminated

Sanford / Intermountain
Authors: Torrey McClary, Ropes & Gray, and Nathan Money

In December 2020, Sanford Health and Intermountain suspended merger talks. In March 2021, Sanford Health CEO confirmed to reporters that the merger talks were fully abandoned

- The initial suspension corresponded with a leadership transition at Sanford, with Bill Gassen, CEO taking over on November 24, 2020.

- Gassen cited the COVID-19 pandemic as the primary reason for talks ending as he wanted to prioritize "fighting the pandemic"

- *Note*: worth noting the timing of his comments – before widespread availability of vaccines in the US. More recent comments by various hospital leaders across the country have not cited the pandemic as a rationale for changing plans.

Atrium Health Navicent / Houston Healthcare
Authors: Torrey McClary, Ropes & Gray, and Nathan Money

Two Georgia-based hospital systems, Atrium Health Navicent and Houston Healthcare, abandoned plans to merge, as announced in a joint statement on February 25, 2021.

- The joint statement cited the challenges presented by the COVID-19 pandemic as the primary reason the talks ended

- Talks to merge began in 2017

- However, on March 3, 2021 the FTC announced that they had reviewed the proposed merger and only ended their inquiry after the deal was called off.

- The FTC determined that the proposed merger would "eliminate the intense competition" between the two systems and would harm patients.

- The joint statement did not mention the FTC inquiry

Link to FTC Press Release: https://www.ftc.gov/news-events/press-releases/2021/03/following-federal-trade-commission-staff-recommendation-challenge

Article on FTC Inquiry: http://www.georgiahealthnews.com/2021/03/federal-antitrust-scrutiny-revealed-wake-navicent-houston-merger-collapse/

Trends in 2021 Deal Cancellations
Authors: Torrey McClary, Ropes & Gray, and Nathan Money

After a year of pandemic induced delays and cancellations in hospital transactions, 2021 brought more varied difficulties.

Increased antitrust activity by federal and state regulators created challenges for transactions (3/8 of the above ended, at least in part, because of government antitrust inquiries).

- Two unanswered questions: (1) Is this part of a recent trend of increased public attention and appetite for antitrust activity, as is most notably seen in the tech industry; or (2) Is this simply the result of a change in administration in DC?

- The FTC ordered six insurance companies to provide information that will allow the agency to study the effects of physician group and healthcare facility mergers (link)

- The FTC initiated a review of its merger review process to determine how best to use its limited resources in the face of a recent surge in merger filings (non-healthcare specific) (link).

We also saw the impact of increased organized labor activity on hospital transactions, with the abandonment of the Essentia acquisition.

- While one cancelled deal isn't enough to establish a trend, 2021 saw a large increase in labor activity impact business organizations across several industries.

- Worth keeping an eye on labor activity in healthcare in 2022 to anticipate impacts on transactions – particularly as employee burnout from COVID-19 caseloads intensifies.

C. Developments in Governance

1. DOJ Updated Guidance: "Evaluation of Corporate Compliance Programs"

Authors: Anne M. Murphy, Arent Fox, Rachel D. Ludwig and Sarah A. Gaskell, Jones Day

- In June 2020, the U.S. Department of Justice issued updated guidance regarding the evaluation of corporate compliance programs.

- DOJ "emphasized the importance of continuing education . . ., including the importance of an active and informed board oversight role in compliance and continuous improvement in management of compliance risks."

- DOJ "emphasize[d] the importance of compliance due diligence of acquisition targets, and of a process for orderly integration of an acquired target into the compliance structure of the acquiring enterprise."

- Sources: U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs*, https://www.justice.gov/criminal-fraud/page/file/937501/download (updated June 2020); Anne Murphy, *Governance Oversight in Challenging Times: Sustaining Healthcare Board Education Remains Imperative*, The Governance Institute E-Briefings (Sept. 2020), https://www.governanceinstitute.com/resource/collection/14082583-FA83-45CD-9EFA-D9F250246B38/E-Briefings_Sept2020.pdf; https://mcusercontent.com/31e15e5fee7b5a6208b646806/files/2c6ae559-78ef-4786-8fb9-a701cf98f271/HomeHealthSectorDueDiligence.pdf.

2. Heightened Fiduciary Standards: The *In re Boeing* Decision

- **Summary**: On September 7, 2021, the Delaware Court of Chancery allowed a derivative stockholder lawsuit to proceed against The Boeing Company (Boeing) which alleges that Boeing's board of directors breached their fiduciary duties by failing to properly oversee and monitor airplane safety procedures and potential risks. At issue in *In re Boeing* is whether the board's actions in connection with the two fatal crashes of the 737 Max airplane constituted bad faith and a failure to oversee "mission critical" risks. Historically it has been difficult to assert a failure of oversight claim against a corporation's directors, but this case is indicative of a recent trend toward heightening the fiduciary standard as it relates to regulatory oversight.

- **Corporations should consider the following key points:**

  - The standard set forth in the 2019 Delaware case *Marchand v. Barnhill* is that a board must "make a good faith effort to put in place a reasonable system of monitoring and reporting about the corporation's central compliance risks" and that a board's failure to take steps "to make sure it is informed of a compliance issue intrinsically critical to the company's business operation" would "support[] an inference that the board has not made the good faith effort that *Caremark* requires";

  - Boards and board committees should review existing oversight procedures, duties, and systems, as well as internal reporting and auditing mechanisms to ensure alignment with the heightened *Marchand* standard;

  - Risk categories that are essential (i.e., "mission critical") to the company's business should be expressly monitored, including by establishing or strengthening systems that guarantee adequate board oversight of the risk(s);

  - The director's oversight efforts should be accurately reflected in all board and committee minutes, and other internal documents should be prepared with the expectation that they may be disclosed in the future if a lawsuit does arise; and

  - In the event of mission critical risk materializing, it is imperative that the board respond quickly and proactively, and maintain a record of its response to the issue.

- **Sources**: Martin L. Seidel et al., *Recent Delaware Decision Highlight Heightened Board Oversight Requirements in Caremark Case*s, Holland & Knight (Sept. 30, 2021), https://www.hklaw.com/en/insights/publications/2021/09/recent-delaware-decision-highlights-heightened-board-oversight; Courtney Hague Andrews et al., In Re Boeing Decision Underscores Need for Risk-Based Corporate Governance by Directors, White & Case LLP (Oct. 21, 2021), https://www.jdsupra.com/legalnews/in-re-boeing-decision-underscores-need-4897734/

3. The Evolving Nature of In-House Legal Departments

- **Summary**: The role of chief legal officers (CLOs) and in-house legal departments has continued to evolve in the context of corporate governance. A 2021 report revealed that CLOs only spend about one-third of their time providing legal advice and typically dedicate the remainder to board matters, governance issues, business development, and advising executives on non-legal issues. CLOs are increasingly in positions of substantial influence within a company that stretch well beyond those traditionally expected of a legal advisor. CLOs and in-house legal departments are therefore expected to proffer a more well-rounded and business savvy set of skills and experience than ever before. This is also coupled

with a reported shift in the issue areas that businesses consider to be the most critical. For the first time, cybersecurity was at the top of the list followed by compliance and data privacy concerns. As companies adjust their expectations and legal priorities, CLOs and in-house legal departments will need to evolve to keep up with the changing demands.

- **Sources**: 2021 ACC Chief Legal Officers Survey, ©2021 The Association of Corporate Counsel, ACC_CLOreport21_FINAL.pdf; Michael W. Peregrine, *Key Governance Take-Aways from the Association of Corporate Counsel Chief Legal Officer Survey*, The CLS Blue Sky Blog (Feb. 26, 2021), https://clsbluesky.law.columbia.edu/2021/02/26/key-governance-take-aways-from-the-association-of-corporate-counsel-chief-legal-officer-survey/

4. Governing Board Oversight of COVID-19 Vaccine Mandates

- **Summary**: As the COVID-19 vaccine became readily available in 2021, governing boards began to grapple with the decision of whether to mandate the vaccine as part of the terms of employment. This determination has been further complicated by the Supreme Court's recent ruling which failed to impose a vaccination and testing mandate on private employers with more than 100 employees. Governing boards are therefore left to make the decision on their own, so long as there are no state or local mandates in place, and are likely to face backlash regardless of the decision. For most health care facilities, the vaccine mandate is in effect and while undoubtably creating less ambiguity, this and other factors have led to a shortage of health care workers nationwide.

- **Key developments**:

  On January 13, 2022, the Supreme Court blocked the Biden administration's effort to mandate the COVID-19 vaccine for large employers. The Supreme Court upheld the vaccine mandate for federal workers, but a federal judge in Texas recently blocked that effort, as well.

  - The vaccine mandate for health care workers is in effect and requires all employees of hospitals and other health care facilities that receive payments from the government through Medicare or Medicaid to be fully vaccinated. This impacts roughly 17 million health care workers across the U.S.

  - Major companies such as Starbucks and Carhartt have taken opposite approaches following the Supreme Court's recent decision with Starbucks scrapping its vaccine mandate and Carhartt promising to uphold its policy. Both approaches have been met with a mixture of support and condemnation.

  - Major banks, such as Citigroup and Goldman Sachs, are continuing to keep vaccine mandates in place.

- **Sources**: Anna Kaplan, *Starbucks Scraps Vaccine Mandate – Here's How Large Companies Are Responding to Supreme Court Ruling*, Forbes (Jan. 19, 2022), https://www.forbes.com/sites/annakaplan/2022/01/19/starbucks-scraps-vaccine-mandate---heres-how-large-companies-are-responding-to-supreme-court-ruling/?sh=4688297a1fa9; Jessica Rendall and Corinne Reichert, *Supreme Court blocks Biden vaccine mandate for businesses, keeps mandate for health care workers*, CNET (Jan. 13, 2022), https://www.cnet.com/health/medical/supreme-court-blocks-biden-vaccine-mandate-for-businesses-keeps-mandate-for-health-care-workers/; Jonathan Ronciano, *These 13 States are Facing the Worst Hospital Shortages as Omicron Fuels a New Surge*, Forbes (Dec. 25, 2021), https://www.forbes.com/sites/jonathanponciano/2021/12/25/these-13-states-are-facing-the-worst-hospital-worker-shortages-as-omicron-fuels-a-new-covid-surge/?sh=6a99603a7df8.

5. Governing Board Oversight of Efforts to Increase Diversity and Inclusion (DE&I)

- **Summary**: One of the most prominent trends in U.S. corporate governance in the past few years has been the effort to increase diversity and inclusion in the workplace, particularly at the upper levels of management. This increased demand for racial, ethnic, and gender diversity has continued to drive changes to board structure and agenda, hiring efforts, and regulatory initiatives.

- **Key developments**:

  - On August 6, 2021, the SEC issued an order accepting Nasdaq's proposal to require companies listed on the stock exchange to either (i) include on their boards at least one woman, as well as one individual who identifies as a racial minority or as LGBTQ+ or (ii) if they fail to meet this standard, to file a written explanation for why they are unable to meet the diversity targets.

  - A joint report by State Street Global Advisors and Russell Reynolds Associates identified the following 10 key recommendations for integrating diversity and inclusion efforts into their oversight practices:

    1. Ensure the CEO and board chair have the capacity and commitment to drive the organization's racial equity efforts long term.

    2. Build a board whose directors are racially and ethnically diverse and have experience with oversight of DEI.

    3. Make racial equity an active part of the business strategy and work toward clear and quantitative key performance indicators.

    4. Make racial and ethnic diversity, equity, and inclusion both a committee and a full-board responsibility.

5. Regularly evaluate the potential impacts of the company's operations on communities of color, embracing relevant opportunities and mitigating relevant risks.

6. Facilitate boardroom discussions that are thoughtful, balanced and intentional, and build a culture where directors are empowered to challenge ideas.

7. Include the perspectives of stakeholders (including employees) in board discussions.

8. Create a structured onboarding and ongoing training process that prepares all directors for effective oversight of DE&I.

9. Build a coalition, share best practices and learn from peers and experts.

10. Realize this is a long journey – be patient and don't give up.

- **Sources**: Rusty O'Kelley et al*., 2021 Global and Regional Trends in Corporate Governance*, Harvard Law School Forum on Corporate Governance (Mar. 3, 2021), https://corpgov.law.harvard.edu/2021/03/03/2021-global-and-regional-trends-in-corporate-governance/; Christopher S. Auguste et al., *SEC Approves Nasdaq Rule Changes Aimed at Expanding Boardroom Diversity*, Kramer Levin (Aug. 11, 2021), https://www.kramerlevin.com/en/perspectives-search/sec-approves-nasdaq-rule-changes-aimed-at-expanding-boardroom-diversity.html; Benjamin Colton et al., *Board's Oversight of Racial DE&I*, Harvard Law School Forum on Corporate Governance (Jul. 22, 2021), https://corpgov.law.harvard.edu/2021/07/22/boards-oversight-of-racial-dei/.

6. Governing Board Oversight of the No Surprises Act

- **Summary**: On January 1, 2022, the federal No Surprises Act went into effect. The Act is designed to limit the phenomenon of "surprise billing" which occurs when an out-of-network health care provider seeks to recover the cost differential between the payer's reimbursement amount and the provider's billed charges directly from the patient. This typically occurs when a patient is unaware that they have received a service, in whole or in part, from an out-of-network provider and are then placed in the middle of a dispute between the provider and the payer. The Act received bi-partisan support in Congress and has also been generally endorsed by the American Hospital Association and the American Medical Association. Moving forward, governing boards will need to oversee compliance with the No Surprises Act to avoid any penalties.

- **Key provisions of the Act:**

  - The Act governs three health care delivery situations: (1) emergency services, (2) non- emergency services furnished by out-of-network providers at in-network facilities, and (3) air ambulance services. It does not apply to services provided at an out-of-network facility that has no contractual relationship with the covering payer.

  - Out-of-network charges are limited in the following ways:

    1. Patient payments are capped at the patient's cost-sharing requirement for in-network care.

    2. The health plan/payer must pay the out-of-network provider an "out-of-network rate," as determined by state law, agreement between the payer and provider, or through the independent dispute resolution process.

  - Providers must provide notice to patients with a one-page description of the Act.

  - Providers must also provide a good-faith estimate to uninsured or self-pay individuals of expected charges for scheduled health care services and may have to participate in the payment dispute resolution process if the actual charges are higher than the good-faith estimates.

  - The Act creates a floor for consumer protection against surprise bills, meaning states may have their own version of the No Surprise Act which go above and beyond the responsibilities imposed on providers with the federal law.

- **Sources**: Anne M. Murphy, *Oh, the Irony: An Unwelcome Surprise for Providers in Implementation of the No Surprises Act*, (insert publication date) (insert publication link); *No Surprises Act: Overview of rules & fact sheets*, CMS.gov (Jan. 3, 2022), https://www.cms.gov/nosurprises/policies-and-resources/overview-of-rules-fact-sheets.

III. EMTALA

Authors: Louise Joy, Joy & Young, and Emily Mizell, Conner & Winters
(Updated January 2022)

A. Case Law-2021

- **Transferring Hospital did not violate EMTALA when Accepting Hospital could not provide needed care.** Plaintiff alleged that EMTALA was violated asserting that a transferring hospital made an inappropriate transfer because the receiving hospital could not provide the care needed. The transferring hospital arranged a transfer for a patient whom they could not treat because the patient needed vascular surgery. They

had an accepting hospital and the patient was en route to the accepting hospital when the on-call surgeon at the accepting hospital said they could not perform the surgery needed by the patient. The patient was transferred to a third hospital, but ended up having to undergo an amputation because too much time had passed. The court granted a motion for summary judgment for the original treating hospital. Basically, the court held that the transferring hospital did not violate the EMTALA transfer requirements by transferring the patient to a hospital that turned out not be able to provide the services that the patient needed. At the time of the transfer, the transferring hospital and physician reasonably believed that the receiving hospital could provide the care that they believed the patient needed. The fact that additional information revealed that the receiving hospital could not provide the care did not make the transfer by the original treating hospital "inappropriate" and thus violate EMTALA transfer requirements. *Ruloph v. Lammico,*2021 WL 517044 (W.D. Ark. 2/11/21) (Appeal filed 3/11/2021); please check if there have been any rulings on that)

- **Delay in transfer does not give rise to EMTALA violation:** Next friend brought EMTALA claim based on nerve damage to a child's eye. The child was seen at Crisp ED at 9PM and was diagnosed with diabetic ketoacidosis. At 10:30PM, transfer paperwork was signed. The transfer did not take place until 2:30AM and the child arrived at the children's hospital at 3:25AM. Plaintiff alleges eye damage was due to delay in transfer. 11 Circuit reviewed de novo the district court's dismissal of the case for failure to state a cause of action. On appeal, plaintiff alleged EMTALA violation because the transfer was not appropriate due to the delay. While Appellate court determined that the argument was not raised in the district court, the Appellate Court dicta concludes that EMTALA's "appropriate transfer" provision does not include any prohibition against delay or other time limitation. Instead, such an allegation may be appropriate for a medical malpractice case. The dismissal was affirmed. *Smith v. Crisp Reg. Hosp.*, 985 F.3d 1306 (11 Cir. 2021)

- **EMTALA does not apply to claim inpatient was discharged without being stabilized**: A 25-year-old law student was admitted for head trauma at Geisinger Medical Center. She was discharged 8 days later with prescriptions for methadone, Prozac, and Neurontin. At 7:00 AM the next day she was found with no pulse and later pronounced dead. Plaintiffs claim that EMTALA was violated because the patient was discharged without being stabilized. Court granted defendants' motion on the pleadings because patient had been admitted to the hospital and the claims belong in state court. *Grages v. Geisinger Health*, 2021 WL 880475 (M.D. Penn. 3/9/21).

- **EMTALA does not apply to inpatients**. Stroke patient was screened in the ED and admitted to ICU. The patient's family requested that the patient be transferred, but no transfer took place. Patient died. EMTALA is not a malpractice statute covering treatment after an emergency patient is screened and admitted; it cannot be used to challenge the quality of care. *Nartey v. Franciscan Health*, 2 F.4th 1020 (2021)

- **Admission to observation is not an inpatient admission under EMTALA.** A suicidal patient was evaluated at the hospital ED on 11/24/18. ED physician determined that patient required inpatient psychiatric care. Patient was admitted to observation while hospital found an accepting hospital. On 11/25/18 a psychiatric hospital accepted the transfer. The patient was transferred by private vehicle 160 miles by private vehicle by an 80 year-old relative and paraplegic individual. No instructions were given to family regarding precautions to take and patient was not restrained. Patient jumped out of the car at 65 MPH. Hospital sought to have EMTALA claim dismissed based on patient having been "admitted." Court held admission to observation is not an inpatient admission that would end EMTALA obligations of hospital. Court also held that plaintiff alleged sufficient facts to support an allegation that the hospital failed to perform an appropriate transfer. Motions to dismiss were denied. *Harmon v. Uintah Basin Med. Ctr,* 2021 WL 25328626 (D. Utah 06/21/21)

- **EMTALA and qui tam-US may dismiss Qui Tam Claims over objection of relator**. Vanderlan filed a qui tam suit based asserting on violations of the False Claims Act arising from alleged violations of EMTALA. The government moved to dismiss counts of the suit related to the alleged EMTALA violations. Without hearing, the district court granted the motion based on the government's "unfettered right" to seek dismissal of an action brought in its name and the fact the relator was given an opportunity to submit briefs challenging the dismissal. *US ex rel Vanderlan v. Jackson HMA LLC* (S.D. Miss. 1/5/2021).

- **EMTALA's 2-year Statute of Limitation and claims "relating back"**: Trial court should have granted motion to amend complaint to add EMTALA claim despite expiration of 2-year statute of limitation. Federal courts allow amendments to add claims arising out of same set of facts and such amendment is allowed under Indiana law. Indiana Supreme Court remanded case to permit amendment of claim. (Trial court case has a good review of statute of limitations issues including provisions that might allow the amendment under the theory the amendment relates back to the date of the original pleading). *Miller v. Patel*, 2020 WL 7019300 (Ind. Ct of App 11/30/20), *overturned Miller v. Patel*, 174 NE3d 1061 (Ind. 2021) (decided 10/7/21).

- **EMTALA Whistleblower action regarding refusal to accept transfers to psychiatric unit.** Hartman, a registered nurse who managed the inpatient child and adolescent psychiatric unit, reported to management that the transfer requests for two patients were improperly denied. Four days later Hartman was fired. Hartman alleged that her firing was due to reporting the alleged EMTALA violations arising from refusing to accept "appropriate transfers." Hospital sought dismissal of EMTALA whistleblower claim asserting that an appropriate transfer requires acceptance by the hospital, and the transfers were not accepted. Court held that such defense would render EMTALA's requirement to accept transfers meaningless and has allowed the case to proceed. *Hartman v. Centra Health,*__ F. Supp.3d __*,* 2021 WL 3130051 (W.D. Vir. 07/23/21)

- **Bankruptcy and Medical Debt**: Debt arising from Emergency Care is not consumer debt despite the fact that "most medical debts" are characterized as consumer debts in personal bankruptcy cases. Debt related to emergency care is not considered consumer debt because it was not voluntarily incurred. Bankruptcy cases may be dismissed when debts are primarily consumer debts. *In re Sijan*, 611 B.R. 850 (Bankr. S.D. Ohio 2020)

- **Improper Motive Requirement still alive in 6th Circuit:** Courts in the 6th Circuit require that the plaintiff allege an improper motive as basis for EMTALA screening requirement violation. *Galuten v. Williamson Cty Hosp.*, Dist., 2021 WL 3043275, 5 (6th Cir. 07/20/21)

- **Stabilization of EMC is *NOT* required prior to transfer.** After reading about 60 EMTALA cases for 2021, we saw quite a few courts state that EMTALA requires a hospital to stabilize a patient prior to transfer. This is stated as "EMTALA imposes two basic dues on hospitals: (1) provide an "appropriate medical screening examination with the capability of the hospital's emergency department…and (2) to stabilize the condition before transferring or discharging the patient." (Eg. *Galuten v. Williamson Cty Hosp.*, Dist., 2021 WL 3043275, 5 (6th Cir. 07/20/21), *Smith v. Crisp Reg. Hosp*., 985 F.3d 1306 (11 Cir. 2021), *Lemon v. Aurora Health Care N, Inc.* 2021 WL 689550, 3 (E.D. Wisc. 02/23/21). That is not true. If a hospital lacks the capability or capacity to stabilize a patient's emergency medical condition and the hospital transfers the patient based on a physician's certification that the benefits of transfer outweigh the risks despite the fact that the patient's emergency medical condition may or will deteriorate during transfer, such a transfer does not violate EMTALA. *Martindale v. Indiana U. Health Bloomington, Inc.,* 2021 WL 5029518, 2 (S.D. Ind. 09/30/21) (stating the stabilization vs. transfer options correctly).A hospital that cannot stabilize a patient's emergency medical condition is under an obligation to seek an appropriate transfer of the patient. Unfortunately, this incorrect interpretation of EMTALA can cause transfers to be refused and/or patient's conditions to be represented as stabilized when the patients are not stabilized. The actual requirement is that the sending hospital provide care within its capability/capacity to minimize risks during transfer.

- **Lots of *Pro Se* EMTALA or EMTALA related cases-** We were surprised to see so many cases that touch on EMTALA directly or indirectly be filed *Pro Se.* 23 of 66 cases were filed Pro Se and 3 of the cases had more than one reported decision in 2021.

- **EMTALA-Related**

    - **Physician subjected to disciplinary action and State Medical Quality Assurance Commission and Medical Board Action related to alleged EMTALA violations.** Dr. Dang, an ENT, was on call when he received a request to take care of an ED patient at a hospital for which he did not have privileges. A request was made to transfer the patient to the hospital where he had privileges.

An ED physician at his hospital accepted the patient transfer and requested Dr. Dang to care for the patient after arrival. Dr. Dang allegedly refused to come in and said that the ED physician could drain the abscess. The patient was transferred to a third hospital and received care. The case was self-reported to CMS and a violation was cited after a EMTALA survey was performed. The case was also reported to the Washington State Medical Quality Assurance Commission (MQAC) and four other incidents involving Dr. Dang refusing to care for patients. The MQAC ordered that Dr. Dang's medical license be subject to oversight with two years of monitoring. He was also required to, pay a $5,000, take an ethics course, write a research paper, and other conditions. He filed a complaint with the EEOC alleging discrimination. All actions against private defendants were dismissed. *Dang v. Moore*, 2021 WL 5083591, (W.D. Wash 11/2/21)

- **Challenging Balance Billing**: There continue to be cases that involve high charges for emergency services and transportation that is "out-of-network. *Scarlett v. Air Methods* is a putative class action challenging what are alleged to be "exorbitant fees by defendants for medical transport by helicopter." Due to the various classes, the case is complex, but the plaintiffs are succeeding. *Scarlett v. Air Methods Corp*, 2021 WL 1885986 (D. Colo 5/11/21).

- **Payment for On-call specialists at Critical Access Hospital**: HHS PRRB decisions contradict CMS position concerning the need for on-call physician under EMTALA. St. Helena Clear Lake, Critical Access Hospital, included costs for on-call specialists in its cost report. The costs were disallowed by the PRRB. According to PRRB on-call specialty physicians are not necessary to comply with EMTALA therefore on-call payments were not reimbursable to CAH. On call specialists are not needed, because the ER physicians have the necessary skills to stabilize a patient, and if necessary, transfer the patient to another hospital. (emergency room physician on-call costs are the only on-call costs that are reimbursable.") *St. Helena Clear Lake Hosp v. Becerra*, 2021 WL 1226713 (D. DC 3/31/21)

- **Medicaid Programs imposing caps on reimburse for nonemergency care.** In 2011 Tenncare, Tennessee Medicaid, imposed $50 payment cap for nonemergent ED care and the cap was upheld despite EMTALA requirements to provide medical screening examinations. *Emergency Medical Care Facilities PC v. Division of Tenncare,* 2021 WL 4641485 (Tenn. Ct. of Appeals Nashville 10/7/21)

- **Reasonable Payment for O-O-N ED Physicians being litigated**: There are several reported cases related to Out-of-Network ED physician groups challenging how reasonable rates are determined for payment of emergency physician services. The plaintiffs in *Emergency Physicians of NY v. United Healthcare,* 2021 WL 4437166 (SD NY 09/28/21), alleged two federal RICO claims and state law implied contract and unjust enrichment claims arising out of

an agreement between United Healthcare and Multiplan. As background, Ingenix had been used to pay claims prior to 2009. The NY Attorney General (Andrew Cuomo) investigated and United Healthcare was required to use FAIR Database starting in 2009. That requirement ended in 2015 and United Healthcare entered into an agreement with Multiplan to determine reimbursement rates for OON claims. Plaintiffs Mulitplan used Data iSight to determine price was being paid 6-9% of difference between United Healthcare's target rate and a lower rate that was identified using Data iSight rate. Federal district court dismissed RICO claims and state claim of implied-in-fact contract but has allowed claims under unjust enrichment to go forward. *Deanco Healthcare LLC v. Blue Cross of California,* 2021 WL 3704375, (C.D. Calif. 01/06/21); *Emergency Care Servs. Of Penn. v. United Healthcare Group, Inc.,* 515 F.Supp.3d 298 (E.D. Penn. 2021).

B. COVID-19 Waivers and Impacts (remain in effect in 2021)

- On January 31, 2020, Secretary of HHS issued the first COVID19 Public Health Emergency Declaration effective January 27,2020. The Public Health Emergency (PHE) Declarations are valid for 90 days and have been renewed periodically since that time. The most recent PHE was renewed on October 15, 2021 and took effect on October 18, 2021. It is due to expire on January 16, 2021. The following waivers remain valid as long as there as the COVID19 PHE is in effect.

- On March 9, 2020, CMS issued Memo QSO-20-15 Hospital/CAH/EMTALA, entitled Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to coronavirus Disease 2019 (COVID-19). The Memo clarifies the application of EMTALA's requirements in light of the pandemic, including transfer requirements of COVID-19 patients, screening sites, and testing/treatment for COVID-19 patients in an emergency department setting.

- On March 13, 2020, the Secretary of Department of Health and Human Services exercised authority under Section 1135 of Social Security Act to waive sanctions imposed for certain violations of EMTALA and other laws, entitled Waiver of Modification Requirements Under Section 1135 of the Social Security Act. Hospitals operating under this waiver will not be sanctioned for (1) directing or relocating "an individual to another location for the purpose of receiving medical screening pursuant to an appropriate state emergency or pandemic preparedness plan" or (2) transferring "an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic." The waiver is retroactive to March 1, 2020 and ongoing through the duration of the declared public health emergency.

    - On December 1, 2020, CMS issued the COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, similarly waiving the enforcement of Section 1867 of EMTALA allowing hospitals, psychiatric hospitals, and critical access hospitals, to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with a state's

emergency preparedness or pandemic plan.

  - Waivers to provide Medical Screening Examinations at an offsite alternate screening location not owned or operated by the hospital will be reviewed on a case-by-case basis.

- On March 30, 2020, CMS announced its "Hospitals Without Walls" initiative which, among other things, invokes the EMTALA waiver effective immediately. The Hospital Without Walls initiative also waives other CMS requirements, including certain conditions of participation, provider-based department requirements, and physical environment requirements, to permit hospitals to provide inpatient and outpatient hospital services (*e.g.*, room and board, nursing, and other hospital services) at remote locations or sites not considered part of a healthcare facility such as hotels or community facilities. The waiver of EMTALA sanctions is applicable only to actions that do not discriminate on the basis of a patient's source of payment or ability to pay and is effective until the termination of the declaration of emergency related to the COVID-19 pandemic.

- Also on March 30, 2020, CMS issued a revised version of Memo QSO-20-15 Hospital/CAH/EMTALA, Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19) (Revised). The memo was revised to include additional guidance related to drive through testing sites, clarifications of expectations related to the triage process and medical screening examination, and use of telehealth. For the first time, in this guidance CMS provides that a receiving hospital may refuse a transfer if they do not have the capacity to provide the necessary care and services.

- On April 30, 2020, CMS posted Frequently Asked Questions for Hospitals and Critical Access Hospitals regarding EMTALA providing further clarification of the obligations for hospitals managing the COVID-19 pandemic.

- Mask requirements—Hospitals may impose requirements that patients wear masks to prevent transmission of COVID19 to hospital staff and other patients. Individuals who present to seek care but who refuse to wear masks may be deemed to be refusing care and hospitals may follow EMTALA refusal of care provisions. Refusal of care terminates EMTALA obligations. Thus, the refusal to provide care because an individual refuses to wear a mask is not a violation of EMTALA.

- Survey Activity: On January 20, 2021, CMS issued QSO-21-13 regarding current priorities for Hospital Surveys, including surveys related to EMTALA compliance and it touched on "crisis standards of care" which may be implemented when hospitals experience extreme conditions due to patient surges, staffing shortages, lack of supplies or other resources.

  - Hospitals implementing crisis standards of care are asked to notify their State Agency. States, in turn, are asked to report to CMS.

- Only immediate jeopardy surveys will be performed between 1/21/21 and 2/20/21. Additional 30-day renewals may occur.

- Hospital recertification surveys are suspended and their current certifications will be extended for at least 30 day.

- Additional guidance for accrediting surveys will be issued advising them to suspend reaccreditation surveys for 30 days and perform targeted samples.

- Hospitals facing 90-day termination tracks will have their termination dates extended at least 30 days and there is no requirement to submit a plan of correction. Once the 30-day period is completed hospitals will have up to 60 days to demonstrate compliance.

C. Updates in the News

- Notably, in keeping with the litigation challenging large emergency department bills, UnitedHealthcare recently announced that its policy regarding emergency department claims will be updated effective July 1, 2021. Similar to Anthem's current policy, UnitedHealthcare intends to update its policy for evaluating ER claims based on a patient's presenting problems, the intensity of the diagnostic services performed and other patient factors and external causes.

IV. FRAUD AND ABUSE

(Updated January 2022)

A. DOJ Dismissals under 3730(c)(2)(A):

Authors: Laura F. Laemmle-Weidenfeld, Taylor A. Goodspeed, and Mikayla M. Paolini, Jones Day

- *False Claims Act Amendments of 2021*:

  - On October 28, 2021, the Senate Judiciary Committee passed an amended version of the False Claims Act Amendments of 2021 by a vote of 15-7, which was reported to the Senate on November 16, 2021. The bill's original language squarely placed the burden on the Government to demonstrate a reason for dismissing FCA actions under 31 U.S.C. § 3730(c)(2)(A), while giving relators the opportunity to show that the proposed reasons were "fraudulent, arbitrary and capricious, or contrary to law."

  - The amended bill requires the Government to "identify a valid government purpose and a rational relation between the dismissal and accomplishment of the purpose." Once the Government passes this test, the burden is placed on the relator to "demonstrat[e] that the dismissal is fraudulent, arbitrary and capricious, or illegal." Accordingly, if passed, the amended bill would effectively codify the

standard for DOJ dismissals adopted by the Ninth Circuit in *U.S. ex rel., Sequoia Orange Co.* v. *Baird-Neece Packing Corp.*

- *Polansky* v. *Executive Health Resources, Inc., et al*., No. 19-3810, 17 F.4th 376 (3d Cir. Oct. 28, 2021)

  - Relator alleged that Executive Health Resources, Inc., a physician advisory company, caused its client hospitals to over-admit patients by certifying inpatient services that should have been provided on an outpatient basis, and then billing those services to Medicare. The Government initially declined to intervene, then filed a motion to dismiss pursuant to § 3730(c)(3) several years later, which was granted by the District Court for the Eastern District of Pennsylvania.

  - On appeal, the Third Circuit considered two relevant circuit splits:

    - Government intervention authority – The Seventh Circuit and Sixth Circuit have interpreted the FCA as requiring DOJ to intervene before moving to dismiss a *qui tam* lawsuit, while the D.C. Circuit and Tenth Circuit have held that DOJ is not required to intervene before moving to dismiss.

    - Government dismissal authority – The D.C. Circuit has held that the Government has an "unfettered right" to dismiss, while the Ninth Circuit and Tenth Circuit have held the Government to a "rational relation" standard. The Seventh Circuit has recently taken a third approach, holding that Federal Rule of Civil Procedure 41(a) applies in FCA cases.

  - Third Circuit affirmed the dismissal order, holding that that the Government must intervene pursuant to § 3730(c)(3) before it can seek to dismiss a *qui tam* lawsuit under § 3730(c)(2)(A), but that it can seek leave to intervene at any point in the litigation upon a showing of "good cause," which it defined as any "legally sufficient reason." The Third Circuit also held that Federal Rules of Civil Procedure apply to government dismissals in FCA *qui tam* actions, just as they would in any other suit.

- *United States v. Republic of Honduras,* No. 20-10604, 2021 WL 6143686 (11th Cir. Dec. 30, 2021)

  - While this case is not directly related to health care, it analyzes: (1) whether the Government must first formally intervene prior to filing a motion to dismiss in a *qui tam* action; and (2) what standard of review the court must use at the hearing.

  - Eleventh Circuit had previously determined that the Government need not formally intervene before filing a motion to settle a *qui tam* action, and reasoned that the same applies to dismissals. The court noted, "[a]fter all, it is the Government's claim and the Government's damages. The decision to dismiss the case for the Government's damages lies within the prosecutorial discretion of the

Executive Branch." As such, the Eleventh Circuit held that the Government is not required to formally intervene before moving to dismiss a *qui tam* case even though it had earlier declined to intervene.

- The court also held that once the Government has filed a motion to dismiss, "it must exercise its executive authority in accordance with the Federal Rules of Civil Procedure (41 and 11), other applicable statutes, and the Constitution." In doing so, the Eleventh Circuit sided with the Seventh Circuit's recent decision in *United States ex rel. Cimznhca, L.L.C. v. UCB, Inc.*, 970 F.3d 835, 852 (7th Cir. 2020), as well as one facet of the Third Circuit's decision in *Polansky*, summarized directly above.

- *U.S. ex rel. Cimznhca v. UCB, Inc.*, 970 F.3d 835, 838-56 (7th Cir. 2020), cert. denied (June 28, 2021).

  - Relator was corporate entity established for purpose of bringing qui tam action.

  - DOJ had argued at district level that it had investigated and found relator's claims "to lack sufficient merit to justify the cost of investigation and prosecution and otherwise to be contrary to the public interest." District court denied motion to dismiss, rejecting DOJ position as "arbitrary and capricious" and "not rationally related to a valid governmental purpose."

  - 7th Circuit interpreted section 3730(c)(2)(a) to require DOJ to intervene before dismissing, held that motion to dismiss should have been treated as motion to intervene and to dismiss, and then applied F.R.C.P. 41 standards to dismissal analysis.

  - Circuit court held that 3730(c)(2)(a) confers on relator only the right to a hearing. District court had improperly held DOJ to inappropriately high dismissal standard akin to "reasoned decisionmaking" required under administrative law. Reversed and remanded for dismissal.

  - Supreme Court denied certiorari on 06/28/2021, leaving the 7th Circuit's holding intact.

- *United States v. Eli Lilly & Co., Inc.,* 4 F.4th 255 (5th Cir. 2021).

  - Fifth Circuit affirmed the district court's decision that dismissal was proper under 3730(c)(2)(a), because DOJ offered two valid purposes to justify dismissal: (1) relator's allegations lacked sufficient merit to justify cost of investigation and prosecution; and (2) further litigation would undermine practices that benefit federal healthcare programs. Relator then failed to meet the burden of showing that DOJ's motion to dismiss was fraudulent, arbitrary, capricious, or illegal under the *Sequoia Orange* standard.

- National Health Care Analysis Group ("NHCA")—a watchdog organization focused on health care fraud—brought 11 FCA qui tam actions against 38 parties, including Eli Lilly and Bayer Corporation, accusing defendants of engaging in an illegal kickback scheme by offering free patient-education services to providers in exchange for providers prescribing their products.

- After initially declining to intervene, DOJ moved to dismiss NHCA's complaints, citing concerns over the merits of the complaints, burdensome litigation costs, and potential health policy implications of litigation. The district court granted DOJ's motions to dismiss.

- The Fifth Circuit gave a detailed discussion of the circuit split between *Sequoia Orange* and *Swift*, then stated that "[a]ssuming, without deciding, that *Sequoia Orange*'s more burdensome test applies, we hold that dismissal was proper."

B. Dismissals under Rule 9(b)

Authors: Laura F. Laemmle-Weidenfeld, Taylor A. Goodspeed, and Mikayla M. Paolini, Jones Day

- *United States ex rel. Prose* v. *Molina Healthcare of Illinois, Inc*. 10 F.4th 765 (7th Cir. 2021)

  - Relator, the founder of General Medicine PC, a company providing skilled nursing facility services, alleged that Molina submitted false claims to Medicaid for nursing services provided through General Medicine PC for approximately two years after their contract ended.

  - In August 2021, a split panel of the Seventh Circuit reversed the district court's holding that Molina did not know that certain healthcare services it allegedly failed to provide played "a material role in the delivery of Medicaid benefits."

    - The majority opinion held that the complaint met the Seventh Circuit's reasonable inference standard, even taking account of the heightened pleading standards imposed by Rule 9(b). The majority credited the relator for providing "numerous details indicating when, where, how and to whom allegedly false representations were made," and excused the complaint's failure to plead the details about the contracts or contract renewal negotiations with particularity under Rule 9(b), because the relator would not have had access to those documents or conversations.

    - Chief Circuit Judge Diane S. Sykes asserted in dissent that the majority position broke with the circuit's own precedent on Rule 9(b) and conflicted with the *Escobar* ruling.

  - In September 2021, Molina argued in a petition for rehearing *en banc* that the

majority opinion "allows relators to plead FCA claims under multiple theories, all based on generic allegations that the defendant requested payment from the government despite breaching its contract," further stating that the majority "ignores the limiting principles of Escobar and Rule 9(b) [pleading standards], and offers no alternative limiting principle in their place."

- In November 2021, the Seventh Circuit issued an amended opinion, which came to the same conclusion on the topic of Rule 9(b): even under Rule 9(b)'s demanding standards, relator stated a claim under all three recognized theories of FCA liability (fraud in the inducement, express factual falsity, and implied false certification).

- *United States ex rel. Mamalakis* v. *Anesthetix Management,* No. 19-3117, 2021 WL 5818476 (7th Cir. Dec. 8, 2021)

  - Relator alleged that Anesthetix anesthesiologists regularly billed Medicare and Medicaid using the code for "medically directed" services when their services qualified for payment only at the lower rate for "medically supervised." A magistrate ruled that the complaint did not provide enough factual particularity to satisfy Rule 9(b), allowing relator a chance to amend.

  - The amended complaint included ten specific examples of inflated billing, each identifying the procedure in question, the anesthesiologist involved, and the specific ways in which he or she did not perform the services required to bill at the medical-direction rate. The magistrate held that the amended complaint still fell short under Rule 9(b) and dismissed the case with prejudice.

  - The Seventh Circuit reversed and remanded the case, finding that the ten representative examples provided a particularized basis from which to plausibly infer that at least on these occasions, Defendant presented false claims to the Government. The court allowed the case to proceed but under the bounds of "carefully managed discovery to test whether it in fact has evidentiary support."

- *United States ex rel. Owsley v. Fazzi Associates, Inc.,* 16 F.4th 192 (4th Cir. 2021)

  - Relator alleged that her former employer engaged in an upcoding scheme to submit inflated claims for payment to federal and Indiana state governments. The district court granted defendants' motion to dismiss for failure to state a claim.

  - The Fourth Circuit affirmed the district court's dismissal, finding that relator's complaint "provided few details that would allow the defendants to identify any specific claims—of the hundreds or likely thousands they presumably submitted—that she thinks were fraudulent."

  - The court reasoned that the relator did not identify a "representative claim that was actually submitted to the government for payment" or "otherwise allege

facts—based on personal knowledge of billing practices—supporting a strong inference that particular identified claims were submitted to the government for payment" (citing to 6th Circuit precedent for both possible standards).

- *Estate of Helmly v. Bethany Hospice and Palliative Care of Coastal Georgia, LLC,* No. 20-11624, 2021 WL 1609823 (11th Cir. Apr. 26, 2021).

  - Eleventh Circuit upheld the dismissal with prejudice of a qui tam suit brought by two former employees against Bethany Hospice, reasoning that allegations based on numerical probability are mere inferences that do not suffice to plead fraud with particularity under Rule 9(b).

    - Relators alleged that Bethany Hospice violated the FCA by submitting false claims when it billed the government for services provided to patients obtained through a kickback scheme. Namely, they argued that because a significant number of Medicare recipients were referred to the hospice, and because "all or nearly all" of the patients at the hospice received coverage from Medicare, it was mathematically plausible that the hospice had submitted to the government claims for patients obtained under kickback agreements.

    - 11th Cir. rejected this argument, holding that "numerical probability is not an indicium of reliability" sufficient to "meet Rule 9(b)'s particularity requirement." The court reasoned that "relators cannot 'rely on mathematical probability to conclude that [a defendant] surely must have submitted a false claim at some point.'" (quoting *Carrel v. AIDS Healthcare Found., Inc*., 898 F.3d 1267, 1277 (11th Cir. 2018).

    - Petition of writ for certiorari currently pending. On January 18, 2022, the U.S. Supreme Court invited the Solicitor General to file a brief expressing the views of the United States. *Johnson v. Bethany Hospice*, No. 21-462, 2022 WL 145173 (U.S. Jan. 18, 2022).

C. False Claims Act: Public Disclosure

Author: Scott Cameron, King & Spalding

United States ex rel. Zafirov v. Florida Medical Associates LLC, 2021 WL 4443119 (M.D. Fla. September 28, 2021)

- Relator filed a qui tam suit in May 2019, alleging that Provider Defendants engaged in fraudulent activity to increase their gainsharing payments from the Medicare Advantage Defendants. Relator also alleges that the MA Defendants, in turn, submitted false and incorrect diagnosis codes to CMS to increase the capitated payments.

- Defendants moved to dismiss, arguing that the complaint failed to plead fraud with

the particularity required by Federal Rule of Civil Procedure 9(b). The court agreed, and dismissed the claims on that basis.

- The court then found that the public disclosure bar also required dismissal as to the Medicare Advantage Defendants and the individual defendant, Pagidipati. The court employed a three-part inquiry to decide whether the public-disclosure bar applies: (1) before the filing of the qui tam complaint, had there been any public disclosures alleging fraud or from which fraud might be inferred? (2) If so, are the allegations in the complaint substantially the same as allegations or transactions described in the public disclosure? (3) If yes, is the complaint nonetheless allowed because the relator is an original source of the information?

- As for the first prong, the defendants argue that Relator's claims are based on a publicly disclosed False Claims Act case previously settled: *United States ex rel. Sewell v. Freedom Health Inc.*, No. 8:09-cv-1625-MSS-AEP (M.D. Fla. Aug. 17, 2009), which also included the Medicare Advantage Defendants and Pagidipati as defendants. Specifically, the defendants cite as public disclosures the settlement agreement in *Sewell*, the Corporate Integrity Agreement (CIA) in that case, a Department of Justice press release about that case, and various news articles discussing the fraud in that case. Relator did not dispute that the *Sewell* litigation was a public disclosure, and focused her arguments on the other two prongs.

- After comparing the allegations in *Sewell* with Relator's complaint, the court found the claims against the Medicare Advantage Defendants and Pagidipati were substantially the same in both. Thus, as to those defendants, the second prong was satisfied.

- Relator failed to allege that she voluntarily disclosed her allegations to the government before the public disclosures in Sewell. Nor does she allege in her complaint that she voluntarily disclosed her allegations to the government before she initiated this action. More fundamentally, the court found that Relator also does not qualify as an original source because her allegations fail to materially add to the public disclosures in *Sewell*. Her allegations about the MA Defendants' fraudulent scheme are largely addressed in the *Sewell* action. The court noted that a side-by-side review of Zafirov's compliant and the allegations publicly disclosed in *Sewell* reveals that Zafirov is not alleging a new scheme as much as she is alleging a perpetuation of a previously disclosed scheme.

United States ex rel. Rahimi v. Rite Aid Corp., 3 F.4th 813 (6th Cir. 2021)

- Relator filed a qui tam suit alleging that Rite Aid was defrauding the government by charging higher rates to customers covered by government-funded insurance plans than to other customers. Specifically, the amounts charged to government-funded plans did not receive the same discounts available to other customers through Rite Aid's Rx Savings Program. Relator alleged Rite Aid should base its usual and customary rate, which is the rate charged to the government, on the same discounted

rate it routinely offers other customers.

- Rite Aid moved for judgment on the pleadings claiming that the public disclosure bar precluded Rahimi's suit. There were several prior public disclosures. Rite Aid's own advertisement of its program clearly stated that "prescriptions paid for in whole or in part by publicly funded health care programs were ineligible." The State of Connecticut learned prior to Rahimi's disclosure that several pharmacies were charging Connecticut Medicaid recipients more than their membership discount prices and publicly announced it was investigating Rite Aid for such practices. The Inspector General of the U.S. Department of Health and Human Services had announced it was reviewing Medicaid claims for generic drugs to determine the extent to which large chain pharmacies were billing Medicaid the usual and customary charges for drugs provided under their retail discount generic programs. And another qui tam lawsuit was unsealed a month prior detailing an identical scheme by Kmart Pharmacies.

- The Sixth Circuit employed its three-part test to analyze the public disclosure bar: (1) whether a prior public disclosure had been made from which fraud might be inferred; (2) how closely related the allegations in the complaint are to those in the public disclosures; and (3) whether the qui tam plaintiff is the original source of the public disclosures. The court agreed with the district court that Rite Aid established all three required elements in its public disclosure bar defense, and affirmed the district court's grant of judgment on the pleadings.

United States ex rel. CKD Project, LLC v. Fresenius Medical Care Holdings, Inc., --- F. Supp. 3d --- 2021 WL 3240280 (E.D.N.Y. 2021)

- Relator sued under the False Claims Act, alleging that Fresenius maintained a "systematic and nationwide kickback scheme" in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

- Fresenius moved to dismiss, arguing that its prior disclosures contained in its SEC Form 20-F filings bar Relator's suit under the public disclosure bar. The Form 20-F filings stated that its dialysis centers are "joint ventures in which [Fresenius] hold[s] a controlling interest and one or more hospitals, physicians or physician practice groups hold a minority interest. . . . While we have structured our joint ventures to comply with many of the criteria for safe harbor protection under the U.S. Federal Anti-Kickback Statute, our investments in these joint venture arrangements do not satisfy all elements of such safe harbor.... [I]f one or more of our joint ventures were found to be in violation of the Anti-Kickback Statute ..., we could be required to ... repay to Medicare amounts received by the joint ventures pursuant to any prohibited referrals, and we could be subject to criminal and monetary penalties and exclusion from Medicare, Medicaid and other U.S. federal and state healthcare programs. Imposition of any of these penalties could have a material adverse effect on our business, financial condition and results of operations."

- The court agreed with Fresenius that this was enough to "set the government squarely upon the trail of the alleged fraud" and granted the motion to dismiss. The court also rejected Relator's argument that because it provided more information about the alleged scheme, that meant it was the original source. The court noted that "providing 'greater detail about the underlying conduct' is not enough to avoid the public disclosure bar when the complaint 'targets' the same fraudulent scheme that was revealed in a prior public disclosure."

United States ex. rel. Fernandez v. Freedom Health, Inc., No. 8:18-CV-1959-MSS-JSS, 2021 WL 2954415 (M.D. Fla. May 26, 2021)

- Relator brought a qui tam suit under the False Claims Act alleging that defendants submitted false claims to the government through the Medicare Advantage program by submitting "incorrect and/or unsubstantiated risk adjustment data" to increase their capitation payment. Defendants moved to dismiss, arguing that the public disclosure bar precluded relator's suit.

- Defendants argued that a prior suit against the same defendants, *United States ex rel. Sewell v. Freedom Health, Inc.*, which was based on virtually the same conduct, was a prior public disclosure that required dismissal.

- The court disagreed. *Sewell* involved conduct between 2008 and 2013. But Fernandez sued over conduct starting in 2014 – well after that in *Sewell*. The court found that even though the same conduct was previously disclosed, that did not preclude Fernandez's suit because he is an original source of his allegations. The court explained that a "relator qualifies as an original source where, as here, he offers 'evidence of new fraudulent activity—even new fraud that is perpetrated by old modus operandi.'"

D. False Claims Act: Medical Necessity

Dan Abrams Co. LLC v. Medtronic, Inc., 850 Fed. Appx. 508, 2021 WL 1235845 (9th Cir. April 2, 2021)

- Relator filed suit under the False Claims Act alleging that Medtronic fraudulently obtained Food and Drug Administration clearance for several devices used in spinal fusion surgeries and unlawfully marketed them for an off-label and contraindicated use. Relator alleged that this caused physicians to submit false claims to Medicare.

- Relator argued that the services were not medically necessary because they were an off-label or contraindicated use. The Ninth Circuit rejected the argument because off-label use of medical devices can be reasonable and necessary. Under CMS guidance, a device is not reasonable and necessary if it is (1) not safe and effective, (2) experimental, (3) not appropriate for the individual beneficiary's needs, or (4) substantially more costly than a medically appropriate alternative. Relator failed to allege facts sufficient to establish any of these.

- Relator also argued that the use was contraindicated, and therefore not reasonable and necessary. But the court found that as long as a doctor finds an off-label use to be medically reasonable and necessary, then the off-label use is permitted, even if the particular use is contraindicated on the label.

United States ex rel. Arik v. DVH Hospital Alliance, LLC, 2021 WL 1773495 (D. Nev. May 4, 2021)

- Relator brought a qui tam suit under the False Claims Act alleging that defendants conspired to defraud the federal government by seeking reimbursement for medically unnecessary and improper services, treatments, tests and hospitalizations. Defendants moved to dismiss, arguing that relator failed to plead claims with the requisite specificity.

- The court analyzed medical necessity under the standard recently articulated by the Ninth Circuit in *U.S. ex rel. Winter v. Gardens Regional Hospital and Medical Center, Inc.*

- The court ruled that most, but not all, of relator's improper patient care accounts satisfied this standard by alleging that certain inpatient admissions failed to satisfy the hospital's own admissions criteria. He also claimed that many of the patients were admitted for treatments that the hospital could not perform because it lacked the necessary facilities.

- But some accounts merely documented relator's disagreements with medical decisions, asserting little more than his reasonable difference of opinion on medical care. The court held that those accounts lacked entirely the indicia of subjective falsity required by the Ninth Circuit. These claims were dismissed with leave to amend.

United States ex. rel. Fernandez v. Freedom Health, Inc., No. 8:18-CV-1959-MSS-JSS, 2021 WL 2954415 (M.D. Fla. May 26, 2021)

- Relator brought a qui tam suit under the False Claims Act alleging that Defendants submitted false claims to the government through the Medicare Advantage program by submitting "incorrect and/or unsubstantiated risk adjustment data" to increase their capitation payment. Defendants moved to dismiss, arguing that relator failed to plead claims with the requisite specificity.

- Relator alleged that defendants forged prescription for certain screenings and pressured patients to receive medically unnecessary services. Relator cited to communications with defendants regarding NPIs, state license numbers, and facility numbers to "apparently" assist with submitting fraudulent billings to the Medicare Advantage program.

- Court granted defendants' motion to dismiss because Relator failed to provide sufficient "indicia or reliability" to support the allegation that defendants submitted a false claim to the government needed to satisfy Rule 9(b)'s heightened pleading standard. Relator did not worked in or supervise the billing department or have first-hand knowledge of the Relator submitting a false claim to the government. Relators' emails with defendants regarding requests for information to facilitate billing was not enough.

United States ex rel. SW Challenger, LLC v. Evicore Healthcare MSI, LLC, No. 19 CIV. 2501 (VM), 2021 WL 3620427 (S.D.N.Y. Aug. 13, 2021)

- Relators brought a qui tam suit under the False Claims Act alleging that defendants did not provide prior authorization and utilization services to MCOs that cover Medicare and Medicaid beneficiaries. Defendants moved to dismiss relators' Second Amended Complaint (SAC). The court granted defendants' motion and gave relators' leave to amend.

- Relators allege that defendants used an automated data analytics system with criteria that does not meaningful determine the need for certain services. Relators also allege that artificial intelligence would grant requests from providers without performing a clinical review. Relators also allege that a different software system restricted clinical reviewers from denying certain categories of requests. Relators also allege that defendants directed clinical reviewers to approve specific services for certain populations in certain areas.

- The court dismissed Counts 1 and 2 because Relators failed to satisfy Rule 9(b)'s standard. The court rejected defendants' argument that no claims have been alleged because MCOs do not submit claims to CMS. However, the court also found that Relators did not allege falsity because the utilization and prior authorization services were not so worthless that they were the same as providing no services at all. The court also found that relators also failed to plead these claims with sufficient particularity because the SAC did not identify any requests for payment submitted by defendants to MCOs. Relators also failed to identify who made requests for prior authorization services.

- The court dismissed the reverse false claims count because the relators failed to plead falsity and the court noted that a reverse false claim cannot be based solely on a decision to retain rather than return government funds.

United States v. Medtronic, Inc., No. 17-2060-DDC-KGG, 2021 WL 4168140 (D. Kan. Sept. 14, 2021)

- Relator brought a qui tam suit under the False Claims Act alleging that defendant caused Dole VA to perform medically unnecessary procedures. Defendant moved to dismiss, arguing that relator failed to plead the claim with the requisite specificity.

- Relator alleged that Medtronic sales representatives were present during the procedures and encouraged, marketed or instructed the overuse of Medtronic's devices. However, the court found that relator failed to provide specificity about which physicians were influenced by the sales representatives or how the sales representatives encouraged physicians to overuse Medtronic devices. The court also noted that the time span was a seven year period from 2011 to 2018.

- The court granted defendant's motion to dismiss relator's claim that Medtronic caused Dole VA to perform medically unnecessary procedures because relator failed to plead the facts with the requisite particularity required by Rule 9(b).

United States ex rel. White v. Mobile Care EMS & Transport, Inc., 2021 WL 6064363 (S.D. Ohio Dec. 21, 2021)

- Relators brought a qui tam suit under the False Claims Act alleging that defendants, medical transport services providers, instructed them to overbill government payors for transport services and pressured EMTs to add statements to reports to give the impression that the transport services were medically necessary when they were not.

- LogistiCare, a defendant, moved to dismiss relators Second Amended Complaint arguing that relators only sufficiently plead non-medically necessary transport for MyCare Ohio participants and MyCare Ohio has a capitated payment structure meaning that there is a set payment amount for each participant. Thus, LogistiCare argued that there could not be an overpayment for the medically unnecessary transport services provided to MyCare Ohio participants.

- The court disagreed and found that even if Aetna's payment from MyCare Ohio were capitated, it did not mean that defendants also received a set amount from the public fisc for its services. As a third-party vendor, LogistiCare's payment were not necessarily capitated like Aetna's payments. Based on this analysis, the court found that LogistiCare's statements may have been material and denied LogistiCare's motion to dismiss. The court distinguished other FCA cases with capitated payments by noting that in those cases the defendants were the recipients of the capitated payments unlike LogistiCare.

E. False Claims Act: Materiality

Authors: Brad Robertson and Lyndsay Medlin, Bradley

1. False Claims Amendments Act of 2021 (S.2428)

- The Senate Committee on the Judiciary has approved for the Senate's full consideration an amendment to the FCA that would explicitly provide that "the [g]overnment's decision to forego a refund or to pay a claim despite knowledge of fraud or falsity is not dispositive" on the issue of materiality.

***Yates v. Pinellas Hematology & Oncology, P.A.*, No. 20-10276, 2021 WL 6133175, at *6 (11th Cir. Dec. 29, 2021)**

- On appeal from a jury verdict rendered against it, defendant argued that, because a certificate required by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") was not a condition of payment, lacking the required certificate number could not be a material, actionable violation of the FCA.

- Citing *Escobar*, the Eleventh Circuit disagreed, holding that the lack of an explicit label on the certificate stating that it is a condition of payment was not dispositive to the question of materiality.

- Further, the Eleventh Circuit found that the fact that the laboratory had a certificate prior to an ownership change did not render the lack of certificate at the time of claim submission immaterial. Although the government did not sanction defendant or seek reimbursement of the claims, it had originally denied the claims lacking a certificate number. That fact, in combination with the defendant's conduct in attempting to hide the lack of certificate by re-filing the claims using another facility's location and certificate number, as well as the fact that the Florida agency that regulated the CLIA program within the state closed the facility in October of 2015 upon learning that it had been operating without a certificate, were dispositive of materiality.

***Druding v. Care Alternatives, Inc.*, No. CV 08-2126, 2021 WL 5923883 (D.N.J. Dec. 15, 2021)**

- After the district court awarded summary judgment to defendant in 2018 based on relators' failure to demonstrate falsity, the Third Circuit reversed and remanded in 2020, finding falsity was met and requiring consideration of the other elements.

- On remand from the Third Circuit, the district court again granted defendant summary judgment, this time finding that relators failed to prove that hospice documentation deficiencies were material to the government's payment decision because the government continued to pay the provider despite being aware of the poor documentation.

- The court found in defendant's favor despite acknowledging that defendant "had longstanding problems with maintaining necessary and proper documentation and that it was well aware of those problems," as "it is incumbent upon the Relators to present **some** evidence suggesting the Government's apparent disregard of the inadequacies in Care Alternatives' billing documentation was not the result of its having concluded those inadequacies were immaterial to its decision to make those payments anyway."

Cases Included in August 2021 Submission[47]

***United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732 (7th Cir. 2021)**[48]

- The United States District Court dismissed the complaint, finding that relator's allegations that the defendant knew services were material were too conclusory.

- The Seventh Circuit reversed, holding that the district court failed to give proper weight to the defendant's status as a "highly sophisticated member of the medical-services industry," and, further, that the complaint included "ample detail to support a finding that Molina either had actual knowledge that the government would view skilled nursing services as a critical part of the Nursing Facility rate cell (*i.e.*, as material), or that it was deliberately ignorant on this point."

- The Seventh Circuit further concluded that defendant's arguments regarding the government's continued payment and renewal of contracts with the defendant even after the relator brought the lawsuit were "better saved for a later stage, once both sides have conducted discovery."

***U.S. ex rel. Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.*, 5 F.4th 315 (3d Cir. 2021)**

- The United States District Court for the Eastern District of Pennsylvania entered judgment against defendant construction contractor, awarding $1,055,320.62 in treble damages and statutory civil penalties based on claims that defendant misclassified workers in its payroll invoices.

- On appeal, the Third Circuit affirmed, finding that the falsely certified payrolls were material.

- The Third Circuit rejected defendant's arguments based on the purportedly small value of the contract, the discretionary nature of the government's contractual ability to withhold payment, and the government's failure to take action against defendant while the suit was pending.
- Rather, the Court held that the government's undisputed right to withhold payment, regardless of whether the power was discretionary, in combination with evidence of the defendant's actual knowledge that the condition was material even if not expressly called a condition of payment, and a lack of evidence that the government would overlook misclassification demonstrated materiality.

***U.S. ex rel. Jehl v. GGNSC Southaven, LLC*, No. 3:19-cv-00091-MPM-JMV, 2021 WL 2815974, at *1 (N.D. Miss. July 6, 2021)**

[47] One case previously included in a prior submission dated back to December 2020. That case has been removed from this submission.

[48] The opinion Bradley cited in August 2021 was been amended and superseded by the above opinion on November 15, 2021. The holding on materiality did not change.

- The United States District Court for the Northern District of Mississippi, facing the possibility of trial on what the Court termed a "novel theory of liability" based on a "rather minor licensing issue," *sua sponte* ordered plaintiff to show cause why the case should not be dismissed.

- The Court suggested that the matter should be dismissed because the matter was better left to state and federal regulators to police given that "[t]he mandatory penalties and treble damages which exist in FCA claims are much too strong medicine for the conduct alleged."

- Particularly, the Court concluded that the FCA was an inappropriate enforcement mechanism under the circumstances, because evidence developed during discovery suggested that "actual Medicaid regulators would not have regarded the alleged violation in this case as something worthy of their time."

- The Court similarly found CMS guidance "clearly tends to reduce the importance of the licensing issues."

- After the close of discovery, relator sought to introduce an affidavit from a Mississippi state Medicaid official declaring the licensing violation would have been material to his office. The Court determined "the opinion of a single state official, offered in support of litigation, to be much less reliable than formal guidance issued by CMS to its surveyors."

- On August 12, 2021, Judge Michael P. Mills, author of the *sua sponte* order, recused himself due to friendship (and, seemingly, book club membership) with plaintiff's counsel. He stated in his recusal order that he was "completely undecided regarding whether [the] case should go to trial or not." The matter has now been assigned to Senior Judge Neal B. Biggers for ultimate determination.

***United States v. Wal-Mart Stores E., LP*, 858 F. App'x 876 (Mem), 2021 WL 2287488, at *1 (6th Cir. June 4, 2021)**

- The United States District Court for the Eastern District of Michigan dismissed relator's complaint and declined to reconsider dismissal. Relator appealed to the Sixth Circuit.

- On appeal, the Sixth Circuit affirmed the district court, holding that, because the government had access to the same knowledge as the defendant regarding the allegedly high doses of opiates prescribed, the government's decision to pay claims relating to the prescriptions was strong evidence that the dosage amounts were not material.

***Dan Abrams Company LLC v. Medtronic Inc.*, 850 F. App'x 508 (Mem), 2021 WL 1235845, at *1 (9th Cir. Apr. 2, 2021)**

- The United States District Court for the Central District of California dismissed relator's claims, and the Ninth Circuit affirmed in part and reversed in part.

- The Court separated relator's fraud claims into two distinct buckets: "Extra-Use" device claims and "Contraindicated-only" device claims and found that only the latter could meet the materiality requirement.

    - With respect to the "Extra-Use" devices, which had valid U.S. Food and Drug Administration (FDA) approval but were being used off-label, the Court affirmed dismissal and held that relator could not establish materiality because the federal government historically "allow[ed] reimbursement for off-label and even contraindicated uses."

    - With respect to the "Contraindicated-only" devices, which were "not properly cleared for any use" by the FDA and could only be used in a contraindicated fashion, the Court found that the complaint established plausible fraud in several areas which were "precisely those that the FDA considers in granting Class II certification." For that reason, the Court found that the fraud went "'to the very essence of the bargain'" between defendant, the FDA, and Medicare, and reversed the district court, reinstating the claim for those devices.

***U.S. ex rel. Bibby v. Mortgage Investors Corp.*, 987 F.3d 1340, 1343 (11th Cir. 2021)**

- As a prerequisite to obtain a Veteran's Administration (VA) loan guaranty, lenders are required to certify compliance with various VA regulations, including limitations on the fees charged to veterans. In *Bibby*, former mortgage brokers who specialized in originating VA mortgage loans alleged that defendant charged veterans unallowable fees and failed to disclose its practices.

- The United States District Court for the Northern District of Georgia granted defendant's motion for summary judgment on materiality grounds because the government continued making payments even after learning of defendant's allegedly fraudulently fee practices.

- The Eleventh Circuit reversed, holding that the government had established a sufficient basis for a jury to find the misrepresented fee compliance was material. In a seeming departure from sister circuits and traditional understandings of *Escobar*, rather than emphasizing the decision of the government to continue payment, the Court instead noted that "the significance of continued payment may vary."

    - Because the VA was required by law to continue its payments and hold its guaranties, the Eleventh Circuit held that the VA's other efforts to curb noncompliance (sending notice letters and auditing more regularly) were enough

to establish the requisite materiality for the purposes of surviving summary judgment.

***United States v. Kindred Healthcare, Inc.*, 517 F.Supp.3d 367 (E.D.Pa. Feb. 5, 2021)**

- The former director of a skilled nursing facility (SNF) operated by defendants alleged, among other things, that defendants understaffed the SNF to such a degree that the needs of residents could not be met in violation of federal and state regulations. Such understaffing purportedly made defendants' certifications with such regulations false.

- Although it ultimately granted defendants' motion to dismiss in part on other grounds, the United States District Court for the Eastern District of Pennsylvania rejected defendants' materiality argument.

- Because relator's complaint included two examples of CMS denying payments to SNFs purportedly "found to have significant and pervasive staffing violations" of a similar nature, relator adequately alleged materiality.

- Defendants argued that they could not have known that staffing levels were material to the government based on relator's stated examples of the government's prospective refusal to pay SNFs not affiliated with defendants.

    - Defendants argued that relator instead had to allege that CMS retroactively denied or recouped claims from facilities based on findings that they were understaffed

    - However, the Court held that the FCA "does not draw a distinction between prospective denial of payments and retroactive recoupment of payments."

F. FCA Developments Involving "Knowledge":
Author: Brian Roark, Bass Berry

***U.S. ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. 2021)**

- Relators alleged that the defendants' pharmacies falsely reported their "usual and customary" (U&C) prices to Medicare and Medicaid by listing their retail cash prices as their U&C price, rather than lower prices provided to customers requesting a match of a competitor's price

- In *Safeco Ins. Co. v. Burr*, the Supreme Court had held in a Fair Credit Reporting Act case that scienter is an objective standard under which defendants do not act "knowingly" if: (1) their interpretation of the relevant statute or regulation was objectively reasonable, even if mistaken, and (2) "authoritative guidance" did not warn them away from their interpretation.

- District court granted summary judgment to SuperValu, holding held that even if its

understanding of U&C price was incorrect, under *SafeCo*, SuperValu's interpretation was objectively reasonable and between 2006 and 2015, there was no clear authority setting forth how "usual and customary" prices should be determined.

- Seventh Circuit affirmed and joined the Third, Eighth, Ninth, and DC Circuits in holding that the *Safeco* scienter standard applies in FCA cases. Even if SuperValu believed it was violating the requirement, it is not enough that a defendant suspect or believe that a claim is false. A defendant's subjective intent does not matter because the inquiry is an objective one.

- This standard "does not shield bad faith defendants that turn a blind eye to guidance indicating that their practices are likely wrong," given the second prong of *Safeco*'s standard. "[A]uthoritative guidance," at a minimum, "must come from a governmental source—either circuit court precedent or guidance from the relevant agency" and "must have a high level of specificity to control an issue."

***U.S. ex rel. Skibo v. Greer Laboratories, Inc.*, 841 Fed. Appx. 527 (4th Cir. 2021)**

- Relators alleged that defendant manufacturer caused the submission of false claims by selling "custom mixes" of unlicensed allergenic extracts that physicians injected into patients to increase tolerance to allergens

- The defendant argued that Relators could not demonstrate scienter because manufacturer reasonably believed that custom mixes were covered by their FDA license and it was not required to have separate licenses to manufacture custom mixes until 2015 when the FDA issued guidance clarifying that separate licenses were required for custom mixes

- The district court granted summary judgment to defendant for Relators' failure to show that manufacturer acted with requisite intent. The Fourth Circuit affirmed, noting that prior to 2015, nearly the entire industry manufactured custom mixes without acquiring separate licenses for each individual mix. And, the FDA had inspected manufacturer more than 50 times over the years and had not raised an issue until 2013.

- The Fourth Circuit held that the record demonstrated that the common industry understanding of FDA guidance was to allow use of custom mixes and that defendant had acted according to that understanding.

***U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc.*, 10 F.4th 765 (7th Cir. 2021)**

- Relator alleged that Molina defrauded the government by continuing to accept capitated payments for providing a nursing-facility services package, even after it ceased offering skilled nursing facility (SNF) services that had previously been part of that package.

- District court granted Molina's motion to dismiss, reasoning that although the complaint sufficiently alleged that Molina knew it had violated a contractual requirement to provide SNF services, there were only conclusory allegations that Molina knew this requirement was material to payment.

- On appeal, the Seventh Circuit reversed, finding that the complaint plausibly alleged that "as a sophisticated player in the medical-services industry, Molina was aware that these kinds of services play a material role in the delivery of Medicaid benefits."

***Lupinetti v. Exeltis USA, Inc.*, 2021 WL 5407424 (N.D. Ill., Nov. 19, 2021)**

- Relator alleged defendants falsely labeled and identified their prenatal vitamins as requiring prescriptions so that Medicaid programs could not exclude them from coverage

- Applying *SuperValu* (discussed above), the district court dismissed Relator's claims, holding that the complaint cited no statute or regulation preventing defendants from labeling their prenatal vitamins as "prescription only"

- Defendants had an objectively reasonable belief that they were legally permitted to describe their prenatal vitamins as "prescription only" and there was no authoritative guidance to the contrary

***U.S. ex rel. Lewis v. California Institute of Technology*, 2021 WL 1600488 (C.D. Cal. Apr. 19, 2021)**

- Relator alleged that defendants violated the FCA by falsely certifying compliance with change control and conflict of interest provisions of agreement between Department of Energy (DOE) and university

- District court granted summary judgment to university on element of scienter because relator did not adduce evidence that defendants "knowingly violated a requirement" that they knew was material to the government's payment decision where the university made repeated disclosures to the DOE regarding the conduct at issue but DOE approved of those actions and continued its payments

***U.S. ex rel. Heller v. Guardian Pharmacy*, LLC, 2021 WL 488305 (N.D. Ga. Feb. 10, 2021)**

- Relator alleged that defendant long-term care pharmacy offered assisted living communities free, below market value, or below cost services in exchange for selecting defendant as their pharmacy

- District court denied pharmacy's motion to dismiss for failure to plead scienter, holding that scienter need only be pled generally, which relator had done by alleging that defendant's executive team consistent of "experienced healthcare executives" and by pointing to a prior FCA case involving somewhat similar inducements and to

OIG guidance that provision of non-fair-market value services presented a high risk of fraud and abuse

***U.S. ex rel. Blankenship v. Lincare, Inc.*, 2021 WL 649795 (S.D. Ala. Jan. 29, 2021)**

- Relator alleged that defendant DME company fraudulently billed Medicare for certain ventilators that were not given to patients

- District court ruled that relator failed to adequately plead scienter where she alleged only that DME company's center manager had ordered ventilators that patients did not receive but did not allege that the center manager was involved with or aware of any billing or submission of claims

- As such, relator had not alleged "more than a sheer possibility" that the center manager or any other defendant employee had knowledge that fraudulent claims for ventilators would be submitted to Medicare

***U.S. ex rel. Kuzma v. Northern Arizona Healthcare Corp.*, 2021 WL 75827 (D. Ariz. Jan. 8, 2021)**

- Relator alleged that defendant healthcare entities fraudulently obtained federal reimbursement under Medicaid through provider-related donations intended to disguise the source and destination of the funds

- Defendants moved to dismiss on the grounds that relator had not sufficiently alleged scienter because the regulation governing provider-related donations was ambiguous and that their interpretation of the regulation was reasonable

- District court held that the record did not support that defendants' interpretation of the relevant statutes and regulations was objectively reasonable

***U.S. ex rel. Martino-Fleming v. S. Bay Mental Health Centers*, 2021 WL 2003016 (D. Mass. May 19, 2021)**

- Relators alleged that defendants sought Medicaid reimbursement for mental health services provided by unlicensed and improperly supervised social workers and counselors

- Defendants moved for summary judgment on multiple grounds, including failure to develop proof of scienter on the grounds that the regulations at issue were ambiguous and that they reasonably interpreted them

- District court acknowledged that the relators must show that defendants knew that compliance with the underlying regulations was material to the payment of claims but denied summary judgment where relators presented sufficient evidence for jury to find that officers, directors, and corporate entities recklessly disregarded the

regulations which the court determined were not ambiguous

***United States v. Nora*, 988 F.3d 823 (5th Cir. 2021)**

- Nora was one of 23 persons indicted as part of home health fraud scheme involving paying for referrals, certifying patients who were not homebound, and "ghosting" of patients

- Nora, who was 22 when hired as data clerk, was later promoted to office manager. Nora was convicted of conspiracy to commit health care fraud and conspiracy to violate the AKS and sentenced to 40 months and ordered to pay restitution of $12,921,797.

- Fifth Circuit reversed Nora's conviction for lack of proof that he acted "willfully." While he may have understood that company was making referral payments for new patients, the Court held that there was no evidence that Nora "knew these payments constituted unlawful kickbacks"

- "[E]ven if a reasonable person in Nora's shoes should have known (or at least suspected) that ghosting was unlawful, that would only make Nora guilty of negligently participating in a fraud-it does not prove Nora acted "willfully." Additionally, testimony that "everyone knew" of the fraud cannot impute scienter to all 150 employees of a healthcare business subject to a complex system of laws and regulations.

***U.S. ex rel. Integra Med Analytics, LLC v. Mariner Health Care, Inc.*, 2021 WL 4259907 (N.D. Cal., Aug. 5, 2021)**

- Integra alleged that defendant's SNFs billed for excessive rehab services based on statistical analysis comparing defendant's rate of therapy to other SNFs. Integra also supplied testimonials from family members of former patients and former employees that unnecessary therapy was provided.

- Among other grounds, defendant moved to dismiss for failure to adequately allege scienter

- District court held that accepting the allegations as true, Integra's allegations that defendant pushed staff to bill for non-therapeutic activities and sought to maximize billing above the health needs of patients was sufficient to plead scienter

G. Anti-Kickback Statute: COVID-19 – AKS Guidance and Enforcement

Authors: Alicia Siani, Paul Shaw, Verrill Law, Kim Looney, and Hannah Maroney, K&L Gates

1. AKS Enforcement and Investigations related to COVID-19

As discussed in greater detail below, the DOJ and OIG continued to enforce claims related to kickbacks for medically unnecessary genetic testing. The Boca Toxicology LLC indictment and *Parris* case below demonstrate how the Government's enforcement efforts have expanded to incorporate charges for schemes that involve kickbacks for COVID-19 tests. As stated by the OIG Deputy Inspector General for Investigations in a press release dated May 26, 2021, "it's clear fraudsters see the COVID-19 pandemic as a money making opportunity -- creating fraudulent schemes to victimize beneficiaries and steal from federal health care programs."

- *DOJ-led coordinated law enforcement action to combat COVID-19 health care fraud*
    - Press release is available here:
        - https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19
    - On May 26, 2021 the DOJ announced a series of charges in New Jersey, California, and Florida (among other states) in which medical professionals allegedly offered and paid bribes in exchange for referrals of medically unnecessary testing frequently bundled with COVID-19 tests.
    - For example, the owner of Florida-based Boca Toxicology LLC was indicted on charges for his alleged participation in $9.3 million kickback scheme in which he paid patient brokers kickbacks in exchange for referring Medicare beneficiaries to the laboratory for genetic or other tests. The government asserts that Boca Toxicology LLC submitted $422,748 in claims related to medically unnecessary Respiratory Pathogen (RPP) tests bundled with COVID-19 testing.
- *U.S. v. Parris*
    - Criminal Complaint filed May 5, 2020 in the United States District Court Middle District of Florida
    - The press release is available here:
        - https://www.justice.gov/opa/pr/georgia-woman-arrested-role-scheme-defraud-health-care-benefit-programs-related-cancer;
    - The criminal complaint is available here:

- https://www.justice.gov/usao-mdfl/press-release/file/1276866/download

- On October 31, 2020, Defendant Hoobler Parris plead guilty to conspiracy to commit health care fraud by participating in a scheme to receive kickbacks from a laboratory that performed medically unnecessary cancer genetic testing ("CGX") tests. Specifically, Hoobler Parris ran a marketing company that solicited DNA samples (or "swabs") from Medicare enrollees. Additionally, Hoobler Parris would offer kickbacks to telehealth providers when they placed doctors' orders for medically unnecessary tests. Upon receiving the swabs and doctors' orders, the lab would send Hoobler Parris roughly 40-50% of the Medicare reimbursement it received for processing the tests.

- Hoobler Parris admitted that between September 2018 and March 2020 the participating labs billed more than $3 million dollars for cancer genetic tests, with Hoobler Parris personally obtaining more than $100,000 in kickbacks. Further, in response to the COVID-19 pandemic, Hoobler Parris expanded the scheme to receive kickbacks for medically unnecessary COVID-19 and Respiratory Pathogen Panel (RPP) tests.

- A sentencing hearing is scheduled for February 17, 2022.

H. Anti-Kickback Statute: Other Notable Cases and Trends

Notable case:

- *Purdue Pharmaceuticals admits to two counts of conspiracy to violate AKS in landmark $8.3 billion global settlement*

  - The press release describing the Purdue settlement is available here:

    - https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid; the press release describing the Practice

  - In October 2020, Purdue Pharmaceuticals entered into a global settlement that included criminal guilty pleas, more than $8 billion in penalties, and the dissolution of the company. The criminal resolution includes the largest penalties ever levied against a pharmaceutical manufacturer, though it remains contingent upon inclusion of specific conditions related to a Chapter 11 plan of reorganization that requires approval from a federal bankruptcy court. Initially, at least 24 states, as well as local and state governments, opposed the bankruptcy plan, which would require the Sackler family (the owners of Purdue Pharmaceuticals) to pay $4.3 billion but would otherwise protect the family's remaining $7 billion fortune from future legal action.

  - Pursuant to the landmark settlement, Purdue plead guilty to two counts of

conspiracy to violate the AKS (and one count of dual-object conspiracy to defraud the United States and to violate the federal Food Drug and Cosmetic Act). Specifically, Purdue admitted to making payments through its doctor speaker program to induce doctors to write more Purdue opioid prescriptions.

- Although opposed by a number of states, in September 2021, the federal bankruptcy judge approved the bankruptcy plan, releasing the Sacklers from liability in any civil opioid-related lawsuits, even though the Sacklers had not filed for personal bankruptcy protection. However, on December 16, 2021, the federal District Court overturned the bankruptcy judge's confirmation of Purdue Pharma's Chapter 11 plan. The District Court ruled the bankruptcy court had no authority to grant immunity from civil liability to parties who did not seek bankruptcy protection. The case is currently on appeal to the Second Circuit.

- The District Court opinion can be found at:

  - https://www.sdnyblog.com/files/2021/12/21-Civ.-07532-Order-Vacating-Perdue-Settlement.pdf

- Additionally, in a related settlement agreement, in January 2020, an electronic health record vendor, Practice Fusion, Inc., admitted to receiving kickbacks from Purdue and paid a total of $145 million in penalties. According to the settlement agreement, in 2016 Purdue made payments to Practice Fusion in exchange for Practice Fusion creating special "alerts" to prompt providers to prescribe Purdue opioids during patient visits.

- The Practice Fusion settlement is available here:

  - https://www.justice.gov/usao-vt/pr/electronic-health-records-vendor-pay-largest-criminal-fine-vermont-history-and-total-145

- *11th Circuit addresses the "one purpose" test in United States v. Shah*, 981 F.3d 920 (11th Cir. 2020)

  - Opinion is available here:

    - https://media.ca11.uscourts.gov/opinions/pub/files/201912319.pdf

  - A jury convicted Dr. Alap Shaw of violating the AKS by receiving kickbacks in exchange for writing prescriptions for medically unnecessary compounded drugs.

  - In his appeal the Eleventh Circuit, Shaw argued that district court erred by issuing (at the government's request) jury instructions consistent with the "one purpose" test. Under the one purpose test, a jury can convict under the AKS if "one purpose" of the defendant's acceptance of payment was to induce referrals. Shah contended that the district court should have instead instructed the jury that the

government was required to prove that his main or only reason for accepting the payment was made in return for writing prescriptions.

- In November 2020, the Eleventh Circuit ruled that the "one purpose" test was actually too high a standard (rather than too low, as Shah argued). The Court concluded that the jury instruction was erroneous because the AKS does not require proof of a payee's motivation for accepting a payment. The Court decided that the error was harmless, however, because the jury instructions required the government to prove more than the statute required.

- Importantly, the Court instructed that while the AKS does not require proof of the motive for the *payee's* crime under the AKS, the statute does require proof of motive to convict the *payor*.

- In January 2021, the Eleventh Circuit denied the petition for rehearing en banc.

- *4th Circuit affirms that commissions to independent contractors based on volume violates AKS in United States ex rel. Lutz v. Mallory, et al., 988 F.3d 730 (4th Cir. 2021)*

  - The decision is available here:

    - https://www.ca4.uscourts.gov/Opinions/181811.P.pdf

  - On February 22, 2021 the Fourth Circuit affirmed a $114 million judgment against Floyd Calhoun "Cal" Dent III, of Lexington, and his two co-conspirators for violating the Anti-Kickback Statute, and in turn, the False Claims Act.

  - In this case, the defendants, Health Diagnostic Laboratory ("HDL") and another laboratory, Singulex, entered into an exclusive contract with the marketing firm BlueWave Healthcare Consultants, Inc. ("BlueWave"). In return for selling laboratory tests, BlueWave received a base fee as well as additional commissions based on the volume of tests physicians ordered. The government argued that the AKS prohibited the labs from paying BlueWave for inducing others to arrange the tests, and that the AKS also prohibited BlueWave from paying its workforce of independent contractors for recommending purchase of the tests.

  - The defendants contended on appeal that the government failed to prove that they "knowingly and willfully" violated the AKS, and thus, they could not "knowingly" violate the False Claims Act. The Fourth Circuit held that the government provided "abundant evidence" at trial of the defendants' knowledge and intent. Specifically, the Court cited HDL's internal memo stating that its contract with BlueWave created a "high degree of risk" for violating the AKS because the commissions of the independent contractors depended on the contractors' volume of sales. Further, BlueWave attorneys also received legal advice that the arrangement would violate the AKS.

- The Fourth Circuit also rejected the Defendants' argument that the Defendants could not "knowingly" violate the statute because the statute was ambiguous. Though the Court acknowledged the AKS safe harbor for bona fide employees, the Court reasoned that there was no room for ambiguity regarding volume-based sales commissions for independent contractors because HHS guidance, as well as federal appellate courts, have repeatedly and consistently affirmed that volume-based commission payments to third parties violate the AKS.

- *Seventh Circuit affirms broad interpretation of "referral" under AKS*

  - *Stop Illinois Health Care Fraud, LLC v. Sayeed et al*., No. 12-cv-09306, 2021 WL 2331338 (N.D. Ill. Jun. 8, 2021).

  - The initial trial in the Northern District of Illinois focused on allegations that Management Principles, Inc. (MPI), a home health care company, violated the AKS by paying Health Consortium of Illinois (HCI) $5,000 a month for information about clients. MPI then used this information to market its home health services to beneficiaries of federal healthcare programs. The District Court found insufficient evidence to prove a violation of the AKS.

  - On appeal, the Seventh Circuit held that the Northern District of Illinois failed to apply the correct definition of "referral." According to the Seventh Circuit, the definition of a referral under the AKS is "broad, encapsulating both direct and indirect means of connecting a patient with a provider." The Court relied on *U.S. v. Patel*, in which the Seventh Circuit previously found that "refer" includes "a doctor's authorization to receive medical care." The Seventh Circuit remanded the case, instructing the district court to consider whether MPI was paying for indirect referrals under a broader definition of referral.

  - On remand in June 2021, the District Court applied the broader definition of referral and found that HCI made referrals to MPI within the meaning of the AKS.

- *Pfizer challenges HHS on copay assistance programs*

  - Pfizer's complaint for declaratory judgment is available here:

    - https://1.next.westlaw.com/Link/Document/Blob/I003ec1f0b7e811eaa3c7c8f96b970dd0.pdf?targetType=dct-docket-pdf&originationContext=document&transitionType=DocumentImage&uniqueId=1ac8b87d-1fab-4c9c-86a8-836dbfbf247d&contextData=(sc.Keycite)

  - In June 2020, Pfizer filed a complaint in New York federal court seeking declaratory judgment that its proposed copay assistance programs do not violate the AKS or the Beneficiary Inducement Statute (BIS).

- Briefly, Pfizer contended that its proposed charitable programs designed to provide copay assistance did not violate the AKS because the programs (1) were not remunerations; and (2) were not intended to induce the purchase, prescription or recommendation of health care items or services.

- Further, Pfizer asserted that OIG's interpretation of the AKS to prohibit the pharmaceutical company's donations to charities providing copay assistance infringes upon the company's first amendment rights by singling out pharmaceutical manufacturers' and imposing restrictions on their charitable giving.

- On September 30, 2021, the District Court ruled against Pfizer. The court refused to make a determination of Pfizer's proposed charity assistance program because the OIG had declined Pfizer's request for an advisory opinion on that program, and therefor never decided whether the charity program violated the AKS. The court further ruled the OIG appropriately determined that Pfizer's other copay program to directly fund patients' copays could potentially violate the AKS.

  - www.nysd.uscourts.gov/sites/default/files/2021-10/20cv4920%20Opinion%20on%20Summary%20Judgment%20Motions.pdf

I. Telehealth

- As CMS expanded its coverage of telehealth services during the pandemic, enforcement of kickback schemes related to telehealth remained a priority for the DOJ and OIG. In a May 13, 2020 press release, the DOJ explained "[a]s telemedicine becomes an increasing part of our healthcare system, particularly during the COVID-19 pandemic, vigilance in ensuring that fraud and kickbacks do not usurp the legitimate practice of medicine by electronic means is more important than ever."

- *Operation Rubber Stamp:*

  - The DOJ Press release describing charges brought under Operation Rubber Stamp is available here:

    - https://www.justice.gov/usao-sdga/pr/operation-rubber-stamp-major-health-care-fraud-investigation-results-significant-new;

    - the Beaufils indictment is available at https://www.justice.gov/criminal-fraud/file/1322026/download

  - "Operation Rubber Stamp" is the third DOJ-HHS nationwide enforcement effort focused on telehealth over the past several years. In October 2020, the DOJ announced that the Operation Rubber Stamp investigation resulted in charges against more than 40 individuals participating in an elaborate multi-year kickback

scheme in which telemedicine executives allegedly paid doctors and nurse practitioners practicing on telehealth platforms kickbacks for ordering medically unnecessary durable medical equipment (DME), genetic tests, and prescriptions.

  - While dozens of individuals will face various health fraud charges in connection with Operation Rubberstamp, the common thread to the scheme are the kickback arrangements to (1) marketers who identify unwitting Medicare beneficiaries, and (2) telehealth providers who order medically unnecessary services on behalf of those beneficiaries, often without ever performing any type of examination.

  - One nurse practitioner charged, Sherley Beaufils, allegedly ordered more than 3,000 DME items over the course of 14 months for patients she had never examined. In return for the nearly $3 million in services she billed to Medicare, Beaufils received cash payments as a kickback from co-conspirators.

- *Owner Of Telemedicine Company Pleads Guilty To Health Care Fraud Conspiracy*

  - Press release describing the case can be found here:

    - https://www.justice.gov/usao-mdtn/pr/owner-telemedicine-company-pleads-guilty-health-care-fraud-conspiracy

  - On December 20, 2021, a Kentucky woman pleaded guilty to conspiracy to pay and receive health care kickbacks from marketers in exchange for providing signed doctors' orders for Cancer genomic testing. The marketers targeted Medicare and Medicaid patients through door-to-door marketing, a senior citizen fairs, and nursing homes, convincing the patients to provide their genetic material via a mouth swab kit. In turn, the defendant provided kickbacks to doctors to obtain the orders for genetic tests, even though they were not the patients' treating physician and there was no medical necessity for the testing. Sentencing is scheduled for May 2, 2022.

- *Laboratory Owner Pleads Guilty and Sentenced to 82 months in Prison for $73 Million Medicare Telehealth Kickback Scheme*

  - Press release describing the case can be found here:

    - https://www.justice.gov/opa/pr/laboratory-owner-pleads-guilty-73-million-medicare-kickback-scheme-0

  - On October 31, 2021, a Florida man pleaded guilty in the Southern District of Florida for his role in a $73 million conspiracy to defraud Medicare by paying kickbacks to a telemedicine company to arrange for doctors to authorize medically unnecessary genetic testing. The scheme exploited temporary amendments to telehealth restrictions enacted during the COVID-19 pandemic that were intended to ensure access to care for Medicare beneficiaries.

- On November 9, 2021, the defendant was sentenced to 82 months in prison.
    - https://www.justice.gov/opa/pr/laboratory-owner-sentenced-82-months-prison-covid-19-kickback-scheme

J. Electronic Health Records (EHR)

- *Athenahealth enters into $18.25 million settlement agreement to resolve kickback claims*
    - Press release describing the settlement can be found here:
        - https://www.justice.gov/usao-ma/pr/athenahealth-agrees-pay-1825-million-resolve-allegations-it-paid-illegal-kickbacks
    - The settlement agreement is available here:
        - https://www.justice.gov/usao-ma/press-release/file/1361181/download
    - EHR company Athenahealth ("Athena") entered into a settlement agreement with the government and two qui tam relators in January 2021 resolving AKS and FCA allegations.
    - Specifically, the settlement agreement alleges that beginning in 2014, Athena violated the AKS by engaged in the following activities in order to generate sales:
        - provided existing and potential clients all-expense-paid trips to recreational events, including the Kentucky Derby and the Masters;
        - paid for referrals of potential new clients; and
        - entered into "conversion deals" with competitors which Athena paid the companies based on the number and value of the clients who began using Athena products.
    - Per the settlement agreement, Athena paid $18.25 million to resolve the AKS and FCA claims.

K. Recent AKS Prosecutions/Convictions

- *Thirteen Defendants Plead Guilty in $126 Million Compounding Fraud Scheme*
    - (Press release describing the case can be found here:
        - https://www.justice.gov/opa/pr/thirteen-defendants-plead-guilty-126-million-

compounding-fraud-scheme

- On October 27, 2021, thirteen defendants, including three compounding pharmacy owners, three physicians, two pharmacists, and three patient recruiters, pleaded guilty in the Southern District of Texas to a years-long, multi-state scheme to defraud the U.S. Department of Labor's (DOL) Office of Workers' Compensation Programs (OWCP) and TRICARE.

- According to court documents, the defendants submitted false and fraudulent claims to the OWCP and TRICARE for prescriptions for compounded and other drugs prescribed to injured federal workers and members of the armed forces. The defendants also paid kickbacks to patient recruiters and to physicians to induce them to prescribe these drugs. The defendants chose the particular compounds and other drugs based not on the patients' medical needs but in light of the amount of reimbursement for the drugs. The drugs were then mailed to patients, even though the patients often never requested, wanted, or needed them.

- *South Florida Addiction Treatment Facility Operators Convicted in $112 Million Addiction Treatment Fraud Scheme*

  - Press release describing the case can be found here:

    - https://www.justice.gov/opa/pr/south-florida-addiction-treatment-facility-operators-convicted-112-million-addiction

  - After a seven-week trial, on November 3, 2021, a federal jury in the Southern District of Florida convicted two operators of two South Florida addiction treatment facilities for fraudulently billing approximately $112 million for services that were never provided or were medically unnecessary, and for paying kickbacks to patients through patient recruiters, and receiving kickbacks from testing laboratories.

- *Medical Equipment Company Owners Sentenced to More Than 12 Years for $27 Million Fraud Scheme*

  - Press release describing the case can be found here:

    - https://www.justice.gov/opa/pr/medical-equipment-company-owners-sentenced-more-12-years-27-million-fraud-scheme

  - On December 15, 2021, a Texas woman and an Austrian national were sentenced yesterday to 151 months in prison for a $27 million Medicare kickback conspiracy. According to the evidence presented at trial, the two defendants owned and operated two durable medical equipment (DME) companies. From March 2016 to January 2019, the defendants paid kickbacks and bribes to their co-conspirator's call center in the Philippines in exchange for signed doctors'

orders for DME that were used to submit false claims in excess of $59 million to Medicare. From those claims, Medicare paid the defendants more than $27 million.

L. Anti-Kickback Statute: Developments

Authors: Kim Looney and Alexa Sengupta, K&L Gates

1. OIG Special Fraud Alert

Unlike 2020, there were no special fraud alerts issued in 2021. The 2020 Special Fraud Alert is available at https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf.

2. OIG Advisory Opinions

Advisory Opinion 21-01, published March 23, 2021, available at https://oig.hhs.gov?fraud/docs/advisoryopinions/2021/AdvOpn21-01.pdf.

Approved: Request for provision of free drug to patients who satisfy specified criteria. Prescribed drug is personalized medicine made from patient's own cells and intended to be a one-time, potentially curative treatment. Drug provided by pharmaceutical manufacturer.

- The OIG approved a request from a pharmaceutical manufacturer to supply a drug free to certain patients concluding that while the arrangement would generate prohibited remuneration under the AKS if the requisite intent was present, no administrative sanctions would be imposed, and the arrangement did not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

- The proposed arrangement involved a drug manufacturer providing a drug manufactured from a patient's own cells free to patient. The drug is generally considered a treatment of last resort and is intended to be a one-time potentially curative treatment. The assistance is offered to all similarly situated patients, regardless of payor, including Federal health care program beneficiaries, although Requestor did not believe any Medicare beneficiary had qualified or anticipated to qualify. Medicaid and TRICARE beneficiaries may qualify to receive drug.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the manufacturer's provision of the free drug despite risk of violation of AKS, including:

- The drug is a potentially curative treatment, individually manufactured using the patient's own drug cells and generally administered only once. Provision of free drug is not contingent on any future orders of the drug, and the risk of seeding (i.e. inducement of future referrals) is unlikely.

- Arrangement is distinguishable from problematic arrangements where manufacturer may offer the initial dose of a drug for a chronic condition free so that patient will continue to purchase the drug, which is then billed to Federal health care programs.

- FDA-approved drug is approved for two indications and the arrangement is available for patients for both. In suspect arrangement, manufacturer may offer drug free for only one clinical indication to maintain a high price for all other indications when paid for by Federal health care programs.

- Drug is offered free to all eligible patients regardless of whether it is administered in an inpatient or outpatient setting. Access in every setting means free drug will not inappropriately steer a patient to one care setting over another.

- While facility and physicians may receive financial benefit in that they earn income in the form of professional service fees and facility fees in connection with the administration of the free drug, the risk that either would over utilize the drug to earn a fee is reduced because drug is generally administered only one time and only available when prescribed on-label for patients who have undergone two or more lines of systemic therapy and did not respond to the initial treatment with other therapies.

Advisory Opinion 21-02, published April 26, 2021, available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2021/AdvOpn21-02.pdf.

Approved: Request for approval of arrangement where a health system, certain orthopedic surgeons and neurosurgeons employed by the health system, and a management company would invest in a new ambulatory surgery center (ASC).

- The OIG determined the arrangement whereby the health system would own 46 percent of the ASC, the physician investors collectively would own 46 percent, and the management entity would own eight percent implicated the AKS, would generate prohibited remuneration if the requisite intent were present, it presented a sufficiently low risk of fraud and abuse under the AKS and therefore the OIG would not impose administrative sanctions on the health system or the management entity. The management entity certified that it would not make or influence referrals, directly or indirectly to the physician investors or to the ASC, and no physician has or will have ownership in the management entity. Both physician investors and the health system would be in a position to make or influence referrals, implicating the AKS statute, Such payments that are a return to health system's or physician's investment interest do not qualify for protection under the ASC Safe Harbor because health system in a position to make or influence referrals directly or indirectly to physician investors, certain physician investors will fail to meet requirements of Safe Harbor, i.e. not all neurosurgeons will derive at least one-third of his or her medical practice income from performance of ASC-Qualified Procedures.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- Although one or more of the neurosurgeon physician investors would fail to meet the Hospital-Physician ASC Safe Harbor Provision requirement of physician investor income, the health system certified that the neurosurgeon physician investors would use the ASC on a regular basis as part of their medical practices and that physician investors would rarely refer patients to each other for ASC-Qualified Procedures. The procedures that would not be personally performed would be fewer than 1 percent, so that the physician investors would not be significant sources of cross-referrals to each other.

- The risk that health system would make or influence referrals to ASC minimized because health system certified that any compensation it paid to affiliated physicians for services furnished (e.g. through employee or personal services arrangement) would be consistent with fair market value and would not be related, directly or indirectly to volume or value of referrals any affiliated physicians would make to ASC or its physician investors. In addition, health system would not track referrals made to ASC by affiliated physicians.

- Neither the ASC, nor any investor, would loan funds or guarantee a loan for any investor to purchase ownership in ASC. ASC would not offer ownership based on any previous or expected volume or value of referrals. Capital contribution and profit distributions would be made in proportion to investor's ownership in ASC. No investor would hold any ownership through a pass-through entity.

- Any space or equipment leased by ASC from health system will comply with AKS safe harbors for space rental and equipment rental, and any services performed by health system would comply with safe harbor for personal services and management contracts and outcomes-based payments. ASC and investors also to provide written notice to patients referred of referral source's investment interest in the new ASC.

- Patients receiving assistance under a Federal health care program will be treated in a nondiscriminatory manner. All ancillary services provided to Federal health care program beneficiaries performed at ASC will be related directly and integrally to primary procedures performed at ASC and will not be billed separately to Medicare or any Federal health care program.

Advisory Opinion 21-03[49], published May 12, 2021, available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2021/AdvOpn21-03.pdf.

[49] Please note that we have not included summaries of Advisory Opinions 21-04, 21-05, 21-07, 21-09 and 21-11, all of which appear to be factually similar to Advisory Opinion 21-03. All Advisory Opinions are available at https://oig.hhs.gov/compliance/advisory-opinions/.

Approved: Request from Medigap Plans and a PHO regarding a proposal to incentivize the Medigap Plans' respective policyholders to seek inpatient care from a hospital within the PHO's network.

- The OIG approved a request for Medigap Plans to offer incentives for policyholders to use a PHO for inpatient care concluding that even though prohibited remuneration would be generated if requisite intent were present under the AKS as well as prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on either the Medigap Plans or the PHO.

- The proposed arrangement involved three distinct streams of remuneration: (i) network hospital's discounts to Medigap Plans on Medicare Part A inpatient deductibles; (ii) premium credit offered by Medigap Plans; and (iii) administrative fee paid by each Medigap Plan to the PHO. All three streams of remuneration implicate the AKS and the premium credit also implicated the Beneficiary Inducements CMP.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- Both the network hospital's discounts described in (i) and the premium credit offered in (ii) above are unlikely to pose a risk of increased costs to Federal health care programs. It is unlikely either of these could be offered to promote inappropriate utilization by their policyholders because Medigap Plans have a financial interest to ensure appropriate utilization and costs.

- The potential for patient harm from the discounts and the premium credit is minimal. The discounts will apply universally to all policyholders and would not be limited by discriminatory eligibility criteria such as length of stay or a policyholder's disease state. Patient choice is also not impacted, as there is no increase in cost-sharing obligations or premiums by the Medigap Plans for a choice to receive care at a hospital that is not a network hospital.

- Competition is unlikely to be significantly impacted by the discount or the premium credit. Medigap Plans will certify that they will not advertise any aspect of the arrangement to potential enrollees. Under the arrangement the Medigap Plans will not limit the choice of inpatient hospitals to the network hospitals and there is no financial penalty for choosing to select an inpatient hospital that is not a network hospital.

- While the offer of a premium credit to qualifying policyholders would implicate the Beneficiary Inducements CMP, and this stream of remuneration is not protected, for the reasons identified above, the OIG would not impose administrative sanctions for the offer of the premium credit.

- The administrative fee paid by each Medigap Plan to the PHO would implicate the AKS because the payments are in exchange for the PHO arranging for the provision of federally reimbursable inpatient services furnished by the network hospitals to policyholders at a reduced rate and no safe harbor is available. The OIG determined that the payment of the administrative fee would be sufficiently low risk under the AKS since it would be consistent with fair market value and does not take into account the volume of value of Federal health care program business and that there is a low risk that the methodology used to calculate the administrative fee would result in overutilization of Federal health care items or services of result in increased costs to any Federal health care program.

Advisory Opinion 21-06, published June 29, 2021, available at
https://oig.hhs.gov/documents/advisory-opinions/792/AO-21-06.pdf

Approved: Request regarding a spinal implant manufacturer's proposal to offer its products to hospitals at a reduced price if the hospitals agree to assume certain duties related to the products.

- The OIG concluded that a medical device manufacturer offering reduced prices to hospitals if the hospitals assume the duties usually performed by third parties that are compensated by the manufacturer (the Arrangement) would not involve an improper payment to physicians to induce the reduction or limitation of medically necessary services under the Gainsharing CMP. The OIG said it would not impose sanctions on the Proposed Arrangement because it neither violated the Gainsharing CMP nor generated prohibited remuneration under AKS.

- The Arrangement does not involve any payments from a hospital or critical access hospital to physicians and therefore does not implicate the Gainsharing CMP and the lower prices offered participating hospitals for the products without the intermediaries' services would not constitute remuneration.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement including:

- Participating hospitals would purchase the products directly from Requestor with no intermediary assistance or involvement; rather, participating hospitals would assume all of the duties that otherwise would have been performed by the intermediaries in connection with the products.

- In exchange for a hospital agreeing to assume intermediaries' duties, Requestor would offer the products to the participating hospital at a reduced price. The reduction would be approximately equal to the compensation otherwise paid to the intermediaries. The arrangement would also be optional; a hospital would have the ability to choose to participate in this program as a participating hospital or to

continue purchasing the products through traditional channels where intermediaries would perform their usual duties.

- The price Requestor currently charges hospitals includes not just the price of the product but also the cost of the intermediaries' services associated with the product. Participating hospitals would be purchasing only a product rather than a "package" of a product, including the intermediary's services. Rather than bestowing something of value, the reduction in price simply would reflect the reduction in services the participating hospital would be purchasing.

Advisory Opinion 21-08, published July 8, 2021, available at
https://oig.hhs.gov/documents/advisory-opinions/823/AO-21-08.pdf

Approved: Request from pharmaceutical manufacturer regarding financial assistance for transportation, lodging, and meals provided by pharmaceutical manufacturer to certain patients potentially eligible for treatment with the pharmaceutical manufacturer's drug.

- The OIG stated that the arrangement in which a pharmaceutical manufacturer provides certain financial assistance for transportation, lodging, and meals to certain patients receiving the manufacturer's drug and treatment does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- The arrangement provides access to the drug for Federal health care program beneficiaries who lack the financial resources to cover travel and lodging expenses associated with the drug treatment and who, because of their distance from the closest center that accepts their insurance and that can treat them within 3 months, otherwise may not be able to access the drug.

- Patients must undergo treatment at a treatment center because of objective safety criteria that a facility administering the drug must meet.

- The cost of the extensive travel required to undergo administration of the drug could inhibit eligible patients from receiving treatment that has the potential to improve their vision.

- The travel and lodging assistance Requestor provides under the arrangement facilitates the ability of eligible patients to undergo treatment consistent with the drug's label. The travel and lodging assistance enables eligible patients to adhere to the label's requirements that: (i) the treating physician determine if the patient has viable retinal cells; (ii) surgical injections take place in each eye, as applicable, at least 6 days apart; and (iii) the treating physician monitor the patient after each

injection for infections, visual disturbances, and retinal abnormalities.

- A facility may become a "center" only if it agrees to become a treatment center for the administration of the drug, completes Requestor's training on the drug and its administration, and meets the objective safety criteria established by Requestor.

Advisory Opinion 21-10, published August 6, 2021, available at
https://oig.hhs.gov/documents/advisory-opinions/951/AO-21-10.pdf

Approved: Request regarding a dental provider's provision of free routine and emergency dental services to certain indigent residents of skilled nursing facilities and nursing facilities.

- The OIG stated that an arrangement in which the Requestor, a dental provider, provides free routine and emergency dental services to certain indigent residents of skilled nursing facilities would not generate prohibited remuneration under AKS or Beneficiary Inducements CMP.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- It is not clear that the arrangement confers anything of value on the facilities, such as reducing the facilities' administrative burden.

- There would be no referrals for any items or services for which payment may be made by a Federal health care program. Particularly, (i) None of the items or services that Requestor, the owner, or the contracted providers furnish under the program are or would be paid for, in whole or in part, by a Federal health care program; (ii) neither Requestor nor the owner provides any items or services outside of the Program or would provide any items or services outside of the arrangement.

- The facts do not suggest that the free dental services would be likely to influence a beneficiary's selection of a particular facility for such services. Requester would make the free dental services available to qualifying residents of any facility with at least one resident, and it would not advertise or market the proposed arrangement. The program is itself available to residents of any facility in the state. Thus, the free dental services offered would not influence a beneficiary to select one facility over another.

Advisory Opinion 21-12, published September 15, 2021, available at
https://oig.hhs.gov/documents/advisory-opinions/983/AO-21-12.pdf

Approved: Request regarding a critical access hospital's proposal to offer an arrangement similar to a warranty to patients undergoing certain joint replacement procedures at the

hospital.

- Requestor, a not-for-profit critical access hospital serving a rural, eight-county region across two states, would offer an arrangement similar to a warranty applicable to specific joint replacement procedures performed by two employed orthopedic surgeons. For patients who meet certain qualifying criteria, Requestor would not bill the patient or the patient's insurer for certain items and services provided to treat complications that occur within 90 days of a qualifying joint replacement procedure.

- The proposed arrangement would constitute remuneration to payors—including, for example, Medicare advantage plans—in the form of costs avoided because Requestor would not bill for covered items and services furnished following a covered complication (up to the $50,000 limit). Additionally, the arrangement does not fit into the warranties safe harbor or any exception.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- The arrangement promotes quality of care and better outcomes with respect to the surgeries by providing an incentive for Requestor to reduce its financial exposure by attempting to prevent covered complications. The arrangement also has the potential to benefit patients, Federal health care programs, and other payors. It is possible that the arrangement could result in decreased costs to Federal health care programs and beneficiaries because Requestor would not bill for otherwise billable services up to the $50,000 cap in the event of a covered complication.

- Risks are also mitigated, in part, by the surgeons' independent exercise of their medical judgment. Clinical decisions relating to patients or potential patients would be made exclusively by the surgeons, and the surgeons do not have a direct financial stake in the program.

- The potential for inappropriate steering is reduced by mitigating factors, such as Requestor being a critical access hospital serving a rural, eight-county region across two states, and the nearest hospital is more than 40 miles away. Because a potential patient's options of health care providers may be limited, it would make it less likely that the arrangement would inappropriately influence a patient's choice of provider.

Advisory Opinion 21-13[50], published October 4, 2021, available at https://oig.hhs.gov/documents/advisory-opinions/1001/AO-21-13.pdf

Approved: Request regarding the proposed subsidization of beneficiary cost-sharing

[50] Please also see Advisory Opinion 21-17, which we have omitted because of its similarity in analysis and conclusion to Advisory Opinion 21-13. Advisory Opinion 21-17 is available at https://oig.hhs.gov/compliance/advisory-opinions/.

obligations for Medicare-covered services provided as part of a clinical trial involving Alzeimers disease.

- A professional association is the sponsor of the clinical study designed to evaluate the association between a certain brain imaging procedure and patient-centered outcomes in a clinically diverse group of Medicare participants experiencing cognitive impairment. A non-profit charity is the study director.

- The study, focusing on Alzeimer's disease ("AD") would present a minimal risk of fraud and abuse under the Federal anti-kickback statute, and the OIG would not impose administrative sanctions under the Beneficiary Inducements CMP regarding the proposed subsidization of certain Medicare cost-sharing obligations in the context of the clinical study.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- The proposed arrangement is part of a clinical study that has been developed in consultation with, and approved by, CMS.

- The coinsurance subsidy appears to be designed to meet the policy objective of advancing treatment and prevention of AD, particularly for minorities. Most notably, the study is specifically designed to collect and analyze data on underrepresented minorities by enrolling a substantial but fixed number of subjects: of an anticipated 7,000 subjects, the study aims to enroll at least 4,000 minorities.

- The study potentially could address a real or perceived evidence gap on racial and ethnic factors in AD research.

- The coinsurance subsidies offered appear to be a reasonable means to facilitate enrollment of a diverse set of subjects by removing a potential financial barrier to participation in the study.

- Because the coinsurance subsidy is specifically designed to facilitate participation in the study by a diverse group of subjects, it is possible that overall utilization of items and services may increase, but there is nothing to suggest that such an increase would be inappropriate. The proposed arrangement would include various guardrails that mitigate the risk of inappropriate utilization or an improper increase in costs to Federal health care programs.

- Requestors certified that neither they nor the study team nor the investigators would advertise the availability of coinsurance subsidies.

- In addition, beneficiaries must satisfy the enrollment criteria set forth in the study

protocol and execute an informed consent document to be eligible to participate in the study. Further, investigators must comply with the study protocol and are subject to oversight and monitoring by an IRB.

- The proposed arrangement is distinguishable from problematic seeding arrangements, such as those in which manufacturers offer subsidies initially to lock in future reimbursable utilization of an item or service. Beneficiaries would receive only one Medicare-billable PET Aβ scan and three Medicare-billable office visits as part of the study, and there is no expectation that participation in the study would trigger subsequent utilization of items or services billable to Federal health care programs.

Advisory Opinion 21-14, published October 5, 2021, available at
https://oig.hhs.gov/documents/advisory-opinions/1002/AO-21-14.pdf

Approved: Request regarding a proposal to extend an existing discount program for chiropractic patients to include Federal health care program beneficiaries.

- The OIG stated that the arrangement, in which a chiropractic office extends the same discounts/offers to Medicare patients as it does the general public, would not meet the requirements of the discount safe harbor, and thus would also not meet the exception to the Beneficiary Inducements CMP. Because access to the discounted price would be available only if the patient received all services in the bundle, and all services would not be reimbursed by the same methodology, the discounted price would not meet the definition of a "discount" for purposes of the safe harbor. Although the arrangement would not be protected under an AKS exception or safe harbor regulations, the OIG stated that it was using its discretion in not imposing administrative sanctions.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- The OIG stated that the concerns previously expressed when excluding bundled discounts from protection would not be present here.

- The reimbursable services furnished to Medicare beneficiaries would all be services reimbursed under the same payment methodology, Medicare Part B, pursuant to the physician fee schedule.

- Requestor certified it would allocate the discounts proportionally across each of the services in the package and would reflect such allocation on any receipt, billing statement, or claim, such that payors, including Medicare, would know the amount charged for each service, i.e., the discount would be readily attributable to each service purchased.

- Requestor would not, for example, be offering a deep discount on a non-reimbursable service to induce a patient to get additional reimbursable services.

Advisory Opinion 21-15, published November 10, 2021, available at https://oig.hhs.gov/documents/advisory-opinions/1007/AO-21-15.pdf

Approved: Request regarding a pain management practice's proposal to retain net profits from services provided by an employed CRNA pursuant to a reassignment of billing rights.

- Requestor is a pain management practice solely owned by a physician that employs a part-time CRNA to provide anesthesia services at locations where Requestor provides pain management services.

- Requestor's proposed arrangement implicates AKS in two ways. First, Requestor pays the CRNA remuneration in the form of salary payments in exchange for the CRNA furnishing anesthesia services. Second, the CRNA's reassignment of billing rights to Requestor gives Requestor the opportunity to earn a profit from the CRNA's performance of services because Requestor would retain net profits from the escrow account and future net profits.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- Requestor held all net profits from the CRNA's provision of anesthesia services in escrow and, upon the issuance of a favorable advisory opinion, stated that it would collect and retain the net profits from the escrow account and future net profits generated from the CRNA services.

- The first stream of remuneration—salary payments from Requestor to the CRNA for the ordering and furnishing of anesthesia items and services—is protected by the employment safe harbor because: (i) Requestor certified that the CRNA is a bona fide employee according to the definition of the term "employee" set forth at 26 U.S.C. § 3121(d)(2); 13 and (ii) salary payments from Requestor to the CRNA for the ordering and furnishing of anesthesia items and services constitute amounts paid by an employer to an employee for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

- The second remuneration stream—the opportunity for Requestor to earn a profit from the CRNA's performance of services as a result of the CRNA's reassignment of billing rights—the safe harbor would not offer protection because it protects remuneration only in one direction: from "an employer to an employee." Nevertheless, employment arrangements in which a health care professional who is a

bona fide employee reassigns billing rights to an employer in exchange for salary payments are a commonplace practice in the health care industry.

- The employment arrangement is a straightforward employment arrangement involving the reassignment of billing rights by the CRNA, where Requestor assumes certain duties that may be typical of an employer and where Requestor certified that the CRNA is a bona fide employee.

Advisory Opinion 21-16, published November 16, 2021, available at https://oig.hhs.gov/documents/advisory-opinions/1008/AO-21-16.pdf

Approved: Request regarding a pharmaceutical manufacturer's arrangement to provide up to a specified number of trial units of a long-acting antipsychotic drug to certain hospitals for inpatient use.

- The OIG found that the arrangement, under which the manufacturer provides free trial units of an injectable anti-psychotic drug for inpatient administration, presented a low risk under AKS for the following reasons:

- There was low risk of patient steering of the drug due to the nature of its administration and because the course of treatment also required a daily oral medication which would not be provided for free. There was a low risk of overutilization because prescribers must agree to use independent clinical decision making to ensure the drug is clinically appropriate.

- The drug would also not increase Federal healthcare program spending because it is not separately billable in the inpatient setting. Even if prescribed in the outpatient setting post-free trial where Medicare Part B is the payor, the drug has been shown to increase medication adherence as compared to other treatments. If greater medication adherence is achieved, as indicated by the Requestor, the risk of negative outcomes such as hospitalizations should decrease and therefore, the total cost of care would decrease.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement including:

- There is no known clinical barrier to switching from the free drug to another type of medication after the free supply ends.

- There are guardrails in place to ensure the drug is not misused such as prohibition on resale and the manufacturer placing limits (explicit caps) on the number of free trial units per patient and per hospital.

- There is no financial incentive for physicians to prescribe this drug over another

course of treatment given that the free trial units are limited to inpatient use.

- There was evidence that the product would reduce Federal program costs, and that the program does not remove a cost that the hospital would otherwise bear.

Advisory Opinion 21-19, published November 22, 2021, available at https://oig.hhs.gov/documents/advisory-opinions/1010/AO-21-18.pdf

Denied: Regarding a proposed joint venture for the provision of therapy services. The OIG concluded that the proposed arrangement, if undertaken, would generate prohibited remuneration under AKS, if the requisite intent were present.

- The OIG stated that the remuneration exchanged under the proposed arrangement would not qualify for protection under any safe harbor, and that the proposed arrangement presents a host of concerns, including patient steering, unfair competition, inappropriate utilization, and increased costs to Federal health care programs.

Relevant Facts:

The OIG relied on several relevant facts in analyzing the proposed arrangement including:

- Requestor is a contract therapy services company that provides management of day-to-day operations and therapy staffing for rehabilitation programs in long-term care communities, including skilled nursing facilities, assisted living facilities, and full-service continuing care retirement communities.

- Under the Proposed Arrangement, Requestor would enter into a joint venture with a company that directly or indirectly owns Facilities (the "JV Partner"), and the joint venture entity ("Newco") would provide contract therapy services to rehabilitation programs in facilities.

- The OIG stated that a significant risk of fraud and abuse would be present because in the proposed arrangement, the JV Partner would be in the same position as the "Owner" (a health care provider in one line of business). Requestor would be in the same position as the "Manager/Supplier" (an existing provider of a related item or service).

- The OIG stated that the proposed arrangement permits Requestor to do indirectly what it cannot do directly: pay the JV Partner a share of the profits from the JV Partner's referrals (whether directly or through its affiliated facilities) to Requestor for therapy services that are reimbursable by a Federal health care program. Thus, there is a significant risk that the proposed arrangement could be used as a vehicle to: (i) reward the JV Partner for directing Federal health care program and other business to Requestor; (ii) lock in that referral stream to Requestor; and (iii) block out potential

competitor therapy services providers.

Advisory Opinion 21-19, published December 6, 2021, available at https://oig.hhs.gov/compliance/advisory-opinions/21-19/

Approved: Request regarding Requestor's provision of free eye drops that mitigate side effects for patients using one of its products.

- The OIG stated that Requestor offers free eye drops to all patients who have been prescribed the product for an on-label indication, enrolled in the REMS (Risk Evaluation and Mitigation Strategy), and enrolled in Requestor's free eye drop program.

- The OIG stated under the arrangement, all patients, including Federal health care beneficiaries, are eligible to receive the free eye drops through the REMS vendor regardless of which physician prescribed the product. Enrollment documents that the patient signs make clear that Requestor—not the prescriber— sponsors the free eye drop program.

- The OIG concluded that the remuneration offered by Requestor under the arrangement is not likely to influence a beneficiary to select a particular provider, practitioner, or supplier.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- The eligible patient interacts exclusively with the REMS Vendor regarding the eye drop shipments.

- The eye drops are shipped directly to the eligible patient; neither product prescribers nor eye care professionals take possession of the eye drops nor have any role in the ordering, shipment, delivery, or receipt of the eye drops.

- Before discontinuing shipments of eye drops, the REMS Vendor contacts the prescribing physician to confirm that the inactive patient has discontinued treatment.

- Requestor certified that it neither covers any patient costs for the product in connection with the arrangement nor provides any remuneration to the physicians who prescribe the product in connection with the arrangement.

Advisory Opinion 21-20, published December 16, 2021, available at https://oig.hhs.gov/compliance/advisory-opinions/21-20/

Approved: Request regarding Requestor's proposal to create an online platform for users to search for and contact home-based health care providers, where providers listed on the website would be charged on a per-click basis; and advertising by individuals and entities other than home-based health care providers.

- Under the proposed arrangement, Requestor would operate an online platform in which patients seeking home-based health care services could search for providers. The home-based health care services would include skilled and non-skilled home health services, home-based physician services, nursing services, non-emergency transportation, mental health counseling, therapy services, hospice care, and infusion services.

- Requestor would enroll providers of home-based health care services on the platform who agree to Requestor's terms. Requestor's terms of participation would include paying the fees charged by Requestor and providing Requestor with a list of the: (i) services the provider offers; (ii) geographic areas in which the provider offers such services; and (iii) health insurance that the provider accepts for the services it offers.

- The OIG states that the proposed arrangement would implicate AKS statute in two ways. First, enrolled providers would pay Requestor on a per-click basis to recommend them, and by extension, their items and services, some of which may be reimbursable by a Federal health care program, by listing them on the platform in response to user searches for which they meet the search criteria. Second, Requestor would provide remuneration to users in the form of free use of the platform, and Requestor's provision of this remuneration to users could be intended to induce users to refer themselves to enrolled providers for the provision of items and services that are reimbursable by a Federal health care program. The proposed arrangement also would include payments from advertisers to Requestor for advertising spots on the platform and in the newsletter.

Favorable Facts:

The OIG relied on several favorable facts in analyzing the proposed arrangement, including:

- Requestor's sole role with respect to advertisers would be limited to the sale of space on the platform and in the newsletter.

- Requestor would contract with any individual or entity that wants to advertise on the platform or in the newsletter and who has the technological capabilities to do so (except providers of home-based health care services), and Requestor would not have an exclusive advertising arrangement with any advertiser.

- Requestor would clearly label all advertising spots as such and would include a disclaimer that the advertisements do not constitute a recommendation or endorsement of the products, services, or companies, and advertisers would be

prohibited from implying on their websites that Requestor endorses or has cobranded with any advertiser.

- Requestor would offer advertising spots on the platform and in the newsletter for a fixed monthly fee (i.e., a fee that does not change based on views, clicks, or otherwise) that would be consistent with fair market value and would not vary by advertiser.

- The fixed fees charted under the proposed arrangement would be consistent with fair market value and would not vary by enrolled provider. The fees enrolled providers would pay would not affect the frequency with which enrolled providers appear, or their placement, in the platform listings.

- Although Requestor is owned, in part, by an individual who is licensed to provide certain health care services, none of the owners of Requestor is involved, directly or indirectly, in the provision of any home-based health care services that may be offered by enrolled providers.

- The platform would not claim to be, on its website or in its marketing materials, operated by a health care provider or supplier.

- Any individual, regardless of insurance status or source of payment, can access the platform and view enrolled providers and advertisers.

- Requestor designed the platform to include other safeguards that mitigate the risk of fraud and abuse. For example, the platform's listing of enrolled providers or non-enrolled providers would not promote any specific items or services users could obtain from such providers.

M. Anti-Kickback Statute: OIG Enforcement and Investigations

1. DOJ/OIG Enforcement Statistics [Not AKS specific]

- The DOJ obtained more than $2.2 billion in settlements and judgments from False Claims Act cases in fiscal year 2020, compared to the $3 billion obtained under the FCA in 2019.

Please note that the anticipated press release and accompanying report for data on FY 2021 has not yet been released. The DOJ FY 2020 press release, dated January 14, 2021, is available here: *https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020****. Thus, the following information relates to FY 2020:***

- Despite a lower amount recovered relative to previous years, 2020 saw the most FCA cases filed since the enactment of the FCA.

- During the last five years, the average number of non-qui tam cases filed by the

government was 135. In 2020, the government filed 250 new cases.

- 83 percent – or 1.8 billion – of the recovered FCA dollars in 2020 stemmed from cases involving the health care industry.

- Of the more than $1.8 billion recovered from the health care industry under the FCA, nearly $1.3 – about 70% – derived from cases where the government intervened in a qui tam suit.

- According to the DOJ, the largest recoveries in 2020 came from cases involving the pharmaceutical industry, such as the Novartis settlement described below.

2. Significant Settlement Based on the AKS

- *Prime Healthcare Services and two physicians settling a case for $37.5 Million.*

  - The press release describing this settlement is available here: https://www.justice.gov/opa/pr/prime-healthcare-services-and-two-doctors-agree-pay-375-million-settle-allegations-kickbacks

  - On May 19, 2021, one of the largest hospital systems in the nation and two of its doctors agreed to pay $37.5 million to settle allegations of kickbacks, billing for a suspended doctor, and false claims for implantable medical hardware.

  - The parties, Prime Healthcare Services system and two physicians, one of which was Prime's Founder and CEO, settled to resolve violations of the False Claims Act and the California False Claims Act based on kickbacks paid by Prime to one of the physicians for patient referrals.

  - The settlement resolves allegations that the physicians, Dr. Reddy and Dr. Arunasalam, were paid kickbacks in various forms, including:

    - Kickbacks to purchase Dr. Arunasalam's physician practice and surgery center because the Prime wanted Dr. Arunasalam to refer patients to its Desert Valley Hospital in Victorville, California. The purchase price, which was substantially negotiated by Dr. Reddy, exceeded FMV and was not commercially reasonable. Prime also knowingly overcompensated the doctor, entering into an employment agreement with him that was based on the volume and value of his patient referrals.

    - Between 2015 and 2017, a Prime hospital used Dr. Arunasalam's billing number to bill Medicare and Medi-Cal for services that were provided by a doctor whose Medicare billing privileges had been revoked; and

    - Certain Prime hospitals billed Medi-Cal, the Federal Employees Health Benefits Program and the U.S. Department of Labor's Office of Workers'

Compensation Programs for false claims based on inflated invoices for implantable medical hardware.

- In connection with the settlement, Prime and Dr. Reddy entered into a five-year Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA requires, among other things, that Prime maintain a compliance program and hire an Independent Review Organization to review arrangements entered into by or on behalf of its subsidiaries and affiliates.

- Under the settlement agreement, Dr. Arunasalam will pay $2,000,000; Dr. Reddy paid $1,775,000; and Prime paid $33,725,000. The United States will receive $35,463,057 of the settlement proceeds, and California will receive $2,036,943. Prime and Dr. Reddy paid $65 million to settle previous unrelated allegations of false claims and overbilling in 2018.

N. CMS Final Rule; Modernizing and Clarifying the Physician Self-Referral Regulations[51] (85 Fed. Reg. 77492 (Dec. 2, 2020))

Authors: Justin K. Brown, Bradley, Meredith Eng, Polsinelli, Travis G. Lloyd, Bass Berry, and Neal D. Shah, Polsinelli

On November 20, 2020, CMS unveiled its highly anticipated final rule to modernize the regulations that implement the Stark Law. (The OIG's final rule to modernize the regulations that implement the Anti-Kickback Statute and the portion of the civil monetary penalties law that restricts beneficiary inducements is covered elsewhere in this whitepaper.) The final rule creates new exceptions for value-based care arrangements, clarifies key terms that are fundamental to the application of the Stark Law, and adds new protections for technology infrastructure improvements. With one exception, the final rule took effect on January 19, 2021.

1. Value-Based Arrangements

Author: Neal D. Shah, Polsinelli

The new exceptions for value-based care arrangements are built around a new set of set of terms, each with their own definitions and requirements. Using the new terminology, a "value-based enterprise" made up of "value-based participants" enters into a "value-based arrangement" to engage in "value-based activities" in order to achieve a "value-based purpose" for a defined "target population."

- Value-based enterprise is defined as two or more value-based participants collaborating to achieve at least one value-based purpose, where each is party to a value-based arrangement at least one other value-based participant in the value-based enterprise. The value-based enterprise must have an accountable body or person

[51] This portion of the outline includes certain updates that predate January 2021 because the updates either became effective within the past 12 months or are temporarily Covid-19-related waivers that remain in effect.

responsible for financial and operational oversight and have a governing document that describes the value-based enterprise and how its participants intend to achieve its value-based purpose.

- Value-based participants are individuals or entities that engage in at least one value-based activity as part of a value-based enterprise (other than a patient).

- Value-based arrangement is an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are the value-based enterprise and one or more of its value-based enterprise participants or value-based participants in the same value-based enterprise.

- Value-based activities are providing an item or service, taking an action or refraining from taking an action, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise.

- Value-based purposes are (a) coordinating and managing the care of a target patient population; (b) improving the quality of care for a target population, (c) appropriately reducing the costs to or grown in expenditures of payors without reducing the quality of care for a target population; or (d) transitioning from health care delivery and payment mechanisms based on the volume to mechanisms based on the quality and control of costs for a target patient population.

- Target patient population is an identified patient population selected by the value-based enterprise or its participants using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose.

Using this terminology, CMS created three new Stark Law exceptions for value-based arrangements. These exceptions are based on three different levels of risk sharing and impose additional requirements as the amount of risk shared between the parties decreases.

The first exception applies to value-based arrangements where the value-based enterprise is at full financial risk (or will be within the first year), which means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the payor for each patient in a target population for a specified period of time. Because the parties are at full financial risk, there are relatively few technical requirements to meet this exception. The remuneration must be for or result from value-based activities taken by the recipient of the remuneration for patients in the target population. The remuneration must not be inducement to reduce medically necessary services, must not induce referrals of patients outside the value based arrangements, and must comply with other Stark rules regarding directed referrals. Records of the methodology for determining the actual amount of remuneration paid under the value-based arrangement must be maintained for 6 years.

The second exception applies to value-based arrangements with meaningful downside risk, which means that the physician is responsible to repay or forgo at least 10% of the total value of the payment that the physician receives under the value-based arrangement. Meeting this exception requires complying with several technical requirements, in addition to meeting the requirements that must be met for the full financial risk exception. For example, a description of the nature and extent of the physician's downside financial risk must be set forth in writing, and the methodology used to determine the amount of remuneration must be set in advance.

The third exception, for value-based arrangements, does not require taking on downside risk, but has the highest technical compliance burden. In addition to the requirements for the full risk exception, the value-based arrangement must be commercially reasonable. The value-based enterprise must develop a detailed description of the value-based arrangement that includes the following:

- a description of the value-based activities,
- how the value-based activities are expected to further the value-based purpose of the value-based enterprise,
- the target patient population for the arrangement,
- the type or nature of the remuneration,
- the methodology used to determine the remuneration (which must be set in advance), and
- the outcome measures against which the recipient of the remuneration is assessed, if any.

This exception requires that the value-based arrangement be on outcome measures that are objective, measurable, and based on clinical evidence or credible medical support and must quantify improvements in or maintenance of the quality of patient care or reductions in the cost of care while maintaining or improving the quality of care. Any changes to the outcome measures must be made prospectively and set forth in writing. This exception also requires monitoring of the arrangement and its progress toward achieving the outcome measures at least annually (or at least once if the arrangement last less than a year). If monitoring of the arrangement indicates that the arrangement will not meet the outcome measures or value-based purpose, then the arrangement must be modified or terminated. Finally, value-based arrangements must be commercially reasonable.

2. Fundamental Terminology

Author: Travis G. Lloyd, Bass Berry

Although value-based arrangements take center stage, the final rule modifying the Stark Law regulations includes a number of highly significant changes and clarifications

applicable to a wide range of financial relationships.

- Fair Market Value

In the final rule, CMS revises the regulatory definition of fair market value to more closely align with the statutory definition, and to clarify that the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard. As revised, fair market value generally means the value in an arm's-length transaction, consistent with the general market value of the subject transaction. In the case of equipment rentals, the final rule adds that fair market value is to be determined without taking into account the intended use of the equipment. In the case of office space leases, the final rule requires that fair market value be determined without taking into account the intended use of the property and without adjustment to reflect the additional value the lessor or lessee would attribute to the proximity or convenience to the lessor where the lessor is a potential source of referrals to the lessee. The resulting regulatory definition consists of three parts. CMS also creates a freestanding regulatory definition of "general market value" for assets, compensation, and the rental of equipment or office space—each of which are premised on *bona fide* bargaining between a well-informed buyer and seller that are not in a position to refer to each other—to add clarity.

CMS emphasizes its continued belief that the fair market value of a transaction (including, in particular, compensation for physician services) may not always align with salary surveys or other compilations of valuation data. While consulting salary surveys and the like may be an appropriate "starting point," and in many cases be "all that is required," each compensation arrangement is different and must be evaluated based on its unique factors. CMS also again rejects commenters' requests for "safe harbors" that would deem compensation to be fair market value if certain conditions are met. In doing so, CMS states that it is not CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate.

- Commercially Reasonable

Although many Stark Law exceptions include a requirement that the compensation arrangement at issue be commercially reasonable, the Stark Law regulations do not define the term and CMS has said little about its meaning in commentary. In the final rule, CMS adds a regulatory definition and provides important interpretive guidance.

The final rule defines the term "commercially reasonable" to mean that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. According to CMS, the key question to ask is whether the arrangement makes sense as a means to accomplish the parties' goals. It is necessarily a judgment made from the perspective of the particular parties involved in this arrangement, and it is not a judgment about the value of a transaction.

Indeed, the final rule adds text to the regulations to clarify that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. CMS also offers some examples of legitimate business reasons why parties would enter into unprofitable transactions, including community need, timely access to health care services, fulfillment of licensure or regulatory obligations, the provision of charity care, and the improvement of quality and health outcomes.

- The Volume or Value Standard and the Other Business Generated Standard

Many Stark Law exceptions also include a requirement that the compensation paid under the arrangement is not determined in any manner that takes into account the volume or value of referrals by the physician who is party to the arrangement. Some exceptions also include a requirement that the compensation is not determined in any manner that takes into account the other business generated between the parties. Although CMS has addressed the meaning of these standards at various points in the Stark Law rulemaking process, CMS has not codified regulations defining the standards, and confusion within the regulated community has persisted, particularly as courts have grappled with the standards in recent years.

The final rule addresses the volume or value and other business generated standards through the creation of two sets of special rules to be codified at 42 C.F.R. § 411.354(d). The special rules define precisely when compensation will be considered to take into account the volume or value of referrals, or take into account other business generated between the parties. That is, the rules define the entire "universe of circumstances" under which compensation is considered to take into account the volume or value of referrals or other business generated. Under the rules, compensation takes into account the volume or value of referrals or other business generated if the compensation formula includes referrals or other business generated as a variable, resulting in an increase or decrease in compensation that correlates with the number or value of referrals or other business generated. Any methodology that does not "fall squarely" within these defined circumstances will be permissible.

CMS also addresses stakeholder concerns regarding the potential for compensation based solely on a physician's personally performed services to be seen as violating the volume or value and other business generated standards. Specifically, CMS noted concern about whether, in the wake of the *Tuomey* litigation, compensation paid to a hospital-employed physician paid on the basis of personal productivity could nevertheless be viewed as taking into account the volume or value of the physician's referrals, since the physician's personally performed services are often accompanied by hospital services that are considered designated health services ("DHS"). In the final rule, CMS reaffirms that an association between personally performed services and DHS furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of the physician's referrals or other business generated for the entity.

In addition, in the course of addressing the volume or value standard, the final rule modifies the definition of "indirect compensation arrangement" at 42 C.F.R. § 411.354(c)(2) in such a way that some arrangements that met the previous definition (and therefore must satisfy the requirements of the indirect compensation arrangements exception to avoid noncompliance) no longer do. Effective as of January 19, 2021, the regulations provide that an indirect compensation arrangement exists if aggregate compensation the physician varies with the volume or value of referrals or other business generated by the physician for the entity and the individual unit of compensation received by the physician either (1) is not fair market value or (2) is calculated using the physician's referrals to or other business generated for the entity as a variable, resulting in an increase or decrease in compensation that positively correlates with the number or value of referrals or generation of other business for the entity. CMS declined, however, to finalize its proposal to remove the phrase "varies with" from the definition, leaving open questions as to the meaning of the phrase.

As described below, CMS further revised the definition in the CY 2022 Physician Fee Schedule final rule. These additional revisions went into effect January 1, 2022.

Other Significant Changes

3. Definition of Designated Health Services
Author: Neal D. Shah, Polsinelli

CMS modified the definition of "designated health services" in a way that limits the universe of items and services covered under the Stark Law. Under the revised definition, the term will not include an item or service that does not affect the amount of Medicare's payment to a hospital under the Acute Care Inpatient Prospective Payment System, Inpatient Rehabilitation Facility Prospective Payment System, Inpatient Psychiatric Facility Prospective Payment System, or Long Term Care Hospital Prospective Payment System. For example, under this rule a referral to a hospital that results in an inpatient hospital stay paid under a Diagnosis Related Group (DRG) would be considered DHS. However, subsequent items or services ordered by physicians and covered under the same DRG would not be considered DHS, and orders for such items or services would not be considered "referrals" of DHS.

4. Other Definitional Changes: Physician, Referral, Remuneration
Author: Travis G. Lloyd, Bass Berry

The final rule also modifies the regulatory definitions of several key terms: physician, referral, and remuneration. First, CMS finalizes its proposal to amend the regulatory definition of "physician" so that the term is defined by cross-reference to the Social Security Act (42 U.S.C. § 1395x(r)), thereby eliminating inconsistencies between the statutory and regulatory definitions. Second, the definition of "referral" is modified to expressly reflect CMS's longstanding policy that a referral itself is not an item or service under the Stark Law. This change is intended to ensure that parties do not enter into arrangements to compensation physicians for their referrals, with those referrals

constituting items or services within the meaning of applicable exceptions. Third, CMS modifies the definition of "remuneration" so that "surgical items, devices, or supplies" are not categorically excluded from a carve-out to the definition for certain items that are used solely to collect, transport, process, or store specimens for the entity provided the items. The final rule effectively substitutes a functional test: whether a surgical item, device, or supply fits within this exception to the definition of "remuneration" turns on whether the item is, in fact, used solely for one or more of the six purposes listed in the statute and regulations.

5. Titular Ownership or Investment Interests

Author: Neal D. Shah, Polsinelli

CMS added new flexibility for physicians without economic rights in an entity to own such entity. Expanding on its logic in a 2005 advisory opinion (CMS-AO-2005-08-01), CMS will now allow physician ownership in DHS entities if the interest is merely "titular." A titular ownership interest means that the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment. The new provision is included at 42 C.F.R. § 411.354(b)(3)(vi).

6. Group Practice Changes and Clarifications

Author: Neal D. Shah, Polsinelli

The Stark Law's definition of "group practice" (42 C.F.R. § 411.352) is used in several exceptions, most importantly the in-office ancillary services exception (42 C.F.R. § 411.355(b)). The Regulatory Sprint rule modified several provisions covering the compensation payable to physicians in a group practice.

First, the definition now allows a group practice to distribute profits from DHS to a physician if such profits derive directly from the physician's participation in a value-based enterprise, and such profits will not be deemed to take into account the volume or value of referrals.

Second, the rule clarifies that a distribution of overall profits must include all of the profits from DHS attributable to the group practice's physicians or a pod of five or more and, further, a group may not develop different methodologies to distribute individual categories of DHS. Group practices are not required to use the same methodology for each pod of five or more physicians and may apply eligibility standards to a profit share so long as it does not result in compensation that directly takes into account the volume or value of DHS referrals to the group. Practices also may still define pods of physicians based on factors including specialty, practice patterns, location, tenure, or years of practice. This provision goes into effect on January 1, 2022.

CMS also made several smaller changes to the definition, including reorganizing and renumbering the productivity bonus and profit share provisions of the definition, removing references to Medicaid from the definition of "overall profits," and, consistent

with other changes made in the rule, changing the phrases "based on the volume or value of referrals" and "related to the volume or value of referrals" to "takes into account the volume or value of referrals."

7. Patient Choice and Directed Referrals

Author: Travis G. Lloyd, Bass Berry

Under the existing special rule for directed referrals, a physician's compensation from a *bona fide* employer, under a managed care contract, or under a personal service arrangement may be conditioned on the physician's referrals to a particular provider, so long as certain conditions are met. The final rule makes two substantive changes to this special rule, in part because of the aforementioned changes made to the volume or value standard: First, the final rule incorporates compliance with the special rule for directed referrals into a number of compensation exceptions, including the exceptions for employment relationships, personal service arrangements, and fair market value compensation. Second, the final rule adds a new condition that neither the existence of the compensation nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider. Thus, if a compensation arrangement would be terminated if the physician fails to refer a sufficient number patients for DHS, or if the number or value of the physician's referrals fail to achieve a specified target, the directed referral requirement would be impermissible and the compensation arrangement would not satisfy the applicable exception's requirement of compliance with the special rule. The final rule does, however, specifically permit direct referral requirements based on an established percentage—rather than the number or value—of a physician's referrals.

8. Period of Disallowance

Author: Travis G. Lloyd, Bass Berry

CMS refers to the "period of disallowance" as the period during which a physician may not make referrals for DHS to an entity with whom the physician has a financial relationship, and the entity may not bull Medicare for such services. In prior rulemaking, CMS created regulations that were intended to establish an outside, bright-line limit for the period of disallowance in an attempt to give the regulated community clear guidance on steps that could be taken to ensure that the period of disallowance had ended. Citing stakeholder confusion about the import of these regulations, and criticizing them as overly prescriptive and impractical in application, CMS finalized its proposal to remove them in their entirety. This does not, of course, change the standards for compliance, nor does it preclude parties from relying on the goal posts laid out in the regulations to confirm that the period of disallowance has ended.

In the course of its discussion about the period of disallowance, CMS also takes up the subject of whether unintended administrative errors in the administration of a compensation arrangement (such as invoicing the wrong amount due under a lease agreement or paying the wrong amount under a services agreement due to a typographical error) result in noncompliance. In the proposed rule, CMS stated that

parties that detect and correct administrative errors or payment discrepancies during the course of an arrangement are not necessarily "turning back the clock" to address past noncompliance, and therefore may not run afoul of the Stark Law in resolving such errors or discrepancies. (Failure to remedy these administrative errors, however, could result in noncompliance.)

In the final rule, CMS reaffirms guidance it offered in the proposed rule. In short, when unintentional administrative or operational errors that result in payment discrepancies under a compensation arrangement are identified and rectified in a timely manner, the discrepancies do not cause a compensation arrangement to be noncompliant during the time they existed. To confirm its policy view, CMS codified in regulation a new special rule for reconciling compensation in such instances. The new special rule, 42 C.F.R. § 411.353(h), provides that an entity may submit a claim, and payment may be made to an entity that submits a claim, for DHS if (1) no later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration has been paid as required under the terms and conditions of the arrangements, and (2) the compensation arrangement otherwise fully complies with an applicable exception.

While the final rule provides a regulatory allowance for the timely resolution of payment discrepancies, the commentary does highlight its limits. CMS notes that parties that fail to reconcile known payment discrepancies "risk establishing a second financial relationship (for example, through the forgiveness of debt or the provision of an interest-free loan) that must satisfy the requirements of an applicable exception" to avoid an instance of noncompliance. In particular, CMS casts doubt on whether parties could discover an error in the first few months of a long-term arrangement and suffer no consequences if they wait until the end of the arrangement to reconcile the discrepancies. CMS also highlights the amount of excess compensation or unpaid compensation, and how long the known overpayment or underpayment of the compensation has continued, as relevant factors in the analysis of whether there is a separate financial relationship, and if so, when it should be deemed to have commenced.

9. Special Rules for Writing and Signature Requirements for Compensation Arrangements

Author: Travis G. Lloyd, Bass Berry

Both the writing and signature requirements described above have been the subject of legislative and regulatory attention in recent years, and both requirements were addressed in the final rule.

In the 2016 Medicare Physician Fee Schedule final rule, CMS provided clarification as to what constitutes a "writing" for purposes of meeting Stark Law exceptions that contain a writing requirement. CMS stated that arrangements need not be set forth in a single, formal contract to comply with the requirement that the arrangement be "in writing."

Although in most instances a single written document memorializing the key features of an arrangement provides the "surest and most straightforward means" of establishing compliance, CMS noted that there is no requirement that an arrangement be documented in a single, formal contract. Rather, depending on the particular facts and circumstances, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may be sufficient. According to CMS, the relevant inquiry when analyzing a collection of documents is whether the available contemporaneous documents would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made. CMS emphasized, however, that contemporaneous documents evidencing the course of conduct between the parties cannot be relied upon to protect referrals that predate the documents.

The Bipartisan Budget Act of 2018 ("BBA 2018") added provisions to the Stark Law statute pertaining to the writing and signature requirements. As amended, the relevant statutory provision provides that the writing requirement in various exceptions applicable to compensation arrangements "shall be satisfied by such means as determined by the [HHS] Secretary," including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. In addition, the BBA 2018 created a special statutory rule for temporary noncompliance with signature requirements, providing that the signature requirement of an applicable exception shall be satisfied if the arrangement otherwise complies with all the requirements of the exception and the parties obtain the required signatures no later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant. In the 2019 Medicare Physician Fee Schedule final rule, CMS finalized in its regulations this clarification of the writing requirement. It also removed the existing three-year limitation on the special rule on temporary noncompliance with signature requirements at 42 C.F.R. § 411.353(g)(2) to align the regulations with the amended statute.

In the final rule, CMS made additional changes to the writing and signature requirements. First, CMS included a provision that any requirement for a compensation arrangement to be in writing and signed by the parties will be satisfied if the parties obtain the writing or signature(s) within 90 consecutive calendar days immediately following the date on which the arrangement became noncompliant. To take advantage of this flexibility, the compensation arrangement must fully comply with all requirements of an applicable exception except the writing or signature requirement. As it noted in the 2016 Medicare Physician Fee Schedule final rule, CMS again stated that, depending on the facts and circumstances, the writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct of the parties. Thus, parties to an arrangement would have 90 days to compile the collection of documents if the parties elect to demonstrate compliance with the writing requirement in this manner.

In addition, CMS clarified through regulation its "longstanding policy" that the signature requirement may be satisfied by an electronic or other signature that is valid under applicable federal or state law. Although CMS declined to address particular scenarios,

such as whether a sender's typed or printed name on an email or letterhead would satisfy the signature requirement, it noted that if such an endorsement constitutes an electronic signature for purposes of applicable federal or state law, then it qualifies as a signature for purposes of the Stark Law.

It should be noted that although the final rule provides 90 days to obtain the require writing and signatures at the outset of an arrangement, it does not apply to modifications of the compensation terms. That is, parties do not have 90 days to reduce the modified compensation (or the formula for determining the modified compensation) to writing. Rather, the modified compensation (or the formula therefore) must be set forth in writing before the furnishing of the items or services for which it is to be paid. CMS based this distinction on its concern that compensation modifications could be made, either retroactively or prospectively, in a manner that takes into account the volume or value of a physician's referrals or other business generated by the physician.

It should also be noted that the special rule permitting parties up to 90 days to satisfy the writing requirement of an applicable exception does not amend or otherwise affect the requirement under various regulatory exceptions that compensation must be set in advance. The amount of or formula for calculating the compensation must be set in advance and the arrangement must satisfy all other requirements of an applicable exception, other than the writing or signature requirements, in order for parties to establish compliance by relying on the special rule. The interplay between the special rule for writing and signature requirements and the set in advance rule can be confusing, particularly because the final rule added regulatory text under which compensation is *deemed to be* set in advance if the compensation is "set out in writing before the furnishing of items or services." It is clear, however, that CMS intended the existence of a compliant writing is not necessary to meet the set in advance requirement.

10. Decoupling the Stark Law from the Anti-Kickback Statute (and Federal and State Laws and Regulations Governing Billing or Claims Submission)

Author: Travis G. Lloyd, Bass Berry

Many of the Stark Law's regulatory exceptions include a requirement that the arrangement does not violate the Anti-Kickback Statute. Most of those exceptions also require that the arrangement not violate any federal or state law or regulation governing billing or claims submission. These conditions are borne of the statutory limitation on CMS's authority to establish regulatory exceptions that the exceptions do not pose a risk of a program or patient abuse.

Citing the potential confusion created by incorporating the intent-based requirement of the Anti-Kickback Statute into a strict liability law, as well as the lack of practical effect on enforcement efforts, CMS decouples the Stark Law from the Anti-Kickback Statute in the final rule. Specifically, CMS removes the requirement that the arrangement does not violate the Anti-Kickback Statute (or any law governing billing or claims submission) from all but one regulatory exception. The holdout is the regulatory exception for fair

market value compensation. Because that exception applies to many arrangements that also could be protected by a statutory exception with additional safeguards (such as, under the final rule, office space lease arrangements), the final rule retains the requirement that the arrangement at issue not violate the Anti-Kickback Statute as a substitute safeguard.

11. Isolated Transactions Exception

Author: Travis G. Lloyd, Bass Berry

The isolated transactions exception provides protection for isolated financial transactions, such as one-time sale of property or practice, provided that certain conditions are met. Although the exception includes conditions related to fair market value, the volume or value and other business generated standards, and commercial reasonableness, it does not include a requirement that the compensation be set in advance and covered by a signed writing. In the proposed rule, CMS observed that some actors have turned to the isolated transactions exception to protect service arrangements where a party makes a single payment for multiple services over an extended period of time, such as when a hospital makes a single payment to a physician for working multiple call coverage shifts over the course of a month, but neglects to set forth the arrangement in writing.

In the final rule, CMS confirms, through modifications to defined terms and to the regulatory exception, that the isolated transactions exception is not available to protect a single payment for multiple or repeated services and it is not available to retroactively cure noncompliance with the Stark Law. However, CMS states that parties may rely on the exception to protect an isolated financial transaction that settles a *bona fide* dispute arising from an arrangement for multiple, repeated, or ongoing services.

12. Exception for Limited Remuneration to a Physician

Author: Travis G. Lloyd, Bass Berry

The final rule includes a new regulatory exception for the provision of limited remuneration by an entity to a physician for items or services actually provided by the physician where the compensation was not set in advance or documented in contemporaneous signed writings. Under the exception, which is codified at 42 C.F.R. § 411.357(z), remuneration from an entity to a physician for the provision of items or services that does not exceed an aggregate of $5,000 per calendar year, as adjusted for inflation, is protected so long as certain familiar requirements are met. These requirements include that the compensation not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician, that the compensation does not exceed the fair market value or the items or services, and that the arrangement would be commercially reasonable even if no referrals were made between the parties. There is no writing or signature requirement. Furthermore, in determining whether payments to a physician under this exception exceed the annual aggregate limit, CMS will not count items or services provided outside of the arrangement so long as the compensation for outside items or services meets another exception.

This new exception may be used in conjunction with other exceptions. CMS indicates in commentary that an entity may rely on the new exception up to the point in the calendar year immediately prior to when the annual aggregate remuneration limit is exceeded. After that point in time, the arrangement must meet another applicable exception to avoid running afoul of the Stark Law.

13. Exceptions for Rental of Office Space, Equipment

Author: Travis G. Lloyd, Bass Berry

The final rule modifies the exceptions for the rental of office space and the rental of equipment to clarify that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment under the requirement that the space or equipment be "used exclusively by the lessee" when being used by the lessee. The exclusive use requirement does not prevent multiple lessees from using the rented space or equipment at the same time, so long as the lessor is excluded.

In addition, CMS modifies the exception for fair market value compensation at 42 C.F.R. § 411.357(l) to permit use of the exception for office space and equipment lease arrangements.

14. Exception for Remuneration Unrelated to Designated Health Services

Author: Travis G. Lloyd, Bass Berry

The Stark Law statute includes an exception under which remuneration provided by a hospital to a physician does not create a compensation arrangement for purposes of the Stark Law if the remuneration does not relate to the provision of DHS. This exception was added to the regulations at 42 C.F.R. § 411.357(g) as part of the Phase II rulemaking. The regulatory exception requires that, to qualify as "unrelated," the remuneration must be "wholly unrelated" to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. The regulation stipulates that remuneration relates to the furnishing of DHS if it: (1) is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles; (2) is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditions manner to medical staff or other persons in a position to make or influence referrals; or (3) otherwise takes into account the volume or value of referrals or other business generated by the referring physician. Although CMS, in the proposed rule, acknowledged that the current regulatory exception is too restrictive and considered making changes that would have classified remuneration for items or services that are not related to patient care services as "unrelated" to the furnishing of DHS, it ultimately declined to finalize any changes, citing risk of program or patient abuse.

15. Exception for Payments by a Physician

Author: Travis G. Lloyd, Bass Berry

The Stark Law statute includes an exception for payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services, or to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value. CMS has interpreted this exception narrowly, taking the position that the exception may not be used to protect financial relationships that are covered by more specific exceptions, such as the exception for office space rentals, that have additional requirements. In its final rule, CMS modifies its position slightly such that, although it remains the case that the exception may not be used to protect compensation arrangements that are specifically excepted by other *statutory* exceptions (codified at 42 C.F.R. § 411.357(a)-(h)), it may be used to protect compensation arrangements that could be excepted by certain *regulatory* exceptions that are not themselves specified in the statute (codified at 42 C.F.R. § 411.357(j)-(bb)). Thus, parties may rely on the exception for payments by a physician to protect fair market value payments by a physician to an entity for items or services furnished by the entity even if a regulatory exception at § 411.357(j) *et seq.*, such as the exception for fair market value compensation, may be applicable.

16. Exception for Physician Recruitment Arrangements

Author: Travis G. Lloyd, Bass Berry

Historically, CMS has interpreted the exception for physician recruitment arrangements to require that the writing documenting the arrangement be signed by all parties, including the hospital, the recruited physician, and, if applicable, the physician practice that the recruited physician plans to join. In the final rule, CMS eliminates the signature requirement for the physician practice if the practice does not receive a financial benefit through the arrangement (as would be the case if, for example, the hospital pays remuneration directly to the recruited physician, or if the practice passes payments received from the hospital through to the recruited physician).

17. Electronic Health Records Items and Services Exception

Author: Travis G. Lloyd, Bass Berry

CMS extended the existing exception for certain arrangements involving the donation of interoperable electronic health records software or information technology and training services by removing the December 31, 2021 sunset provision. It also clarified this exception by expressly including cybersecurity software and services in the list of eligible remuneration that, when "necessary and used predominantly to create, maintain, transmit, receive, or protect" EHR, is eligible for protection, so long as the remaining elements of the exception are satisfied. In addition, CMS removed the prohibition on providing EHR technology that is "equivalent" to technology already possessed by the recipient (and expressly permits the donation of replacement technology). With respect to those remaining elements, CMS revised the definition of "interoperable" to require that the software have a current certification on the date it is donated. CMS also retained but

revised the 15 percent contribution requirement, allowing contribution for updates received after the initial donation (or replacement donation) to be paid at reasonable intervals, rather than requiring a pre-donation contribution, which CMS retained for initial (and replacement) donations. Finally, because ONC's final rule now separately prohibits information blocking, CMS has removed from this exception the information blocking element.

18. Cybersecurity Technology and Services Exception

Author: Travis G. Lloyd, Bass Berry

The final rule adds a new exception for cybersecurity technology and services. The new exception, which is codified at 42 C.F.R. § 411.357(bb), protects the donation of cybersecurity technology and services that are necessary and used predominantly for purposes of cybersecurity (which CMS defined broadly to mean the process of protecting information by preventing, detecting, and responding to cyberattacks), when three elements are satisfied. First, the donation must be memorialized in writing. Second, the cybersecurity technology or services must not be determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. And, third, neither the physician nor the physician's practice may condition doing business with the donor on the receipt of the technology or services.

O. CY 2022 Medicare Physician Fee Schedule Final Rule; Updates to "Indirect Compensation Arrangement" Definition

Author: Travis G. Lloyd, Bass Berry

1. Regulatory Sprint Changes

As noted above, the Regulatory Sprint final rule modified the definition of "indirect compensation arrangement" at 42 C.F.R. § 411.354(c)(2). In an effort to streamline the analysis, CMS built the conditions of the special rules on unit-based compensation into the definition of indirect compensation arrangement. As revised by the Regulatory Sprint final rule, an indirect compensation arrangement exists if the physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that both varies with the volume or value of referrals or other business generated by the physician for the entity *and* for which any of the following are true:

(1) the individual unit of compensation is not fair market value for items or services actually provided;

(2) the individual unit of compensation is calculated using a formula that includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in compensation that positively correlates with the number or value of the physician's referrals to the entity; or

(3) the individual unit of compensation received by the physician is calculated

using a formula that includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in compensation that positively correlates with the physician's generation of other business for the entity.

Unless these conditions were met (as well as the other conditions of 411.354(c)(2) that were not materially revised in the Regulatory Sprint rulemaking), the financial relationship was not considered to be an indirect compensation arrangement for Stark Law purposes.

P. CY 2022 Physician Fee Schedule Changes

In the CY 2022 Physician Fee Schedule proposed rule, 86 Fed. Reg. 39104 (July 23, 2021), CMS noted that, in its efforts to streamline the analysis, it inadvertently failed to consider the impact of its changes on one of its *bêtes noires*: arrangements involving unit of service-based payment for the rental or lease of office space or equipment, often referred to as "per-click" leases. The Regulatory Sprint revisions left open the possibility that, where a per-click lease is the direct financial relationship that is the object of the indirect compensation arrangement analysis, there would be no indirect compensation arrangement.

To close this loophole, CMS modified the definition of indirect compensation arrangement in the CY 2022 Physician Fee Schedule final rule, 86 Fed. Reg. 64996 (Nov. 19, 2021). Under the final rule, if the arrangement at issue is the lease of office space or equipment (or for the use of space or equipment), then the arrangement will constitute an indirect compensation arrangement (provided the "aggregate compensation" test and all other elements of the definition are met). CMS did not, however, finalize its broader proposal to include within the definition all arrangements for anything other than services personally performed by the physician.

The pertinent part of the revised definition, which is set forth at 42 C.F.R. § 411.354(c)(2)(ii) and went into effect January 1, 2022, reads as follows:

> *(A)(1) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and*
>
> *(2) The amount of compensation that the physician (or immediate family member) receives per individual unit—*
>
> *(i) Is not fair market value for items or services actually provided;*
>
> *(ii) Could increase as the number or value of the physician's referrals to the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals to the entity decreases;*
>
> *(iii) Could increase as the amount or value of the other business generated by the physician for the entity furnishing DHS increases,*

or could decrease as the amount or value of the other business generated by the physician for the entity furnishing DHS decreases; or

(iv) Is payment for the lease of office space or equipment or for the use of premises or equipment.

(Emphasis added.) In effect, these changes mean that if the compensation arrangement closest to the physician is for the lease of office space or equipment (or for the use of space or equipment), then the analysis is the same as it was prior to the Regulatory Sprint rule—that is, there will be an indirect compensation arrangement if the "aggregate compensation" test and all other elements of the definition are met, and the arrangement will need to find refuge in an applicable exception to avoid noncompliance. If the financial relationship closest to the physician is not for the lease of office space or equipment, then the analysis follows the formulation articulated by the Regulatory Sprint rule.

- **Other Noteworthy Changes**

  Whether an indirect compensation arrangement exists often requires the evaluation of the individual unit of compensation that the physician (or immediate family member) receives. In the CY 2022 Physician Fee Schedule final rule, CMS adds new regulatory text to clarify how to identify the unit of compensation to analyze in this context. As revised, an individual unit is (1) an item, if the physician is compensated solely per item provided, (2) a service, if the physician is compensation solely per service provided (including where the "service" includes both items and services, as in the case of "under arrangement" service arrangements), or (3) in all other instances, a unit of time.

  "Hybrid" compensation—*i.e.,* compensation that is comprised of payments for both time-based units and service-based or item-based units—should be analyzed by converting it to compensation for a unit of time. For example, if a physician is paid an annual salary plus a wRVU-based productivity bonus, with payments made monthly, the unit of compensation is a month.

  If the arrangement includes more than one unit of the same type, then each unit should be analyzed separately. Thus, if a physician is paid an annual salary plus an hourly stipend for medical director services, each time-based unit must be analyzed to determine whether the conditions for an indirect compensation arrangement exist.

Q. Stark Law Advisory Opinions

Since January 1, 2021, CMS has issued two Stark Law advisory opinions. These opinions are summarized below.

1. Advisory Opinion No. CMS-AO-2021-2
Author: Justin K. Brown, Bradley

CMS-AO-2021-01 presented the question whether a group practice ("Requestor") would fail to satisfy the "single legal entity" requirement under § 411.352(a) if Requestor acquired two physician practices (the "Subsidiaries") and began furnishing DHS through the Subsidiaries. Based on the facts presented (including Requestor's certification that it currently qualified as a group practice under 42 C.F.R. § 411.352), CMS concluded that furnishing DHS through a wholly-owned subsidiary that is a physician practice (but does not itself qualify as a group practice) would not preclude Requestor from satisfying the "single legal entity" requirement at § 411.352(a). Under the proposed transactions, Requestor would become the sole owner of both Subsidiaries. All clinical personnel would become employed or contracted by Requestor, and all material assets and business functions of the Subsidiaries would be transferred to Requestor or a management company that currently managed, and would continue to manage, Requestor and the Subsidiaries. Because many payors and health plan prohibit assignment of contracts, the Subsidiaries would continue to remain credential and contract directly with payors and plans, and the Subsidiaries would remain enrolled in Medicare, using the billing numbers assigned to them as participating suppliers in Medicare to bill for items and services, including DHS. All revenues of the Subsidiaries would be remitted to and treated as revenues of Requestor. In its analysis, CMS pointed to its August 1995 final rule, where it interpreted the Stark Law to permit a single group practice to own other legal entities for the purpose of providing services to the group practice, such provision of equipment, billing services, or ancillary services (60 Fed. Reg. 41914, 41935-36), and to its Phase I commentary, where it reiterated this interpretation and cited the example of a wholly-owned laboratory (66 Fed. Reg. 876, 899). Indeed, § 411.352(a) expressly states that a group practice that is otherwise a single legal entity may itself own subsidiaries, so long as the group practice is a single legal entity operating primarily for the purpose of being a physician group. Based on § 411.352(a) and the commentary CMS cited in the advisory opinion, CMS concluded that Requestor would not be precluded from qualifying as a "single legal entity" if it furnished DHS through the Subsidiaries, so long as the Requestor is the sole owner of the Subsidiaries. In closing, CMS cautioned that, as wholly-owned subsidiaries of Requestor, neither Subsidiary could itself qualify as a group practice under § 411.352.

2. Advisory Opinion No. CMS-AO-2021-2
Authors: Neal D. Shah, Meredith Eng, Polsinelli

In CMS-AO-2021-2 CMS analyzed whether a grandfathered physician-owned hospital's addition of unlicensed observation beds would be deemed a facility expansion under the applicable rules at 42 C.F.R. 411.362(b)(2). CMS reviewed state hospital licensing law and its own prior statements concerning the scope of the "expansion" requirement to determine that the addition of observation beds in this case would not violate this requirement because the state in question did not specifically license or authorize the operation of observation beds or otherwise collect information regarding a hospital's operation of such beds.

Under the Stark Law, a physician's ownership interest in a hospital may be protected under the "whole hospital" exception (42 C.F.R. 411.356(c)(3)) only if the hospital had physician ownership and a valid Medicare enrollment on December 31, 2010 and has continued to comply with the requirements of 42 C.F.R. 411.362 (commonly called a "grandfathered" hospital). A grandfathered hospital must meet various standards, including that it must not increase the aggregate number of operating rooms, procedure rooms, and beds beyond a "baseline" amount reflecting capacity as of March 23, 2010. (42 C.F.R. 411.362(b)(2)).

In this case, a physician-owned hospital (the "Hospital") operated 12 licensed inpatient beds as of March 23, 2010 and sought to add a number of additional observation beds. The Hospital is located in a state that does not require specific licensure of observation beds. CMS reiterated prior preamble guidance that the Stark Law's reference to licensure applies only to beds, not operating rooms or procedure rooms and, further, CMS would rely state law to identify the categories of beds subject to licensure. The state in question did not specifically license hospital beds, but required any facility meeting the state's statutory definition of a "hospital" to register and annually report certain information. The state only required reporting of inpatient beds during the annual registration period; it did not require reporting of observation beds. In sum, because the addition of new observation beds would not require additional licensing, registration, or revisions to the Hospital's current registration under state law, CMS determined such addition would not constitute an "expansion" of the facility under the physician-owned hospital rules.

To provide assurance of ongoing compliance, the Hospital certified that the new observation beds would not be converted to use as inpatient beds, support for inpatient admissions, or operating or procedure rooms. Furthermore, the Hospital certified that it has a formal policy and procedures in place to ensure that the new observation beds are not used as inpatient beds.

R. Stark Law Covid-19 Waivers and Explanatory Guidance[52]

Author: Travis G. Lloyd, Bass Berry

Among the many extraordinary measures taken by the federal government in response to the Covid-19 pandemic is the issuance of blanket waivers of certain provisions of the Stark Law. On March 30, 2020, the Secretary of HHS issued blanket waivers of Section 1877(g) of the Social Security Act, which imposes sanctions for violations of the Stark Law. The waivers apply nationwide and may be used parties without providing notice to or receiving approval from CMS.

Although termed "blanket waivers," the waivers do not suspend the Stark Law entirely; rather, they waive sanctions in a range of specified circumstances. Functionally, the blanket waivers operate as waivers of certain requirements of Stark Law exceptions. Financial relationships still must satisfy all non-waived requirements of an applicable

[52] This portion of the outline includes certain updates that predate January 2021 because the updates either became effective within the past 12 months or are temporarily Covid-19-related waivers that remain in effect.

exception to avoid a violation.

In all, there are 18 blanket waivers in effect at this time. Most of the waivers relate to requirements for remuneration in exceptions for compensation arrangements (such as the requirement in many exceptions that remuneration be consistent with fair market value). Others relate to requirements in exceptions for ownership or investment interests (such as the requirement that physician-owned hospitals not expand bed capacity beyond previously established limits). Still others relate to other Stark Law requirements (such as the requirement that a physician in a group practice furnish certain services only in a location that qualifies as a "same building" or "centralized building" within the meaning of the exception for in-office ancillary services). The waivers may be revised from time to time, though the government has indicated that any revisions which narrow a waiver, and any termination of the blanket waivers, will be effective on a prospective basis only.

The blanket waivers apply only to financial relationships that relate to the COVID-19 pandemic. That is, to be within the scope of the blanket waivers, the remuneration and referrals at issue must be solely related to at least one of six pandemic-related purposes. These "COVID-19 Purposes" run the gamut from the diagnosis or treatment of COVID-19 (regardless of whether the patient is diagnosed with a confirmed case of COVID-19) to addressing medical practice or business interruption due to the COVID-19 pandemic in order to maintain the availability of medical care for the community.

In addition to the waivers, on April 21, 2020, CMS issued explanatory guidance concerning the application of the blanket waivers. The explanatory guidance addresses a number of questions of common concern, including questions related to the amendment of compensation arrangements, the repayment of loans made during the emergency period, and the application of the waivers to physician recruitment arrangements.

S. Stark Law 2022 CPI-U Updates

Authors: Meredith Eng, Neal D. Shah, Polsinelli

The CPI-U update for calendar year 2022 is 5.4%. Accordingly, the amount of non-monetary compensation permissible under 42 CFR 411.357(k) has increased to $452, the maximum value of medical staff incidental benefits protected under 42 C.F.R. 411.357(m) has increased to $39 (per-payment per-physician), and the maximum value protected under the exception for limited remuneration protected under 42 C.F.R. 411.357(z) has increased to $5,270.

T. Stark Law Frequently Asked Questions Update: Location Requirement of the In-Office Ancillary Services Exception

Author: Justin K. Brown, Bradley

On September 20, 2021, CMS added to its FAQs a new question-and-answer regarding where items are considered to be "furnished" for purposes of the "location requirement" of the in-office ancillary services exception at 42 C.F.R. § 411.355(b). Specifically, the question asked: If prosthetic or orthotic devices (*e.g.*, intermittent catheters) are mailed to

the patient from a location that qualifies as a "same building" or "centralized building" (as each is defined in § 411.351), are they considered to be furnished in a location that satisfies the in-office ancillary services exception's location requirement at § 411.355(b)(2)?

No, CMS responded. The location requirement at § 411.355(b)(2) requires that the patient receive the item in the physician's office. If the patient receives the item by mail outside the physician's office, the requirement is not met. This is true even if the Medicare coverage and payment rules would permit the supplier to mail the item to the patient and bill Medicare for the item. In its Phase I rulemaking, CMS explained that "services will be considered 'furnished,' for purposes of the [in-office ancillary services] exception, in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the Medicare billing and coverage rules." 66 Fed. Reg. 856, 882 (Jan. 4, 2001). *See* 42 C.F.R. § 411.355(b)(5). The requirement is twofold, this FAQ makes clear. Not only must the item or service be furnished in a manner that complies with the applicable billing and coverage rules, but it must also actually be performed in the physician's office (if a service) or directly received by the patient in the physician's office (if an item).

U. Stark Law Cases and Settlements

1. Self-Referral Disclosure Protocol Settlements

Author: Meredith Eng, Polsinelli

In 2020, CMS entered into 34 Self-Referral Disclosure Protocol settlements. These settlements ranged from $33 to $191,755 for a total of $4,303,980. The 2021 data are not yet available, but should soon be published on CMS's Self-Referral Disclosure Protocol Settlements page at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.

2. Allstate Hospice LLC and Verge Home Care LLC Settlement (January 2021)

Author: Meredith Eng, Polsinelli

Allstate Hospice LLC ("Allstate"), Verge Home Care LLC, and their founders Onder Ari and Sedat Necipoglu, paid more than $1.8 million to resolve allegations that they violated the Stark Law by compensating referring physicians in excess of fair market value for medical directorships, selling five physicians interests in Allstate, and giving referring physicians gifts and benefits including travel and tickets for sporting events.

3. Physician Pays $215,000 to Resolve Allegations that He Accepted Illegal Kickbacks for Hospital Referrals

Author: Travis G. Lloyd, Bass Berry

On March 3, 2021, the DOJ announced that Dr. Ashok Kumar paid over $215,000 to settle allegations brought against him in a *qui tam* suit that a California hospital,

Memorial Hospital of Gardena, paid remuneration to Dr. Kumar under a series of overlapping medical director arrangements under which he did little or no work, in violation of the Stark Law and the Anti-Kickback Statute. The lawsuit was filed by the hospital's former CEO. Claims against the hospital and other related parties previously settled similar allegations in 2018 for $8.1 million.

4. *United States ex rel. Byrd v. Acadia Healthcare Co., Inc.*, No. CV 18-312-JWD-EWD, 2021 WL 1081121 (M.D. La. Mar. 18, 2021)
Author: Travis G. Lloyd, Bass Berry

The relator, a former CFO of a behavioral health hospital, brought claims against the hospital and its affiliates alleging that they violated the FCA by, among other things, providing free staff to a psychiatrist and paying a family practice physician in excess of fair market value under an arrangement that was not commercially reasonable, both in violation of the Stark Law and the Anti-Kickback Statute. In the former case, the relator alleged that the hospital employed and paid two nurse practitioners who worked at the psychiatrist's office practice and routinely performed patient rounds at local nursing homes on the psychiatrist's behalf. In the latter case, the relator claimed that the family practice physician, a friend of the hospital's CEO, was paid approximately $350,000 despite the fact that he maintained his own private practice and only occasionally saw patients at the hospital. The government declined to intervene in the case. On March 18, 2021, the district court issued an order dismissing these claims on the ground that the relator failed to meet the pleading standard of Fed. R. Civ. P. 9(b) but giving the relator leave to amend the complaint. The court also denied the defendants' motion to dismiss as to the relator's claims that the defendants terminated his employment in violation of the anti-retaliation provisions of the FCA and the Louisiana Medical Assistance Programs Integrity Law.

5. Owner of Defunct Urine Drug Testing Laboratory Agrees to Pay Over $2 Million to Resolve Allegations of Participation in Kickback Schemes
Author: Travis G. Lloyd, Bass Berry

On March 26, 2021, the DOJ announced that it had settled claims against a former owner of Physicians Choice Laboratory Services (PCLS), a defunct diagnostic testing laboratory with locations in North and South Carolina. The settlement resolves allegations that PCLS submitted false claims to the Medicare program as a result of the former owner's participation in various kickback schemes, including (1) the provision of urine drug testing equipment, including desktop analyzers and associated supplies and services, to two physicians; (2) PCLS's payment of volume-based commissions, and later a salary, to an individual in exchange for that individual's exercise of influence over two physician practices; and (3) the provision of loans to two physicians. The case originated as two separate *qui tam* cases, in which the government partially intervened, that alleged violations of both the Stark Law and the Anti-Kickback Statute. The former owner of PCLS agreed to pay more than $2 million to resolve the allegations.

6. Akron General Health System (AGHS) Pays Over $21 Million to Resolve Allegations of Improper Payments to Referring Physicians (July 2021)

Author: Meredith Eng, Polsinelli

AGHS, a regional hospital system based in Akron, Ohio and a member of the Cleveland Clinic Foundation (as of 2015), agreed to pay $21.25 million to resolve allegations that between August 2010 and March 2016 AGHS paid compensation in excess of fair market value to area physician groups to obtain their referrals in violation of the Anti-Kickback Statute and Stark Law and submitted claims for services provided to the illegally-referred patients in violation of the False Claims Act. These claims were brought by the former Director of Internal Audit at AGHS, and Ethical Solutions, LLC.

7. Prime Healthcare Services Settlement (July 2021)

Author: Meredith Eng, Polsinelli

Prime Healthcare Services ("Prime"), its founder and CEO Dr. Prem Reddy, and California interventional cardiologist Dr. Siva Arunasalam agreed to pay $37.5 million to resolve allegations that they violated the False Claims Act and the California False Claims Act. Prime allegedly purchased Dr. Arunasalam's physician practice and surgery center at a price that was not commercially reasonable and exceeded fair market value to induce Dr. Arunasalam to refer his patients to Desert Valley Hospital, a Prime facility in Victorville, California. Prime also allegedly compensated Dr. Arunasalam through an employment agreement with one of its hospitals, High Desert Heart Vascular Institute ("HDHVI"), in which Dr. Arunasalam's compensation was based on the volume and value of his referrals to HDHVI. HDHVI and Dr. Arunasalam also allegedly used Dr. Arunasalam's billing number to bill Medicare and Medi-Cal for services provided by another physician, Dr. George Ponce, who was excluded from those programs. Finally, some Prime hospitals allegedly billed Medi-Cal and federal health care programs for false claims based on inflated invoices for implantable medical hardware. Prime and Dr. Reddy entered into a five-year Corporate Integrity Agreement, which, in part, requires Prime to maintain a compliance program and hire an Independent Review Organization to review arrangements entered into by, or on behalf of, its subsidiaries and affiliates. This settlement resolves claims brought by two *qui tam* relators (a former Prime executive and two former employees in the billing office at Shasta Regional Medical Center, a Prime hospital in Redding, California).

8. United States ex rel. Jennings v. Flower Mound Hospital Partners, LLC Settlement (November 2021)

Authors: Meredith Eng, Neal D. Shah, Polsinelli

In November 2021, Flower Mound Hospital Partners, LLC d/b/a Texas Health Presbyterian Hospital Flower Mound ("Flower Mound Hospital") agreed to pay $18.2 million to resolve allegations that it violated the Stark Law, Anti-Kickback Statute, and False Claims Act. Flower Mound Hospital also agreed to enter into a Corporate Integrity Agreement with the HHS OIG. The allegations in this matter related to the hospital's

repurchasing of membership interests from physician-owners aged 63 or older and its resale of these interests to other physicians.

Flower Mound Hospital is a grandfathered facility owned by physicians and a nonprofit health system. The relator in the case – a former physician-owner whose interests were repurchased – alleged that the hospital improperly conditioned ownership on physicians' actual or expected referrals of business to the hospital. In particular, he claimed the hospital's policy of requiring at least 24 patient contacts per year to maintain active medical staff status indicated that the physicians' ownership in the hospital was conditioned on actual or expected referrals. As evidence, the relator argued the patient contacts requirement was excessively narrow in scope because it focused on surgical cases and alleged it was higher than similar requirements imposed by other hospitals operated by Flower Mound Hospital's nonprofit member and other hospitals in the region. The relator also alleged he was informed that the repurchase of membership interests was motivated by a desire to resell them to higher-producing physicians.

Flower Mound Hospital settled following the government's intervention. The covered conduct described in the Settlement Agreement states that Flower Mound Hospital's relationships with its physician-owners failed to meet the Whole Hospital Exception at 42 U.S.C. § 1395nn(d)(3) and 42 C.F.R. § 411.356(c)(3) because Flower Mound Hospital allegedly conditioned physician ownership or investment interests either directly or indirectly on the physician-owners or investors making or influencing referrals to Flower Mound Hospital or otherwise generating business for Flower Mound Hospital.

This settlement is of particular interest for entities that establish minimum standards for retaining active medical staff status, particularly if that status is a condition of retaining ownership interests.

V. HEALTH CARE LIABILITY AND LITIGATION

Author: Jamie Ballinger, Allison Cooley, Christy Tosh Crider,
Nora Koffman, Jerrick Murrell and Kristine Nelson, Baker Donelson
(Updated January 2022)

A. COVID-19 Section

1. CARES Act

a. Pub. L. 116-136

i. CARES Act was an economic stimulus package. Much of the focus was on financial benefits, e.g., establishment of loans to corporations and local governments.

ii. Also contained provisions regarding immunity to manufacturers, distributors, and administrators of certain protective devices

iii. Treasury guidance provides that administrative costs related to costs incurred by December 31, 2021, are eligible administrative expenses that can be paid for using CARES Act funds even if they are incurred in 2022. https://www.jdsupra.com/legalnews/eligible-uses-of-cares-act-funds-for-9062603/

2. PREP Act Amendment

a. Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. 247d-6d et. seq.

i. Originally signed into law in 2005, PREP Act permits the Secretary of Health and Human Services to issue a declaration to provide liability protections to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of certain medical countermeasures.

ii. In order to properly apply the PREP Act to the COVID-19 response the HHS issued a fourth amendment to the Act:

iii. Expanded access to telehealth services, increase access to authorized PPE, and prepare for the eventual administration of

iv. COVID vaccines.

v. Clarifies immunity implications as they relate to the COVID response.

vi. The amendment also expands the immunities for healthcare providers to include anyone providing and administering vaccines, therefore potentially including pharmacists, pharmacy interns, and pharmacy technicians.

vii. In Maglioli v. All. HC Holdings LLC, 16 F.4th 393 (3d Cir. 2021), nursing homes requested removal to federal court under the PREP Act. The Third Circuit held that the Dept. of Health and Human Services is not delegated authority under the PREP Act to interpret the scope of federal courts' jurisdiction and that simply making the preemption argument is insufficient to get the nursing homes into federal court. In Maglioli, the estates alleged only negligence, not willful misconduct. The PREP Act creates an exclusive cause of action for willful misconduct but first requires all administrative remedies be exhausted.

viii. Maglioli is the first federal circuit court ruling to address federal removal jurisdiction based on PREP Act immunity. There are similar issues currently pending before the Second, Fifth, Sixth, Ninth, Eleventh, and D.C. circuits.

3. Long Term Care Facilities

a. Nursing homes across the US reported nearly 1,800 COVID-19 deaths among residents and staff in August 2021, the highest number of COVID-19 deaths reported in single month since February 2021 and a steady increase from approximately 350 deaths reported in July 2021. https://www.kff.org/coronavirus-covid-19/issue-brief/nursing-homes-experienced-steeper-increase-in-covid-19-cases-and-deaths-in-august-2021-than-the-rest-of-the-country/

b. As of mid-September 2021, about 84% of all nursing home residents and 64% of nursing home staff are vaccinated. Id.

c. On November 4, 2021, CMS issued a regulation requiring all nursing home staff be vaccinated against COVID-19 as a requirement for participating in the Medicare and Medicaid programs. https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23831.pdf

i. CMS updates nursing home guidance to relax the visitation requirements in LTKFs (CMS November 12, 2021) https://www.cms.gov/files/document/qso-20-39-nh-revised.pdf.

4. Mass Litigation

a. Supreme Court Blocks Biden's Vaccine or Test Mandate for Large Employers. https://www.npr.org/2022/01/13/1072165393/supreme-court-blocks-bidens-vaccine-or-test-mandate-for-large-private-companies

b. Michigan Medical Centers, Patient Sue State Over Temporary Ban On "Non-Essential" Medical Services (**Detroit News (5/12/20))**

c. AFL-CIO Sues OSHA to Force Temporary Worker-Safety Standard (Bloomberg (5/17/20))

d. State AGs Sue EPA Over COVID-19 Enforcement Policy (Law360 (5/13/20))

e. NY Law Firm Sues Cuomo Over COVID-19 Closure Orders (Bloomberg (5/14/20))

f. House GOP Sues Pelosi Over Proxy Voting During Pandemic (Law360 (5/26/20))

g. Physicians Sue FDA to Widen Access to Hydroxychloroquine (Bloomberg (5/14/20))

h. GOP sues Pritzker over political rally limits (The Telegraph (6/16/20))

i. Are Insurers prepared for the COVID-19 related litigation avalanche? https://www.propertycasualty360.com/2020/11/11/are-insurers-prepared-for-the-covid-19-related-litigation-avalanche/?slreturn=20210019223336

j. Hair Salons Sue New York State Against COVID-19 Restrictions https://www.wgrz.com/article/news/health/coronavirus/more-lawsuitsagainst-new-york-state-covid-19-restrictions-on-way/71-bfe51ed1-64ec-42f5-9fa5-fab15b83d861

k. Federal judge orders Bank of America to provide preliminary relief to public benefits recipients. Bank of America froze beneficiaries' accounts as opposed to conducting an investigation relating to unauthorized charges appearing on the beneficiaries' accounts. https://www.law360.com/benefits/articles/1385611/bofa-must-workout-relief-for-frozen-benefits-recipients

l. Walmart workers sued Walmart in March, 2021 for failing to pay workers for the time they were required to arrive prior to their shifts to undergo COVID-19 testing. https://www.law360.com/classaction/articles/1367571/walmartworkers-claim-covid-screening-time-went-unpaid

m. Pursuant to the University of Pennsylvania tracker, as of December 6, 2021, over 2000 COVID-19 related lawsuits have been filed in state and federal courts across the United States. https://cclt.law.upenn.edu/#latest

n. An overwhelming majority of federal courts have grated dismissals of most business interruption cases while state courts have granted dismissals of about half of cases. https://cclt.law.upenn.edu/#latest

o. Hospital Employees Sue Hospitals Over COVID Vaccine Mandate. https://www.nbcboston.com/news/coronavirus/8-hospital-employees-sue-mass-general-brigham-over-covid-vaccine-mandate/2523785/; https://www.fisherphillips.com/news-insights/kentucky-hospital-employees-latest-workplace.html

p. Yet another court upholds workplace vaccine mandate. https://www.fisherphillips.com/news-insights/court-upholds-workplace-vaccine-mandate.html

q. TN Attorney General Slatery joined the lawsuit challenging Biden Administration's vaccine mandate for private sector employees alongside attorneys general from Idaho, Kansas, Kentucky, Ohio, Oklahoma, and West Virginia. https://www.tn.gov/attorneygeneral/news/2021/11/5/pr21-43.html

5. Immunity

a. *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 2020 U.S. Dist. LEXIS 145055 (D.N.J. Aug. 12, 2020)

i. Some states have passed differing legislation and rules providing immunity from liability to healthcare providers for treatment during COVID.

ii. Actions were brought in state court by estates of residents of nursing homes due to COVID-19 exposure asserting negligence, wrongful death, and medical malpractice.

iii. Defendants and insurance carriers sought to remove the court to federal court claiming the PREP Act preempted state jurisdiction and that the case should be remanded to federal court because the defendants were acting as federal officers/agent because they were following federal guidelines.

iv. Court held that the PREP Act did not preempt state court jurisdiction over state-law claims of negligence that included acts that were not covered countermeasures under the Act. Nothing in the Act suggest that it was intended to more broadly displace state law causes of action.

v. Further, the court rejected the argument that Defendants were agents of the United States. Simply because one abides by federal law does not make one an agent of the federal government. Accordingly, they were not entitled to a federal forum for claims against them.

vi. Matter is currently on appeal.

b. South Carolina Governor Signs COVID-19 Liability Immunity Act Into Law. https://www.jacksonlewis.com/publication/south-carolina-governor-signs-covid-19-liability-immunity-act-law

c. Businesses Must Prepare to Defend Against Covid-19 Lawsuits Despite Shields. https://news.bloomberglaw.com/us-law-week/businesses-must-prepare-to-defend-against-covid-19-lawsuits-despite-shields

6. Liability

a. Veterans Home Employees Charged

i. The former superintendent and medical director of a Massachusetts veteran home have been indicted over criminal neglect charges having to do with COVID-19.

ii. During the outbreak the heads decided to consolidate two units, one of which had COVID-19 positive residents. This meant close proximity for some of the most vulnerable people in the face of this illness.

iii. The nursing home's actions resulted in the deaths of 76 people.

iv. The charges include "five counts of 'wantonly or recklessly' committing or permitting bodily injury, and five counts of abuse, neglect or mistreatment of an elderly or disabled person."

v. Criminal charges pending as of May, 2021

vi. https://www.wcnc.com/article/news/nation-world/2-charged-forhandling-of-virus-outbreak-at-veterans-home/507-364f44c7-194d-4507-a849-c00b55756d3f

b. FTC and DOJ filed enforcement Action under COVID-19 Consumer Protection Act for Misleading Claims

i. Defendant drug manufacturers claimed that vitamins could treat and prevent COVID-19 despite no supporting evidence

ii. Matter has been filed with the District Court for the Eastern District of Missouri

c. Covid liability suit tracking

i. https://www.huntonak.com/en/covid-19-tracker.html

d. States limiting civil liability of healthcare providers relative to Covid

i. Recent Massachusetts Executive Order -

https://www.bostonglobe.com/2021/12/27/metro/mckee-issues-executive-order-protecting-hospitals-health-care-workers-civil-damages/

ii. https://www.health-law.com/newsroom-advisories-States-Acting-to-Limit-Legal-Liability-of-Healthcare-Providers-Physicians-and-Healthcare-Professionals-for-Care-Provided-During-COVID.html

7. Anti-Discrimination Laws

a. OCR Bulletin (3/28/20)

i. https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf

ii. Covered entities should not unlawfully discriminate against people with disabilities when

iii. Making decisions about their treatment for COVID-19

b. OCR Action Against Pennsylvania Dept. of Health (4/16/20)

i. https://www.hhs.gov/about/news/2020/04/16/ocr-resolves-civilrights-complaint-against-pennsylvania-after-it-revises-itspandemic-health-care.html

ii. OCR alleged PA triaging guidelines unlawfully authorized the denial of treatment to individuals with disabilities when prioritizing access to critical care and ventilators

iii. Complaint was resolved by PA amending its guidelines to remove criteria that automatically deprioritized persons on the basis of particular disabilities

c. Strip Club Owners Sue U.S. Small Business Administration in Federal Court for barring them from relief funding for bars and restaurants impacted by COVID_19

d. Claim that SBA rules improperly classify the businesses as "prurient" and violates their First and Fifth Amendment rights by denying them access to Restaurant Revitalization Fund grants.

e. HHS OCS and DOJ issue joint guidance with DOJ on "Long COVID" as a Disability Under the ADA

i. https://www.hhs.gov/civil-rights/for-providers/civil-rights-

covid19/guidance-long-covid-disability/index.html

ii. https://www.ada.gov/long_covid_joint_guidance.pdf

f. HHS OCS issues guidance on Standards Prohibiting Race, Color and National Origin Discrimination in COVID-19 Vaccination Programs

i. https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/guidance-federal-legal-standards-covid-19-vaccination-programs/index.html

g. EEOC Guidance on Covid-19 Related Employee Medical Issues and ADA

i. https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

h. States are enacting anti-discrimination laws with varying focus

i. New York, for example, has a Covid law protecting against discrimination related to persons in protected classes and Covid.

ii. https://dhr.ny.gov/coronavirus-discrimination

iii. Other states are considering or enacted legislation protecting against discrimination as to vaccination status, such as Indiana

iv. https://www.indystar.com/story/news/politics/2022/01/04/covid-indiana-bill-would-ban-vaccine-status-discrimination/9033808002/

B. Non-COVID-19- Related Litigation

1. Opioid Crisis

a. Purdue Pharma Pleads Guilty in Federal Opioid Case i. Criminal Penalty $3.5 billion ii. Forfeit $2 billion of sales iii. Must fund a $2.8 billion bankruptcy trust iv. https://www.justice.gov/opa/pr/opioid-manufacturer-purduepharma- pleads-guilty-fraud-and-kickback-conspiracies

b. McKesson Corp., Cardinal Health Inc., and AmerisourceBergen Drug Corp. i. McKesson, Cardinal, and AmerisourceBergen agreed in November 2020 to pay up to $21 billion to settle the various litigation alleging their rules in contributing to the national opioid crisis. ii. Multidistrict Litigation (MDL) contains about 3,000 cases filed against

the drug makers and their distributors. iii. https://www.nytimes.com/2020/11/05/health/opioids-settlementdistributors. Html

c. Department of Justice Files Nationwide Lawsuit Against Walmart Inc. for Controlled Substances Act Violations i. Civil complaint filed by Department of Justice alleging Walmart Inc. unlawfully dispensed controlled substances from pharmacies it operated across the country and unlawfully distributed controlled substances to those pharmacies throughout the height of the prescription opioid crisis. ii. DOJ summarized the conduct as follows. "As a wholesale drug distributor, Walmart also had an obligation to notify DEA of suspicious orders of controlled substances. Walmart failed to comply with both of its obligations, and thereby failed in its responsibility to prevent the diversion of controlled substances." iii. The complaint alleges that this unlawful conduct resulted in hundreds of thousands of violations of the Controlled Substances Act (CSA). The Justice Department seeks civil penalties, which could total in the billions of dollars, and injunctive relief. iv. If Walmart is found liable for violating the CSA, it could face civil penalties of up to $67,627 for each unlawful prescription filled and $15,691 for each suspicious order not reported. The court also may award injunctive relief to prevent Walmart from committing further CSA violations. v. https://www.justice.gov/opa/pr/department-justice-filesnationwide- lawsuit-against-walmart-inc-controlled-substances-act

d. Multidistrict Litigation (MDL) i. Ongoing litigation among many pharmacies ii. June 4, 2021 (Law 360 June 4, 2021) – Ohio federal judge presiding over the litigation split five bellwether trials into two phases: a. Public Nuisance Claims b. All other claims c. First Pharmacy bellwether trial to begin October, 2021

e. Johnson and Johnson pays New York $230 million to settle opioid dispute.

    i. June 26, 2021- Cases filed by New York Attorney General and by Nassau and Suffolk Counties stating that J&J misled the public and caused harm by initially denying that opioids were highly addictive, aggressively marketing them, ignoring warnings of abuse, and chasing profits. Drugs included a fentanyl patch and a tablet that was crush-resistant

    ii. https://www.nytimes.com/2021/06/26/nyregion/johnson-johnson-opioid-lawsuit-new-york.html

f. New York State receives $1 Billon of $26 Billion settlement with

opioid distributors i. July 20, 2021- settlement-New York will receive more than $1 billion dollars from the three largest distributors of opioids (Cardinal Health, McKesson Corp and AmerisourceBergen), which was part of $26 billion deal to resolve thousands of lawsuits filed by states and municipalities

i. https://www.nytimes.com/2021/07/20/nyregion/new-york-opioid-settlements.html

g. Ohio Federal Jury holds retail segment liable for opioid crisis

i. November 23, 2021- federal jury in Cleveland, Ohio found CVS Health, Walmart and Walgreens substantially contributed to the crisis of opioid overdoses and deaths in two Ohio counties

ii. This was the first time the retail segment of the drug industry has been held liable

iii. Six week trial

iv. Case now on appeal

v. https://www.nytimes.com/2021/11/23/health/walmart-cvs-opioid-lawsuit-verdict.html

h. Federal Jury in New York holds foreign-owned opioid manufacturer liable for opioid crisis

i. December 30, 2021 – federal jury in New York found that Teva Pharmaceuticals an Israeli based opioid manufacturer and drug distributor contributed to the opioid crisis in New York inundating the State with drugs and killing thousands

ii. Six month trial

iii. Utilized public nuisance theory of liability

iv. Abatement phase of trial will occur in 2022

v. https://www.nytimes.com/2021/12/30/nyregion/teva-opioid-trial-verdict.html

2. Wrongful Termination

a. *Brovont v. KS-I Medical Services, P.A.*, 2020 WL 6038691 (Mo. Ct. App. 10/13/2020)

b. Emergency medicine physician will collect $26MM in wrongful termination suit

c. Fired after raising concern about staffing company only provided 1 physician for night shift to cover regular and pediatric emergency departments

d. When that physician had to respond to emergencies at one department, the other department did not have coverage in violation of EMTALA

e. Jury awarded $29MM f. Both sides appealed, and Missouri Court of Appeals ruled in physician's favor (although reducing jury award slightly):

   i. Economic Damages: $2,817,045

   ii. Noneconomic Damages: $6,000,000

   iii. Punitive Damages: $10,000,000 each against two subsidiaries

3. Corporate Practice of Medicine

a. Physician performed epidural injection leaving patient paralyzed in part due to surgeon's off label use of the drug Kenalog during the procedure.

b. Patient settled with surgeon and surgeon's employer settled outside of trial.

c. Trial court held ASC liable for roughly $7MM as patient argued the ASC had an obligation to prevent the surgeon

d. ASC appealed on corporate practice of medicine (CPOM) doctrine.

e. Colorado's CPOM doctrine prohibits health-care facilities from controlling a physician's independent professional judgment regarding the practice of medicine, diagnosis, or treatment.

f. Patient argued the corporate practice of medicine doctrine didn't apply because surgery center crossed the line into practicing medicine by making the drug available to physicians without limiting its use.

g. Appellate court reversed the verdict, holding plaintiff's position was "flatly inconsistent" with CPOM doctrine and noted the ASC was not obligated to assume any medical responsibilities the surgeon failed to

fulfill.

h. *Smith v. Surgery Ctr. at Lone Tree*, 2020 BL 397428, Colo. Ct. App., No. 19CA0186 Kansas hospital system terminates its contracts with a Texas corporation that provides anesthesia services.

i. Kansas hospital claims that the contract terminations were warranted because the Texas corporation provided medical services that it was not licensed to perform. Hospital claims that the Texas corporation's services therefore violated of Kansas' prohibition against the corporate practice of medicine.

j. The Texas corporation brings suit in federal district court claiming, among other things, that the Kansas corporate practice of medicine doctrine was unconstitutional and thus could not justify contract termination.

k. The Texas corporation relies on the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and its state counterpart in Section 1 of the Kansas Constitution Bill of Rights.

l. The Fourteenth Amendment provides in part "nor shall any State . . . deny to any person within its jurisdiction the equal protection of the laws." The Kansas Bill of Rights provides in part that "[a]ll men are possessed of equal and inalienable natural rights . . . ."

m. The Texas corporation claims that Kansas' corporate practice of medicine doctrine violates both provisions because, allegedly, the doctrine's sole purpose was to protect doctors and doctor-run professional corporations from competition by unlicensed laymen operating through general corporations.

n. The federal district court rejects the Texas corporation's constitutional argument and upholds the Kansas doctrine prohibiting corporate practice of medicine.

o. The federal district court observed that "[b]ecause the corporate practice of medicine 'does not implicate a fundamental right or affect a suspect classification,' rational basis review applies."

p. The federal court held that Kansas' corporate practice of medicine doctrine satisfies that lower constitutional bar.

q. According to the federal district court, Kansas could adopt a legal doctrine preferring a licensed group of professionals over unlicensed groups and relate it to the legitimate government purpose of intrastate

economic protection.

r. The federal district court, situated in the District of Kansas, stated that its ruling was based on Tenth Circuit precedent which it found to be binding. The district court acknowledged that there may be room for additional debate in other circuits.

s. The district court held, though, that at least in the Tenth Circuit, "the Kansas corporate practice of medicine doctrine must be upheld under both federal and state constitutional grounds."

t. Clinical Colleagues, Inc. v. Huchinson Regional Med. Ctr., Inc., Case No. 20-2297-JWB, 2021 WL 4355591 (D. Kan. Sept. 24, 2021).

4. Hoverboarding Dentist Gets 12 Years for Fraud, Endangering Patients

a. Alaskan dentist performed tooth extraction on a patient under sedation while dentist on hoverboard.

b. Dentist recorded a video and sent it to people outside the practice. https://www.youtube.com/watch?v=IUpUuRXxZWU

c. The patient on which this procedure was performed never gave her consent to the way the procedure was performed.

d. Alaskan prosecutor's brought criminal charges based on Medicaid fraud, unlawful dental acts.

e. Dentist sentenced to 20 years in prison

f. *State v. Lookhart*, No. 3AN-17-02990CR, defendant sentenced (Alaska Super. Ct., 3d Jud. Dist. Sept. 14, 2020).

5. Apparent Agency

a. Patient suffered complications during surgery at a hospital. Patient sued all parties involved including the hospital.

b. Hospital moved for summary judgement to dismiss claims against on grounds that it was not liable for injuries caused by an anesthesiologist as the anesthesiologist performing surgery was an independent physician employed by a third party and the hospital shouldn't be held vicariously liable.

c. Trial court granted summary judgement as to this issue ruling that the

hospital sufficiently notified patient that it was not the provider of anesthesia services when it handed the patient a business card of the anesthesiologist with his independent provider status noted thereon.

d. The Indiana Court of Appeals would not find the business card in and of itself qualified as proper notice and believed it presented questions of fact that were more properly reserved for the jury.

e. The Court emphasized that the registration clerk provided no further explanation when she provided the business card to the patient.

f. The Court found that the business card did not conclusively inform the patient that the anesthesiologist was not an employee of the hospital.

g. Ruling demonstrates the difficulty hospitals face in effectively protecting themselves from apparent agency claims.

h. Accordingly, the court suggested that such notices should be explicit and be provided in advance.

i. *Jernagan v Indiana University Health a/k/a Indiana University Health ACO, Inc.*, 156 N.E.3d 734, 736 (Ind. Ct. App. 2020) Patient died after surgery at a hospital. The attending physician was not a hospital employee.

j. Prior to surgery, Patient signed a hospital consent form providing: "I UNDERSTAND THAT ALL PHYSICIANS . . . ARE INDEPENDENT CONTRACTORS AND ARE NOT EMPLOYEES OR AGENTS OF THE HOSPITAL."

k. Notwithstanding this language, the deceased-patient's estate claimed that the hospital was vicariously liable for the negligent acts of the treating physician under a theory of apparent agency.

l. The Plaintiff argued that the hospital consent form and its reference to "all physicians" was insufficient to defeat apparent agency because it did not specify, by name, the precise identity of the treating physician involved in the surgery.

m. As the Illinois Appellate Court described it, "[i]n essence, what [Plaintiff] seeks is a consent form, tailored-made and specific to every treating physician."

n. In a soon-to-be published opinion, the Illinois Appellate Court rejected Plaintiff's argument and held that the reference to "all physicians" was sufficient. The hospital's consent form "clearly and unambiguously

informed [the patient] that 'all physicians' were independent contractors and not employees of the hospital." No greater specificity was required.

o. Indeed, as the Appellate Court observed, "were a hospital to engage in specifically naming every treating physician, we can well imagine what folly would occur if, for instance, the treating physician's name were misspelled, or if his name appeared different in form than the patient had previously or generally known it, or if there was a mistake in identifying the correct physician."

p. The term "all physicians," without more, was "sufficient to put [the patient] on notice that [the treating physician in question] was neither an employee nor an agent" of the hospital.

q. Delegatto v. Advocate Health and Hospitals, -- N.E.3d -- , 2021 IL App (1st) 200484 (Ill. Ct. App. Aug. 10, 2021).

6. Class Action Appeal

a. UnitedHealth Appeals Loss in Treatment Guidelines Case

i. UnitedHealth's plan holders sued UnitedHealth in a class action claiming United mishandled claims resulting in damages to the patients.

ii. The claims centered around allegations that United Health used treatment guidelines that were inconsistent with generally accepted standards of care, thereby violating the terms of their plans and breaching the insurer's fiduciary duty.

iii. Court ordered UnitedHealth to reprocess approximately 67,000 claims for behavioral health treatments.

iv. UnitedHealth claimed reprocessing would cost over $30MM.

v. Appeal currently pending

vi. https://www.law360.com/articles/1334484/unitedhealth-unitappeals-loss-in-treatment-guidelines-case

vii. On January 5, 2022, the district court entered an order granting in part and denying part Plaintiffs' Petition for Attorney's fees and Costs. The court awarded $19,628,071.88 in attorneys' fee and $1,230,729.86 in costs.

7. Workplace Violence

a. *BHC Northwest Psychiatric Hosp. v. Sec'y of Labor*, 2020 WL 1017618 (D.C.Cir. 3/3/20)

i. Ct. upheld $12,000 fine by DOL for violating OSHA "general duty" clause to protect employees from workplace violence

ii. Workplaces may still be unsafe even when hospital's practices were in line with industry standards

b. *Scola v. Facebook Inc.*, #18-CIV-05135 (Cal.Super.Ct., San Mateo Cnty.)

i. $52M to resolve allegations Facebook ignored workplace safety standards & allowed content moderators to sustain psychological trauma as a result of graphic images they saw on the job

ii. Moderators had repeated exposure to graphic content like child sexual abuse, beheadings, terrorism & animal cruelty

c. OakBend Med. Ctr. v. Simons, No. 01-19-00044-CV, 2021 WL 3919218, at *1 (Tex. App. Sept. 2, 2021)

i. Court upheld jury verdict in favor of employee for claims brought under the Texas Whistleblower Act

ii. Plaintiff alleged that she was terminated after filing complaints with OSHA regarding the hospital's inability to protect hospital staff from multiple, patient attacks

8. Sexual Abuse

a. *In re USC Student Health Ctr. Litig.*, #2:18-cv-4258 (C.D. Cal.)

i. $215M settlement of class action alleging USC did nothing to stop a doctor who sexually abused patients at an on-campus medical clinic

ii. Over 16,000 claimants expected to receive payments

b. *Disabato v. Ohio State Univ.*, #19-cv-02237 (S.D. Ohio, motion filed 5/8/20)

i. $40.9M to settle 12 suits by 162 survivors of sexual abuse by an employed physician

ii. Claims of approximately 215 survivors still unresolved; claim amount is too low compared to sex abuse settlements by other universities

c. *Poppel v. Estate of Archibald*, 2020 U.S. Dist. LEXIS 92815 (S.D.N.Y. 5/27/20)

i. Pediatric endocrinologist sexually abused children for over 40 years; hospital sued

ii. Vicarious liability claims dismissed because MD was acting outside scope of employment

iii. Emotional distress claim dismissed because no "extreme & outrageous conduct"

iv. Plaintiff can amend negligent hiring claim to show evidence of MD's propensity to commit sexual abuse before he was hired

v. Claim under New York's Child Victim Act allowed to proceed

d. Jane Does 16, 29, 79, 82, and 84 individually and on behalf of all similarly situated v. Columbia University, et al., #20-cv-01791 (S.D. NY)

i. Class action lawsuit for alleged sexual batteries committed by former gynecologist Dr. Robert Hadden

ii. Plaintiffs' causes of action include: violation of Title IX of the Education Amendment Act of 1972; negligent infliction of emotional distress; intentional infliction of emotional distress; unfair and deceptive business practices; fraud; negligent supervision; negligent hiring, retention, and ratification; gross negligence; and invasion of privacy

iii. Defendants Columbia University Irving Medical Center and New York-Presbyterian Hospital have settled with 79 of the plaintiffs

iv. The settlement agreement established a $71.5 million compensation fund to be administered by an independent special master

VI. HEALTH CARE REFORM

Author: Eric Zimmerman, McDermott Will & Emery
(Updated January 2022)

A. Affordable Care Act, Generally

1. California v. Texas

In 2012, in *NFIB v. Sebelius*, the US Supreme Court held that the ACA's mandate requiring individuals to maintain health insurance was constitutional on the basis that the law imposed a tax penalty on individuals without insurance, which the Court found to be within Congress's taxing power. In 2017, Congress enacted as part of larger tax bill a provision that reduced the mandate penalty to $0. With the taxing-power rationale now undermined, new lawsuits sprang up attacking the ACA's constitutionality. One such suit was brought by Republican state officials in Texas and other Republican attorneys general in more than a dozen other states. The district court in that case held both that the individual mandate was unconstitutional and that it could not be severed from the remainder of the ACA. The district court therefore held that the entire law must fall. In a 2–1 decision, the US Court of Appeals for the Fifth Circuit agreed that the penalty-free mandate was unconstitutional, but remanded the case to the district court to reconsider the severability issue. Subsequently, the Supreme Court agreed to review the Fifth Circuit's decision. Oral arguments were heard November 10, 2020. On June 17, 2021, the Supreme Court held that plaintiffs did not have standing to challenge the individual mandate. Justice Breyer wrote for the majority, with Justices Alito and Gorsuch dissenting. The court did not have to reach the substantive issues of the ACA, because it found that the parties challenging the ACA did not have a legally protected interest and injury. This leaves the ACA intact with a $0 individual mandate penalty. However, this does not preclude future legal challenges on the same issues, because the Court did not take up issues of constitutionality and severability. While this outcome allows the Biden Administration and the Democrat-controlled Congress to build on the ACA, it leaves open the possibility of future challenges.

2. Georgia

On November 1, 2020, CMS approved Georgia's request for a section 1332 waiver to establish a state-based reinsurance program and discontinue participation in the federal exchange. Section 1332 of the Affordable Care Act (ACA) permits states to apply for a State Innovation Waiver (also referred to as a State Relief and Empowerment Waiver) to pursue innovative strategies for providing residents with access to health insurance while retaining the basic protections of the ACA. The move to a state-based exchange presents the most significant changes. Under this plan, Georgia residents will be able to enroll in Qualified Health Plans (QHPs) and non-QHPs that will offer a more limited set of benefits. If implemented, Georgia would be the first state to do away with the Healthcare.gov federal marketplace without establishing a replacement portal through which to purchase coverage. On November 9, 2021, HHS notified Georgia that it is opening a 60-day federal comment period on Georgia's section 1332 waiver, the Georgia

Access Model.

3. Exchange Marketplace Revisions

On January 14, 2021, CMS posted the *final* Notice of Benefit and Payment Parameters for 2022, establishing new ACA marketplace requirements effective for the 2022 plan year. Among other things, the final rule establishes in regulation a new option by which a State Exchange, State-based Exchange on the Federal Platform, or Federally-facilitated Exchange state may allow people to enroll in individual market qualified health plans through approved private-sector, direct enrollment entities, such as QHP issuers and web brokers. Under this new "Exchange Direct Enrollment option," consumers may enroll or receive a determination of eligibility through private-sector websites in addition to a single, Exchange enrollment website. Additionally, the final rule codifies policies and interpretations outlined in the 2018 "State Relief and Empowerment Waivers" guidance (83 *Fed Reg.* 53,575, Oct. 24, 2018) into section 1332 regulations. CMS reasoned that it wished to "give states greater certainty regarding how the Departments will apply section 1332's statutory guardrails when determining whether a state's waiver proposal can receive and maintain approval," but critics assert that the last minute change, just a few days before the end of the Trump Administration, is intended to make it more difficult for the Biden Administration to undue flexibilities previously established through agency guidance.

On December 28, 2021, CMS released the *proposed* Notice of Benefit and Payment Parameters for 2023. 87 Fed. Reg. 584 (Jan. 5, 2022). The proposed rule was published in the Federal Register on January 5, 2022. Public comments are due on n January 27, 2022. This annual rule governs the Affordable Care Act health insurance marketplace, policies and standards. Among other things, CMS proposes to make the following programmatic and policy changes for 2023:

- Eliminate the ability of insurers to require payment of past due premiums as a condition of getting newly covered by the plan;Prohibit plans from discriminating on the basis of sexual orientation or gender identity; and

- Refine the risk adjustment model to better predict adult and child risk models for enrollees at both the lowest and highest risk categories.

4. Affordable Care Act Special Enrollment Period

On January 28, 2021, pursuant to an Executive Order signed that same day by President Biden, the Centers for Medicare and Medicaid Services opened a Special Enrollment Period (SEP) for the Federally Facilitated Marketplace for the period February 15 through May 15, 2021 to facilitate health insurance coverage during the COVID-19 pandemic. On March 23, 2021, CMS extended the SEP for an additional three months through August 15, 2021. Some of the states that do not utilize the healthcare.gov system had previously created special COVID-19 enrollment periods in their state-facilitated marketplaces. On May 11th, HHS Secretary Xavier Becerra announced, "More

than one million Americans have signed up for coverage on HealthCare.gov during the Special Enrollment Period…."

5. Notice of Benefit and Payment Parameters

On March 4, 2021, the federal district court for the District of Maryland sided with several cities that challenged regulatory changes to the Affordable Care Act implemented by the Trump Administration. On April 17, 2018, the U.S. Department of Health and Human Services promulgated its annual Notice of Benefit and Payment Parameters for 2019, 83 *Fed. Reg.* 16,930 (April 17, 2018), which governs many aspects of ACA insurance markets. The cities challenged nine changes in the regulation, arguing that they violate the Administrative Procedure Act. The court vacated the following four provisions challenged by the cities pertaining to federal review of network adequacy, standardized options, income verification and medical loss ratios. The action to vacate means these ACA requirements should revert to previous policy, although the Biden administration may address these developments further in the forthcoming 2022 exchange rule.

On April 30, 2021, CMS posted the final Notice of Benefit and Payment Parameters for 2022. 86 *Fed. Reg.* 24,140 (May 5, 2021). The notice finalizes the Premium Adjustment Percentage Index (PAPI) and Cost-sharing Parameters, as well as reporting requirements for issuers of risk adjustment covered plans who choose to provide temporary premium credits. CMS also approved requests submitted by Alabama to reduce Risk Adjustment transfers by 50% for both the individual market (including both the catastrophic and non-catastrophic risk pools) and the small-group market.

6. American Rescue Plan Medicaid Expansion Incentives

The Affordable Care Act required the federal government to pay 100% of state Medicaid costs for the expansion population through 2016, after which time the matching rate began phasing down to 90% in 2020 and thereafter. Currently, 38 states and the District of Columbia have adopted Medicaid expansion consistent with the ACA. The American Rescue Plan incentivizes non-expansion states to expand Medicaid eligibility for all adults with income up to 138% of the FPL by providing a five-percentage-point increase in the Medicaid FMAP for eight calendar quarters. This FMAP increase is only available to states that have not yet expanded coverage and have not yet started paying for the expansion population prior the enactment of the law. The FMAP bump applies to services provided to traditional eligibility groups and excludes certain payments, such as disproportionate share hospital (DSH) payments and Medicaid allotments to territories.

7. Advanced Premium Tax Credits

The Affordable Care Act established tax subsidies for health insurance purchased through insurance exchange marketplaces, known as advanced premium tax credits (APTCs). APTCs are available to individuals earning between 100% and 400% of the FPL. Under the American Rescue Plan, for two years (2021 and 2022), APTCs will be available to

eligible individuals whose income is above 400% of the FPL, based on a sliding scale. On one end of the sliding scale, individuals whose income is between 100% and 150% of the FPL are eligible for full coverage of their premiums. On the other end of the scale, individuals with incomes above 400% of the FPL will have their premiums capped at 8.5% of their income.

8. Section 1557 Discrimination Protections.

On May 10, 2021, the US Department of Health and Human Services announced, consistent with the US Supreme Court's decision in *Bostock v. Clayton County, GA,* 140 S. Ct. 1731 (2020), beginning May 10, 2021, HHS will interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity. This interpretation will guide the Office for Civil Rights (OCR) in processing complaints and conducting investigations, but does not itself determine the outcome in any particular case or set of facts. By this action, the Biden Administration is reinstating Obama-era protections under Section 1557, which were revised under the Trump Administration. This change was widely expected after the President issued a day-one Executive Order on gender protections. *See,* 86 *Fed. Reg.* 27,984 (May 25, 2021)

B. Medicaid 1115 Waivers

1. Medicaid Work Requirements

On December 4, 2020 the Supreme Court announced that it will hear arguments in *Gresham v. Azar* and *Philbrick v. Azar*, cases challenging the Trump administration's action authorizing Arkansas and New Hampshire to condition Medicaid coverage on work requirements. The D.C. Circuit Court of Appeals previously affirmed district court decisions finding that the Department of Health and Human Services' approval was arbitrary and capricious and violated the Administrative Procedure Act. On March 17, 2021, the US Department of Health and Human Services formally withdrew the prior 1115 waiver approvals that allowed Arkansas and New Hampshire to impose work requirements as a condition for eligibility for Medicaid benefits.

2. Georgia

On October 15, 2020 CMS approved Georgia's five year Section 1115 Medicaid waiver request allowing the state to expand Medicaid eligibility tied work requirements. Under the waiver, Georgia planned to expand Medicaid coverage for residents with incomes up to 100 percent of the Federal Poverty Limit, but for an individual to be eligible for coverage under "Georgia Pathways," the individual must work or participate in community engagement activities for a minimum of 80 hours per month. Activities that satisfy this requirement include unsubsidized employment, subsidized private sector employment, subsidized public sector employment, on-the-job training, job readiness programs, community service, vocational training, and enrollment in an institution of higher education. The program was to be implemented on July 1, 2021, and run through

September 30, 2025, but CMS withdrew the approval on December 23, 2021.

3. Nebraska

On October 20, 2020, CMS approved Nebraska's Heritage Health Adult five year 1115 Medicaid waiver that offers expanded Medicaid benefits (dental, vision, and over the counter medication) to certain expansion beneficiaries who engage in work and participate in healthy behavior activities. Nebraska voluntarily terminated the demonstration in August 2021.

4. Tennessee

On January 8, 2021, CMS approved the Tennessee 1115 waiver entitled "TennCare III." This is the first waiver to change Medicaid's financing from an open-ended funding structure to a "block grant" model. Under this approach, Tennessee will receive aggregate capped funding based on historical state spending, inflation, and future enrollment changes. In exchange, the state has the ability to add benefits and coverage without seeking prior approval from CMS. However, CMS did not approve requested authority to unilaterally reduce benefits or coverage. The new Biden Administration may seek to withdraw the waiver; however, this could then lead to legal action from the state of Tennessee. If it is not withdrawn, it may be challenged by stakeholders. This waiver is approved for ten years, until December 31, 2030.

5. Institutions for Mental Diseases (IMD) Waivers

On December 22, 2020, CMS approved Oklahoma's new demonstration, titled "Institutions for Mental Diseases Waiver for Serious Mental Illness/Substance Use Disorder," and Maine's new demonstration, entitled "Maine Substance Use Disorder (SUD) Care Initiative." These Medicaid SUD demonstration projects are the 30th and 31st approvals to broaden treatment services available to Medicaid beneficiaries diagnosed with SUDs and receiving treatment in institutions for mental disease. Through the waivers, Oklahoma now has the authority to receive federal Medicaid payment for medically necessary residential Serious Mental Illness, Severe Emotional Disturbance and/or SUD treatment in IMDs, and Maine has the authority to receive federal Medicaid payment for SUD treatment in IMDs. Both waivers will run through December 31, 2025.

C. Surprise Billing

Under legislation enacted late in 2020 (the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260), beginning January 1, 2022, plans and providers (including hospitals, facilities, individual practitioners and air ambulance providers) are prohibited from billing patients more than in-network cost-sharing amounts for emergency services and certain non-emergency services. Subject to certain limitations if a provider notifies a patient of the estimated cost of non-emergency out-of-network care at least 72-hours prior to the patient receiving the care, and the patient consents to the care, those services are not subject to the ban on surprise billing.

To reconcile payment disputes between plans and providers, the legislation allows parties to negotiate a resolution, and then provides an arbitration process if negotiations fail to resolve the payment dispute. The arbitration process will be baseball-style whereby each party submits an offer and the mediator selects one of the offers. The decision is then final and payment must be made within 90 days.

The federal agencies responsible for implementing the law issued a series of regulations in 2021, including the following:

- Regulations defining the methodology payers must use to determine cost sharing, information payers must share with out-of-network providers, the process for submitting and receiving consumer complaints, and the format and details of the notice and consent requirements; (86 Fed. Reg. 36,872 (July 13, 2021)) and

- Regulations establishing the independent dispute resolution process, good faith estimate for uninsured (or self-pay) individuals disclosure obligations, and the patient-provider dispute resolution process. (86 Fed. Reg. 55,980 (October 7, 2021)

More regulations are expected in 2022. Additionally, the American Medical Association and American Hospital Association, and three other professional societies and trade associations filed law suits seeking to invalidate aspects of the independent dispute resolution processes. These suits were filed late in 2021; briefing is scheduled for each in early 2022, and decisions are expected later this year.

D. Transparency

The Consolidated Appropriations Act, 2021 (Pub. L. No. 116-260) also includes new transparency obligations that require disclosures to patients on costs and provider networks, and that prohibit contracts that bar disclosing cost, price or quality information, among other things. Specifically, the new legislation makes the following changes:

- Group or individual health plans will be required to identify on insurance cards the amount of the in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitations.

- Health plans will be required to have up-to-date directories of their in-network providers.

- Health plans must provide direct access to certain providers, including obstetrics and gynecology services, without requiring prior authorization or referral.

- Health plans must provide an Advance Explanation of Benefits for scheduled services at least three days in advance of the provision of such services.

- Facilities and practitioners will be required to give patients a list of services received

no later than 15 calendar days after discharge or date of visit.

- Payers are prohibited from entering contracts with providers if such contracts would bar the payer from disclosing provider-specific cost, price or quality information, or from accessing de-identified claims information for the purposes of analysis and improvement.

- Employer-sponsored plans and individual market plans, including short-term limited duration plans, are required to disclose direct or indirect compensation with an agent or broker enrolling individuals into the plan.

- Plans must report spending information on the 50 brand-name prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug; the 50 most-costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan expenditures. Additionally, plans must also report total healthcare spending by hospital costs, provider costs, prescription drug costs and other medical costs, and any impacts on premiums due to rebates, fees or any other remuneration. These changes are effective January 1, 2022.

E. COBRA Coverage

Under long-standing federal law, individuals who lose their job or experience another qualifying event that results in termination of their employment-based health insurance are eligible to continue health insurance coverage through the Consolidated Omnibus Budget Reconciliation Act (COBRA). COBRA is often cost prohibitive for affected individuals, however, as they may be required to pay up to 102% of the total premium. The American Rescue Plan makes COBRA coverage more affordable by subsidizing, on the individual's behalf, 100% of the COBRA premiums during the period beginning the first month after ARP enactment until September 30, 2021. On May 18, 2021, the Internal Revenue Service provided guidance for employers, plan administrators, and health insurers regarding the new credit available for providing continuation health coverage to certain individuals under COBRA. IRS Notice 2021-31.

VII. HEALTH INFORMATION AND TECHNOLOGY

(Updated January 2022)

A. HIPAA Regulatory Developments

Author: Erin Dunlap, Coppersmith Brockelman

1. New OCR Director Appointed

In September 2021, HHS announced the appointment of Lisa J. Pino as Director of OCR. Pino had been serving as the New York State Department of Health's Executive Deputy Commissioner and led New York's operational response to the COVID-19 pandemic, as

well as programming for New York residents, including Medicaid, Medicare, Nutrition Program for Women, Infants, and Children (WIC), Hospital and Alternative Care Facility, Wadsworth Laboratories, Center for Environmental Health, Center for Community Health, and AIDS Institute. Prior to working for the New York State Department, Pino served as a former senior executive service official appointed by President Barack Obama who served at the U.S. Department of Homeland Security (DHS), the U.S. Department of Agriculture (USDA) Deputy Administrator of the Supplemental Nutrition Assistance Program (SNAP) and the USDA Deputy Assistant Secretary for Civil Rights.

According to HHS Secretary Xavier Becerra: "Lisa is an exceptional public servant, and I am delighted to welcome her to the role of the Director of the Office for Civil Rights at HHS… Her breadth of experience and management expertise, particularly her hand in advancing civil rights regulations and policy at the USDA during the Obama-Biden Administration, will help ensure that we protect the rights of every person across the country as we work to build a healthier America."

2. COVID-19 Response

Along with the rest of the world, OCR continued responding to the COVID-19 pandemic in 2021:

- In January 2021, OCR announced it would exercise its enforcement discretion and will not impose penalties for noncompliance with the HIPAA Rules against covered health care providers and business associates in connection with the good faith use of on-line or web-based scheduling applications for the scheduling of individual appointment for COVID-19 vaccinations during the public health emergency. See https://www.hhs.gov/about/news/2021/01/19/ocr-announces-notification-enforcement-discretion-use-online-web-based-scheduling-applications-scheduling-covid-19-vaccination-appointments.html. *The notification of enforcement discretion was published in the Federal Register on February 24, 2021.

- In September 2021, OCR issued guidance on HIPAA, COVID-19 Vaccination, and the Workplace, confirming the HIPAA Privacy Rule does not (i) prohibit any person, including entities subject to HIPAA, from asking whether an individual has received a vaccine, including COVID-19 vaccines; or (ii) prevent an individual from disclosing whether the individual has been vaccinated against COVID-19 or any other disease. The guidance also confirmed that HIPAA does not apply to employment records, and the HIPAA Privacy Rule does not regulate what information can be requested from employees as part of the terms and conditions of employment that an employer may impose on its workforce, such as COVID-19 vaccination documentation, or requiring that a mask be worn while on the employer's property or in the normal course of performing work duties. See https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html

Other Resources:

- OCR page, "HIPAA and COVID-19): https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html (last reviewed September 30, 2021)

- Law firm guidance: https://www.cblawyers.com/coppersmith-briefs/

3. HIPAA Right of Access Initiative

In January 2021, then-OCR Director confirmed that OCR's HIPAA Right of Access Initiative is "still going strong." In 2019, OCR announced this initiative as an enforcement priority. As of January 1, 2022, OCR had settled 25 patient access investigations (See HIPAA Civil Enforcement Actions listed below.)

The last 5 access-related enforcement actions were announced on November 30, 2021. In the press release, OCR Director Lisa J. Pino emphasized: "OCR will continue its enforcement actions by holding covered entities responsible for their HIPAA compliance and pursue civil money penalties for violations that are not addressed." Earlier in the year, OCR issued other patient-access related statements, including:

- "It should not take a federal investigation before a HIPAA covered entity provides a parent with access to their child's medical records… Covered entities owe it to their patients to provide timely access to medical records." (June 2021)

- "OCR's Right of Access Initiative continues to support and enforce individuals' vital right to receive copies of their medical records in a timely manner… Covered entities must comply with their HIPAA obligations and OCR will take appropriate remedial actions if they do not." (March 2021)

- "Health care providers have a duty to provide their patients with timely access to their own health records, and OCR will hold providers accountable to this obligation so that patients can exercise their rights and get needed health information to be active participants in their health care." (March 2021)

- "Patients are entitled to timely access to their medical records. OCR created the Right of Access Initiative to enforce and support this critical right." (February 2021)

- "Access to one's health records is an essential HIPAA right and health care providers have a legal obligation to their patients to provide access to their health information on a timely basis." (February 2021)

4. Proposed Modifications to HIPAA Privacy Rule

On January 21, 2021, OCR published proposed changes to the HIPAA Privacy Rule in

the Federal Register.[53] OCR stated on its website that it developed many of the proposed changes in response to public comments received in response to its 2018 Request for Information (RFI) on Modifying the HIPAA Rules to Improve Coordinated Care.

Public comments on these proposed changes were initially due by March 22, 2021, but OCR extended the comment period to May 6, 2021.

We understand that OCR had already received 772 comments on the proposed changes before it extended the comment period. While the comments largely express support for the goals and ideals of the proposed changes, some comments voice concern for the potentially complex and burdensome requirements when considered in the broader regulatory framework. See https://www.jdsupra.com/legalnews/hipaa-privacy-rule-modification-7104453/

According to OCR, these proposed changes are intended "to support individuals' engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the health care industry."[54] While these are important goals for the transformation to value-based health care, most health care providers and health plans want to know how the proposed changes will impact operations.

a. Reduction of Regulatory Burden

Some proposed changes that would reduce regulatory obligations on HIPAA covered entities (CEs) and allow for greater data sharing for care coordination and care management activities:

- ***No Acknowledgement of NPP*** – Change to 45 C.F.R. § 164.520. Under the proposed changes, CEs would no longer be required to get a written acknowledgment of receipt of the Notice of Privacy Practices (NPP). Some CEs have struggled with how to obtain and maintain these acknowledgments, particularly when the NPP is provided electronically, so this is a welcome change.

- ***Limited Right of Individuals to Direct Disclosure to Third Parties*** – Addition of 45 C.F.R. § 164.524(d). Under the current HIPAA rules, an individual has a right to direct a CE to send the individual's protected health information (PHI) to a third-party (often referred to as a "third-party directive").[55] In January 2020, a federal court vacated the third-party directive rule to the extent it went beyond requests to

[53] 86 Fed. Reg. 6448 (January 21, 2021). The proposed changes can be found here. Please note, while the proposed rule has a publication date of January 21,2021, it appeared in the Federal Register on January 20, 2021.
[54] *See* OCR's press release on the proposed changes here.
[55] In the preamble to the proposed changes, OCR explains that the third-party directive right is distinct from the provision that permits a CE to disclose PHI to a third party with an individual's valid authorization in at least four key respects: (1) the mandatory versus permissive nature of the disclosure; (2) the manner in which the request is made (*e.g.*, with or without a form containing required elements); (3) the form and format of the information provided; and (4) the fees that may be charged. 86 Fed. Reg. at 6462.

transmit an electronic copy of PHI maintained in an electronic health record (EHR).[56] The proposed changes would align the HIPAA rules with that federal court decision.

The proposed changes also add a definition of EHR to the HIPAA rules. The proposed definition of EHR is:

> *Electronic health record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and their staff.* ***Such clinicians shall include, but are not limited to, health care providers that have direct treatment relationships with individuals as defined at § 164.501, such as physicians, nurses, pharmacists, and other allied health professionals.*** *For purposes of this paragraph, "health-related information on an individual" covers the same scope of information as the term individually identifiable health information as defined at § 160.103.*[57]

Although the plain language limiting the definition of EHR to clinicians with a direct treatment relationship includes the modifier "but are not limited to" those clinicians, OCR's commentary clearly demonstrates an intent to limit the application to direct treatment providers only. OCR explains in the preamble that only covered health care providers that have a direct treatment relationship with individuals will maintain an EHR under this proposed definition. OCR said it "does not propose to include covered health care providers who have indirect treatment relationships with individuals," which the HIPAA rules define as "providers that deliver health care based on the orders of another health care provider, and… typically provide services, products, or reports to another health care provider."[58] OCR provided an example: "[T]he term EHR would not include health-related electronic records of [] providers that only supply durable medical equipment to other providers."[59] Another typical example of indirect treatment providers are clinical laboratories that

[56] In *Ciox Health LLC v. Azar, et al*., No. 18-cv-0040 (D.D.C. January 23, 2020), the U.S. District Court for the District of Columbia vacated certain parts of the third-party directive rule (among other provisions of the 2013 Final Omnibus Rule), finding that the rule unlawfully broadened the third-party directive to reach requests for PHI contained in any format, not just in an EHR. A copy of the decision can be found here. *See also* OCR's notice regarding the decision here.
[57] 86 Fed. Reg. at 6532 (amendments to 45 C.F.R. § 164.501) (emphasis added).
[58] 45 C.F.R. § 164.501 ("indirect treatment relationship means a relationship between an individual and a health care provider in which: (1) The health care provider delivers health care to the individual based on the orders of another health care provider; and (2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.").
[59] 86 Fed. Reg. at 6456.

are not part of a large health system (with a potential exception for consumer-ordered testing). OCR also stated that health plans do not maintain an EHR, so the rules relating to third party directives do not apply to health plans. OCR seeks comments on whether the EHR definition is too broad or not broad enough, and whether there are circumstances in which a health plan would create or maintain an EHR.

Overall, this proposed change is good for CEs because they would only be required to treat a third-party directive as an "access request" if CEs maintain the records in an EHR. On the downside, the proposed changes would allow individuals to submit a third-party directive orally, electronically or in writing. Under the current HIPAA rules, a third-party directive must be in writing.

- ***Limitations on Minimum Necessary Rule for Care Coordination and Case Management*** – Change to 45 C.F.R. § 164.502(b). The current minimum necessary rule (MNR) applies in most circumstances, other than treatment. This means most uses or disclosures of PHI must be limited to the minimum necessary to accomplish the intended purpose. However, under the proposed changes, the MNR would not apply to disclosures to or requests by a health plan for care coordination and case management activities with respect to an individual. This change is welcome because the determination of what information may be provided to a health plan for these purposes consistent with the MNR often is not clear. The proposed changes also clarify that the MNR does not apply to disclosures to or requests by health care providers for treatment, including care coordination and case management activities with respect to an individual.

- ***"Good Faith Belief" Standard and Presumption of Compliance*** – Changes to 45 C.F.R. §§ 164.502, 164.510 and 164.514. The proposed changes incorporate a "good faith belief" standard and presumption of compliance with the "good faith" standard (absent evidence of bad faith) when disclosing PHI in certain situations: (i) disclosures to a parent or guardian who is not the personal representative of an unemancipated minor under certain circumstances; (ii) uses or disclosures for a facility's directory under certain emergency circumstances; and (iii) disclosures to an individual's family or others involved in the individual's care under certain conditions. The presumption would also apply when a CE is acting on a good faith belief in making a disclosure to avert a serious threat to health or safety. This change will give covered health care providers more flexibility in sharing data in difficult circumstances. OCR requests comments on whether the good faith standard should be applied to other provisions of the HIPAA rules, including the personal

representative provisions.

- ***Disclosures to Social Service-Type Organizations*** – Change to 45 C.F.R. § 164.506. While OCR issued guidance several years ago clarifying that PHI may be shared with certain social service-type organizations for purposes of treatment/continuity of care, the proposed changes would expressly allow CEs to disclose PHI to a social services agency, community-based organization, home and community-based services provider, or a similar third party that provides health or human services to an individual for individual-level care coordination and case management activities (regardless of whether the activities constitute "treatment" or "health care operations," as defined by the HIPAA rules). This change gives certainty and more flexibility to CEs wishing to care for the entire person and to advance the use of social determinants of health, but the MNR will continue to apply to disclosures to or requests by these types of organizations.

- ***Expanded Scope of Serious Threat to Health or Safety*** – Change to 45 C.F.R. § 164.512(j). The proposed rules would allow a CE to disclose PHI if the CE, in good faith, believes the disclosure is necessary to prevent a serious and reasonably foreseeable harm, or lessen a serious and reasonably foreseeable threat to the health or safety of a person or the public. The term "reasonably foreseeable" means:

  > *[A]n ordinary person could conclude that a threat to health or safety exists and that harm to health or safety is reasonably likely to occur if a use or disclosure is not made, based on the facts and circumstances known at the time of the disclosure.*[60]

This is a departure from the use of the term "imminent" under the current HIPAA rules. OCR explained that the change would "further enable a health care provider to timely notify a family member that an individual is at risk of suicide, even if the provider cannot predict that a suicide attempt is likely to occur 'imminently.'"[61] The proposed changes also include a "heightened deference" to a determination made by a covered health care provider or one of its workforce members who specializes in assessing risk to health or safety, such as a licensed mental or behavioral health professional. This means there would be an express presumption that the provider has met the reasonably foreseeable standard. Overall, this change would give CEs greater ability and comfort in sharing data in difficult circumstances.

[60] 86 Fed. Reg. at 6533 (amendments to 45 C.F.R. § 164.512) (emphasis added).
[61] *Id.* at 6483.

b. Increased Regulatory Burden

Some of the proposed changes create further limitations or obligations on CEs, and will require additional compliance measures:

- ***No Unreasonable Access Requirements*** – Change to 45 C.F.R. § 164.524(b). A CE would be prohibited from imposing "unreasonable" measures that impede individual access to PHI if a less burdensome measure is practicable. The proposed rules state that requiring individuals to complete a standard form containing only the information the CE needs to process the request is reasonable, but requiring an individual to fill out an extensive request form, to obtain notarization, or to submit a request in person or only through an online portal is not reasonable. OCR requests comments on any burdens that CEs believe may result from this proposed change.

- ***No Unreasonable Verification Measures*** – Change to 45 C.F.R. § 164.514(h)(2)(v). Consistent with the prohibition on imposing unreasonable measures on individual access rights, the proposed change to 45 C.F.R. § 164.514(h)(2)(v) would prohibit a CE from imposing unreasonable verification measures on the exercise of individual rights under the HIPAA rules, including access, amendment and accounting requests. An "unreasonable measure" is "one that causes an individual to expend unnecessary effort or resources when a less burdensome verification measure is practicable," considering technical capabilities, safeguards and security and cost.[62] Examples of an unreasonable measure include requiring an individual: (i) to provide proof of identity in person when remote verification is practicable; or (ii) to obtain notarization on a written request to exercise an individual right.[63]

- ***Reduced Time to Respond to Access Requests*** – Change to 45 C.F.R. § 164.524(b). Under the proposed changes:

    - CEs would be required to fulfill a patient access request within 15 calendar days (versus the current 30-day requirement) with the opportunity for an extension of no more than 15 calendar days (versus the current 30-day extension). In proposing this change, OCR said it was persuaded by the fact that several states require patient access to health records in less than 30 calendar days.

    - CEs would be required to implement a written policy for prioritizing urgent or other high priority access requests (especially those related to health and safety) to limit the need to use a 15

[62] 86 Fed. Reg. at 6534 (amendments to 45 C.F.R. § 164.514).
[63] *Id.* at 6493.

calendar-day extension for such requests. Examples of urgent or high priority requests include "when an individual voluntarily reveals that the PHI is needed in preparation for urgent medical treatment, or the individual needs documentation of a diagnosis of severe asthma in order to bring medication to school the next day."[64]

- When PHI is readily available at the point of care, such as an x-ray or ultrasound or lab results performed during or ancillary to an appointment, a provider would not be permitted to delay the individual's right to inspect such PHI. OCR anticipates that "the time and place where an individual obtains health care treatment generally would be considered a convenient time and place for an individual to inspect the PHI that is immediately available in the treatment area."[65]

- ***Requirement to Transmit PHI by Email or to Personal Health Application*** – Change to 45 C.F.R. § 164.524(c). A CE would be required to send PHI electronically at the individual's request, including by email or to or through an individual's personal health application (personal health app), if "readily producible"[66] to or through such an application. According to OCR: "More and more individuals use personal health [apps] to access and manage their personal health information, and [this proposal will] clarify that… one of the mechanisms by which a request for access can be fulfilled is by transmitting an electronic copy of an individual's PHI to a personal health [app] used by the individual."[67]

  Under the proposed changes, a "personal health application" means:

  > *an electronic application used by an individual to access health information about that individual, which can be drawn from multiple sources, provided that such information is managed, shared, and controlled by or primarily for the individual, and not by or primarily for a covered entity or another party such as the application developer.*[68]

[64] *Id.* at 6499.
[65] *Id.* at 6457.
[66] The preamble to the proposed rules includes quite a bit of commentary on form and format of access and what is considered "readily producible," such as any form or format required by applicable state and other laws, internet-based access and standards-based APIs. *See* 86 Fed. Reg. at 6455, 6461, 6491, 6499, 6504 and 6509. We do not cover this commentary in this alert, but it will be important for CEs to consider the commentary in determining how they can and must provide access to PHI.
[67] 86 Fed. Reg. at 6457.
[68] 86 Fed. Reg. at 6533 (amendments to 45 C.F.R. § 164.501).

Put another way, a personal health app is a service offered directly to consumers; a personal health app is not acting on behalf of, or at the direction of a CE or another third party (such as a life insurance company, a research organization, or data aggregator). OCR requests comments on the proposed definition of personal health app.

- ***Required Notice If Summary Is Provided*** – Change to 45 C.F.R. § 164.524. Under the current HIPAA rules, a CE may provide an individual with a summary of PHI requested, in lieu of providing access to the PHI if (i) the individual agrees in advance to such summary, and (ii) the individual agrees in advance to the fees imposed, if any, for such summary. Under the proposed changes, if a covered health care provider offers to transmit such a summary, the provider must inform the individual that she retains the right to access a copy of the PHI – unless the provider is offering the summary because it is denying a request for a copy the PHI (in which case it would be required to follow the denial of access requirements).

- ***No Charge for Access*** – Change to 45 C.F.R. § 164.524(c). CEs would be required to provide access free of charge when an individual (i) inspects PHI in person (*e.g.*, recording/copying using the individual's own device), or (ii) uses an internet-based method such as a personal health app.[69]

- ***Required Revisions to NPP*** – Change to 45 C.F.R. § 164.520. The proposed changes would require several revisions to the NPP, including revisions to the introductory statement and the right of access provision. Providers will also need to include a statement that patients have the right to discuss the notice with a designated contact person, and to provide such person's email address (in addition to a telephone number).

c. Substantial Increase in Regulatory Burden

In our view, three of the proposed changes would place undue burden on CEs, and one change likely would create additional risk and liability:

- ***Requirement to Transmit Access Requests to Other Providers*** – Addition of 45 C.F.R. § 164.524(d). The proposed rule would create a new obligation on CEs to submit an individual's access request to a covered health care provider. Under the proposed changes, upon the written or oral direction of a current or prospective patient of a covered health care provider or a current member (or dependent) of a health

[69] For other types of access, CEs would be limited in the amount they can charge to a "reasonable, cost-based fee." There are host of complicated rules around what constitutes a "reasonable cost-based fee," and the proposed changes add more restrictions. We do not address the "reasonable, cost-based fee" provisions in this alert.

plan, a CE (a "Requester-Recipient") would be required to submit an individual's request for an electronic copy of PHI in an EHR to a covered health care provider ("Discloser") within 15 calendar days. Extensions would not be permitted.

The Discloser would then be required to respond to such a request in accordance with the right of access provisions. (See discussion above on reduced time to respond to access requests.) This change seems unnecessary (and overly burdensome on CEs) given other proposed changes to the right of access. If a patient's ability to request and obtain access is expanded, and CEs are required to respond to those requests in a shorter period of time, it seems unnecessary to require CEs to make those requests on behalf of the individuals, particularly upon an oral request made at any time.[70]

- ***Fee Schedule*** – Addition of 45 C.F.R. § 164.525. Under the proposed changes, if a CE imposes fees for access to PHI and for disclosures with an individual's valid authorization, the CE would be required to: (i) post a fee schedule[71] on its website (if applicable); (ii) provide a fee schedule to an individual at point of service upon request; and (iii) provide, upon request, an individualized estimate of approximate fees that may be imposed for any type of request covered by the fee schedule. A CE would also be required to provide, upon request, an itemized list of the specific charges for labor, supplies, and postage (if applicable), that constitute the total fee charged for any type of request covered by the fee schedule.

  With respect to fee schedule availability at the point of service, the expectation would be that a covered health care provider would make the fee schedule available upon request, in paper or electronic form, at the point of care or at an office that is responsible for releasing medical records, as well as orally (*e.g.*, over the phone), as applicable.

- ***Patient Notes, Videos and Photographs*** – Change to 45 C.F.R. § 164.524(a). In addition to the general right to inspect and make a copy of PHI, the proposed changes would give individuals the right to take notes, videos and photographs of, and to use other personal resources to capture, PHI in a designated record set (DRS), subject to a few limitations. For instance, the proposed rule change expressly provides that: "A [CE] is not required to allow an individual to connect a

[70] 86 Fed. Reg. at 6537 (amendments to 45 C.F.R. § 164.524).
[71] The fee schedule would be required to specify (i) all types of "free of charge" access; (ii) standard fees for copies of PHI (a) provided to individuals pursuant to an access request, with respect to all readily producible electronic and non-electronic forms and formats; (b) in an EHR and directed to third parties designated by the individual, with respect to any available electronic forms and formats; and (c) sent to third parties pursuant to a valid authorization, with respect to any available forms and formats. 86 Fed. Reg. at 6538 (amendments to 45 C.F.R. § 164.525).

personal device to the [CE's] information system and may impose requirements to ensure that an individual records only [PHI] to which the individual has a right of access."[72]

OCR requests comments on whether individuals recording their own PHI through video, still camera photos, or audio recordings would be inconsistent with federal and state recording laws or IP rights protection – as well as possible unintended consequences of the proposed expansion of right to inspect PHI. We believe it will be difficult for workforce members to manage and control individuals using cameras and other recording devices in day-to-day operations. This likely will result in impermissible disclosures of PHI, which will add extra burden (and potential exposure) on CEs.

B. HIPAA Civil Enforcement

Author: Erin Dunlap, Coppersmith Brockelman

According to HHS' website, as of November 30, 2021, OCR has initiated over 1,104 compliance reviews since April 2003, and OCR has resolved 96% of these cases (273,255). As of November 30, 2021, OCR has settled or imposed a civil money penalty (CMP) in 106 cases resulting in a total dollar amount of $131,392,632.00. According to OCR, the compliance issues most often alleged in complaints are:

- impermissible uses and disclosures of protected health information (PHI)
- lack of safeguards of PHI
- lack of patient access to their PHI
- lack of administrative safeguards of electronic PHI; and
- use or disclosure of more than the minimum necessary PHI.

See https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/index.html

There were 14 enforcement actions in 2021, including 1 imposition of a civil monetary penalty. 12 of the 14 enforcement actions were related to patient access. Below is an overview of the 14 enforcement actions:

- **Banner Health – January 2021 *Access Investigation**

Banner Health, on behalf of Banner Health affiliated covered entities (Banner Health ACE) agreed to pay $200,000 and take corrective action measures after OCR received two complaints alleging violation of the right of access standard. The first complaint alleged the individual requested access to her medical records in December 2017, and did not receive records until May 2018. The second complaint alleged that the individual requested access to an electronic copy of his records in September 2019, and the records

[72] 86 Fed. Reg. at 6535 (amendments to 45 C.F.R. § 164.524).

were not sent until February 2020.

- **Excellus Health Plan – January 2021**

Lifetime Healthcare Companies, including its affiliates Excellus Health Plan, Inc. doing business as Excellus BlueCross BlueShield and Univera Healthcare, Lifetime Health Medical Group, Lifetime Benefit Solutions, Lifetime Care, and The MedAmerica Companies (collectively, Excellus Health Plan) agreed to pay $5.1 million and undertake a corrective action plan after cyber-attackers gained access to its information systems from December 23, 2013 through May 11, 2015, resulting in the impermissible disclosure of PHI of more than 9.3 million individuals, including names, addresses, dates of birth, email addresses, Social Security numbers, bank account information, health plan claims and clinical treatment information. OCR found that Excellus Health Plan failed to conduct an enterprise-wide risk analysis, and failed to implement risk management, information system activity review, and access controls.

- **Renown Health, P.C. – February 2021 *Access Investigation**

Renown Health, P.C., a private, not-for-profit health system in Nevada, agreed to take corrective actions and pay $75,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard. In February 2019, OCR received a complaint alleging that Renown Health failed to timely respond to a patient's request that an electronic copy of her PHI, including billing records, be sent to a third party. OCR's investigation determined that Renown Health's failure to provide timely access to the requested records was a potential violation of the HIPAA right of access standard. As a result of OCR's investigation, Renown Health provided access to all of the requested records.

- **Sharp HealthCare d/b/a Sharp Rees-Stealy Medical Centers (SRMC)– February 2021 *Access Investigation**

SRMC agreed to take corrective actions and pay $70,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard. SRMC is located in California and provides health care through four acute-care hospitals, three specialty hospitals, three affiliated medical groups, and a health plan. In June 2019, a complaint was filed with OCR alleging that SRMC failed to take timely action in response to a patient's records access request directing that an electronic copy of PHI in an electronic health record be sent to a third party. OCR provided SRMC with technical assistance on the HIPAA Right of Access requirements. In August 2019, OCR received a second complaint alleging that SRMC still had not responded to the patient's records access request. OCR initiated an investigation and determined that SRMC's failure to provide timely access to the requested medical records was a potential violation of the HIPAA right of access standard. As a result of OCR's investigation, SRMC provided access to the requested records.

- **The Arbour, Inc. d/b/a Arbour Hospital (Arbour) – March 2021 *Access Investigation**

Behavorial health provider Arbour agreed to take corrective actions and pay $65,000 to settle a potential "right of access" violation. A complaint was filed with OCR in July 2019 alleging that Arbour failed to take timely action in response to a patient's records access request made two months earlier -- in May 2019. OCR provided Arbour with technical assistance on the access requirements. Later, in July 2019, OCR received a second complaint alleging that Arbour still had not responded to the same patient's records access request. OCR initiated an investigation and determined that Arbour's failure to provide timely access to the requested medical records was a potential violation of the HIPAA right of access standard.

- **Village Plastic Surgery (VPS) – March 2021 *Access Investigation**

VPS agreed to take corrective actions and pay $30,000 after a complaint was filed with OCR alleging that VPS failed to take timely action in response to a patient's records access request made in August 2019. OCR determined that VPS's failure to provide timely access to the requested medical records was a potential violation of the HIPAA right of access standard, which requires a covered entity to take action on an access request within 30 days of receipt (or within 60 days if an extension is applicable). As a result of OCR's investigation, VPS sent the patient their requested records.

- **Peachstate Health Management, LLC d/b/a AEON Clinical Laboratories (Peachstate) – April 2021**

Peachstate provides diagnostic and laboratory-developed tests, including clinical and genetic testing services. Peachstate agreed to pay $25,000 and to implement a corrective action plan to settle potential violations of the HIPAA Security Rule. In December 2017, OCR initiated a compliance review of Peachstate. The investigation found systemic noncompliance with the HIPAA Security Rule, including failures to conduct an enterprise-wide risk analysis, implement risk management and audit controls, and maintain documentation of HIPAA Security Rule policies and procedures.

- **Office of Dr. Robert Glaser – May 2021 *Access Investigation**

OCR imposed a civil monetary penalty (CMP) of $100,000 on Dr. Glaser after Dr. Glaser failed to respond to several written and verbal requests from a former patient to access his medical records from 2013-2014. In December 2017, OCR closed an initial complaint from the patient with instructions to Dr. Glaser to review the access request and provide access if the request met the requirement under the HIPAA Privacy Rule. OCR received a second complaint from the patient in March 2018, alleging Dr. Glaser still had not provided the records. After numerous attempts to obtain a response from Dr. Glaser (which went unanswered), OCR ultimately determined that Dr. Glaser had denied the patient access to his medical records and failed to cooperate with OCR's investigation.

- **Diabetes, Endocrinology & Lipidology Center, Inc. (DELC) – June 2021 *Access Investigation**

DELC agreed to take corrective actions and pay $5,000 after a complaint was filed with OCR in August 2019, alleging that DELC failed to take timely action in response to a parent's records access request made in July 2019, for a copy of her minor child's protected health information. As a result of OCR's investigation, DELC provided the requested records in May 2021, nearly two years after the parent's request.

- **Children's Hospital & Medical Center (CHMC) – September 2021 *Access Investigation**

CHMC agreed to take corrective actions and pay $80,000 after a complaint was filed with OCR in May 2020, alleging that CHMC failed to provide a parent with timely access to her deceased minor daughter's medical records. According to OCR's press release, CHMC had provided some records, but it did not provide all of the requested records in response to the parent's multiple follow-up requests. As a result of OCR's investigation, the parent finally received all of the requested records.

- **Advanced Spine & Pain Management (ASPM) – November 2021 *Access Investigation**

ASPM agreed to take corrective actions and pay $32,150 after a complaint was filed with OCR, alleging that ASPM failed to provide a patient with timely access to his PHI. The patient submitted a written request for access in person on November 25, 2019, but ASPM did not send the patient a copy of his PHI until March 19, 2020.

- **Denver Retina Center, P.C. (DRC) – November 2021 *Access Investigation**

DRC agreed to take corrective actions and pay $30,000 after a complaint was filed with OCR on June 24, 2019. The complaint alleged that a patient requested her medical records from DRC in December 2018, but she did not receive the records until July 26, 2019. (In this case, the patient had filed a previous complaint with HHS in March 2018. OCR had closed that matter by providing technical assistance to DRC.) OCR also found that DRC did not have compliant access policies and procedures.

- **Rainrock Treatment Center, LLC d/b/a Monte Nido Rainrock (Monte Nido)– November 2021 *Access Investigation**

Monte Nido agreed to a corrective action plan and to pay $160,000 after several complaints were filed with OCR from December 2019 through February 2020 alleging that Monte Nido failed to provide a patient a copy of her medical records (after multiple requests) until May 22, 2020.

- **Wake Health Medical Group (WHMG)– November 2021 *Access Investigation**

WHMG agreed to a corrective action plan and to pay $10,000 after a patient filed a complaint with OCR, alleging that WHMG failed to provide the patient a copy of her medical records despite the patient making a request in June 2019 and paying a $25 fee. During the investigation, OCR learned that WHMG was charging patients a flat fee of $25 to obtain a copy of his/her medical records. As of the date of the Resolution Agreement, WHMG still had not provided the patient a copy of her medical records. All HHS press releases, fact sheets and other news materials are available at https://www.hhs.gov/news.

- **Fifth Circuit Overturns CMP Imposed on MD Anderson**

Another really important enforcement development was the January 14, 2021 decision by the U.S. Court of Appeals for the Fifth Circuit (Fifth Circuit) to overturn of the $4,348,000 civil monetary penalty (CMP) that OCR imposed on the University of Texas M.D. Anderson Cancer Center (MD Anderson). The CMP was imposed in June 2018 after a lengthy investigation by OCR into three data breaches reported by MD Anderson in 2013 and 2014. The breaches involved the loss/theft of an unencrypted laptop containing the PHI of 29,021 individuals and two unencrypted USB thumb drives containing, together, the PHI of 5,862 individuals.

OCR concluded that MD Anderson failed (i) to implement encryption or adopt an alternative and equivalent method to limit access to ePHI stored on electronic devices; and (ii) to prohibit unauthorized disclosures of ePHI. After finding that MD Anderson had "reasonable cause" to know it was in violation of the HIPAA Rules (setting out the second tier of the four-tiered penalty structure), OCR imposed penalties of $1,348,000 for the of lack of encryption and $3 million ($1.5 million per year) for the impermissible disclosures of ePHI. Finding MD Anderson had reasonable cause to know it was in violation of the HIPAA Rules. MD Anderson unsuccessfully sought two levels of administrative review (including with an Administrative Law Judge (ALJ) who sustained the imposition of the CMPs). MD Anderson then petitioned the Fifth Circuit to review the ALJ's ruling. Interestingly, after MD Anderson petitioned the Fifth Circuit, the Government (HHS) conceded that the $4,348,000 financial penalty could not be justified and asked the Fifth Circuit to reduce the fine by a factor of 10 to $450,000.

The Fifth Circuit granted the review and found that HHS had acted arbitrarily, and its decision was capricious and contrary to law for at least four independent reasons:

1. MD Anderson had complied with the HIPAA requirements and implemented a mechanism for encryption as early as 2006, and OCR failed to demonstrate that MD Anderson had not done enough to secure the ePHI of its patients. Rather, the facts showed that three employees had failed to abide by MD Anderson's encryption policies.

2. The definition of "disclosure" under the HIPAA rules suggests "an affirmative act of disclosure, rather than a passive loss of information", and ePHI would need to be accessed by someone outside the covered entity – which could not be determined in this case.

3. The decision to fine some covered entities for loss/theft incidents and not others was inconsistent.

4. Under the "reasonable cause" penalty tier, the maximum fine for violations of an identical provision during a calendar year may not exceed $100,000 – not $1,500,000.

The Fifth Circuit ultimately concluded that HHS had offered no lawful basis for the CMPs, vacated the CMP order, and remanded the matter for further proceedings consistent with the court's opinion, which can be found at: http://www.ca5.uscourts.gov/opinions/pub/19/19-60226-CV0.pdf

C. Other OCR Guidance

Author: Erin Dunlap, Coppersmith Brockelman

On December 20, 2021, HHS/OCR issued guidance on HIPAA and Disclosures of Protected Health Information for Extreme Risk Protection Orders (ERPOs), which may be found at: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/extreme-risk-protection-orders/index.html. An ERPO is a court order that temporarily prevents a person in crisis, who poses a danger to themselves or others, from accessing firearms. The HHS/OCR guidance helps to implement the model ERPO legislation issued by the U.S. Department of Justice (DOJ) on June 7, 2021. This model legislation provides a "framework for states to consider as they determine whether and how to craft laws allowing law enforcement, concerned family members, or others to seek these orders and to intervene before warning signs turn into tragedy." See https://www.justice.gov/doj/reducing-gun-violence/commentary-extreme-risk-protection-order-model-legislation. The HHS/OCR guidance clarifies when covered health care providers can disclose PHI (without individual authorization) to support applications for extreme risk protection orders that temporarily prevent a person in crisis, who poses a danger to themselves or others, from accessing firearms. HHS/OCR gave several examples when a disclosure of PHI under these circumstances is permissible, e.g., when required by law, in response to a court order or in the course of a judicial or administrative proceeding or *necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. But, HHS/OCR also reminded covered health care providers to consider the minimum necessary standard, state ERPO laws and other federal and state laws, including 45 CFR Part 2, that may be more stringent than the HIPAA Privacy Rule.*

D. HIPAA Criminal Enforcement

Author: Scott Bennett, Coppersmith Brockelman

U.S. v. Hameedi (Case No. 17 Crim. 137, S.D.N.Y.) In May of 2021, a cardiologist was sentenced to 20 months in prison after pleading guilty in a case involving charges of healthcare fraud, violations of the Anti-Kickback Statute, and criminal HIPAA violations. As the DOJ press release explains:

> CMA, a cardiology and neurology clinic based in Bayside, Queens, conducted a multifaceted scheme spanning approximately 12 years and involving millions of dollars in falsified claims. HAMEEDI, a board-certified interventional cardiologist, was CMA's president and owner. As HAMEEDI has acknowledged, he was a leader of this long-running, wide-ranging fraud scheme, which involved various co-conspirators and several codefendants.
>
> HAMEEDI's healthcare fraud scheme included, among other things: (1) making false representations to insurance providers about patients' symptoms in order to obtain preauthorization for medical tests and procedures; (2) backdating bills in order to create the false impression that medical procedures had not been performed until after CMA received "pre"-authorization from an insurer; (3) submitting false claims to insurance providers for parts of tests that were not performed, as well as for drug items not used or provided; (4) evading scrutiny from insurers for the large volume of claims that CMA submitted by falsely representing that several doctors – who did not work at CMA – had purportedly ordered or performed tests or procedures there; and (5) violating HIPAA by accessing, without authorization, electronic health records of patients at a particular hospital on Long Island, New York, in order to identify patients to be recruited to CMA. Additionally, HAMEEDI tried to obstruct an investigation by hospital officials into misconduct by his nephew, codefendant Fawad Hameedi.
>
> In addition to his prison sentence, HAMEEDI, 50, of New York, New York, was sentenced to two years of supervised release, restitution of $554,331, and a $100,000 fine.

- Indictment
- Press release re sentencing

U.S. v. Lombardo (Case No. 21-MJ-2687, S.D. Cal.). A former patient financial service representative for Scripps Health, a hospital system in San Diego, was charged in July of 2021 with a criminal HIPAA violation. The Justice Department

alleges that he stole confidential patient files, and provided the files to several codefendants, who used the patients' personal information to apply for Pandemic Unemployment Insurance benefits. The former Scripps Health employee has also been charged with aggravated identity theft and conspiracy to commit wire fraud. The case is still pending.

- Criminal complaint

- Press release re criminal complaint

E. Data Breaches and Breach Litigation
Author: Alisa Chestler, Baker Donelson

At our mid-year update we reported that "2020 was another record-breaking year with the depth and breadth of data breaches and 2021 is shaping up to outpace that record by leaps and bounds. As activity intensified with the COVID-19 pandemic, attempts against organizations spiked . . ." 2021 was no different. Each year, several large organizations publish reports regarding the state of the breach market. The IBM report, issued in early December 2021 reported the following statistics:

- Data breach costs rose from $3.86M to $4.24M

- The average cost was $1.07M higher when remote work was a factor in the breach.

- The most common initial attack vector was compromised credentials (including compromised business emails)- it represented 20% of the breaches and had an average cost of $4.37M.

Data breaches continue to be a prominent cyber threat, with the healthcare industry being one of the most targeted. "For 11 consecutive years, the healthcare industry is paying the most for data breaches. The average cost increased by 29.3% from $7.13 million in 2020 to $9.23 million in 2021." [IBM Report]

The financial impact of the top 4 types of initial attack vectors are as follows:

- Business Email Compromise (BEC) - $5.01 million

- Phishing - $4.65 million

- Malicious insiders - $ 4.61 million

- Social engineering - $4.47 million

The average number of days to identify and contain a breach was 287 days. The longer a breach remains undetected, the higher the financial impact will be. The new average of 287 is well above the absolute maximum threshold of 200 days for reducing data breach

costs.

Data breaches that were identified and contain within 200 days had an average cost of $3.61 million. But breaches that took more than 200 days to identify ad contain had an average cost of $4.87 million - a difference of $1.26 million.

We have provided several cases below for a number of reasons, either they are illustrative of the larger cyber problem in the world, of the issues at hand or of the legal considerations on handling such events. We have provided the information by month based upon when the breach became public or the opinion issued by the court. You should note that many of the breaches occurred many months prior.

JANUARY 2021

Microsoft Exchange Server: In early January, threat researchers reported four critical zero-day vulnerabilities in the Microsoft Exchange Server to Microsoft. On March 2, Microsoft released patches to remediate the critical vulnerabilities, but the bugs were already being actively exploited in targeted attacks.

- Microsoft Exchange Server is an email, calendar, and collaboration platform run exclusively on the Microsoft operating system and used by enterprise giants and small-to-medium sized businesses worldwide.

- Microsoft reported that the original attacks using the zero-day vulnerabilities have been traced to a Chinese state-sponsored advanced persistent threat (APT) known as Hafnium.

- In total, this attack has affected the email systems of an estimated 250,000 global customers, including state and local governments, policy think tanks, academic institutions, infectious disease researchers and businesses such as law firms and defense contractors.

- On March 12, Microsoft reported a variant of ransomware known as DoejoCrypt/DearCry is leveraging the bugs to deploy ransomware on vulnerable Exchange servers.

- On April 13, the U.S. Department of Justice reported that the FBI had remotely removed malicious programs from hundreds of computers in the U.S. that were running unpatched versions of Microsoft Exchange Server.

    - The U.S. District Court for the Southern District of Texas approved a warrant authorizing the FBI to seize, copy, and delete malicious web shells from compromised Microsoft Exchange Servers located in the U.S.

        - This intrusion into private networks by the FBI is predicated upon a 2016 change to Rule 41 of the Federal Rules of Criminal Procedure, which

authorizes courts to approve warrants for law enforcement to access to remotely seize, copy, and delete electronically stored information computers nationwide as part of a Computer Fraud and Abuse Act investigation.

- Web shells are scripts and codes that enable remote administration privileges. Hackers exploit the vulnerabilities to place web shells that allow continuing unauthorized backdoor access for cyber espionage and other malicious activity. It was these web shells that the FBI launched an operation to remove.

M.D. Anderson Case: The U.S. Court of Appeals for the Fifth Circuit overturned a $4,3+M HIPAA violation penalty imposed on University of Texas M.D. Anderson Cancer Center by OCR. The Civil Monetary Penalty was imposed on M.D. Anderson in 2018 following an investigation of three data breaches that were reported to the Office for Civil Rights between 2013 and 2014 that involved the loss/theft of unencrypted devices between 2012 and 2013. Two unencrypted flash drives containing the ePHI of over 5,700 patients were lost, and an unencrypted laptop computer containing the ePHI of another 29,021 patients was stolen. The OCR investigation concluded that M.D. Anderson was in violation of two provisions of the HIPAA Rules. The first violation was the failure to implement encryption or adopt an alternative and equivalent method to limit access to ePHI stored on electronic devices, and the second prohibits unauthorized disclosures of ePHI.

- HIPAA penalties are tiered and are based on the level of culpability, with the OCR determining M.D. Anderson had reasonable cause to know it was in violation of the HIPAA Rules. OCR calculated the appropriate penalties to be $1,348,000 for the of lack of encryption and $1.5 million per year for the impermissible disclosures of ePHI.

- M.D. Anderson contested the financial penalties and after two unsuccessful reviews, OCR imposed the civil monetary in June 2018. M.D. Anderson petitioned the 5th Circuit Court of Appeals to review the ruling.

- M.D. Anderson maintained that the OCR exceeded its authority by imposing the civil monetary penalties, since M.D. Anderson is a state agency and is therefore not a 'person' covered by the Enforcement Provision of HIPAA. M.D. Anderson also alleged the financial penalty was excessive. At the time it was the third largest HIPAA penalty to be imposed on a single covered entity for violations of the HIPAA Rules.

- The two failed reviews resulted in the case going before an Administrative Law Judge (ALJ) who refused to rule on whether HIPAA, the HITECH Act, any other statute applied, nor whether the civil monetary penalty was arbitrary or capricious. The 5th Circuit explained in its ruling it assumed that M.D. Anderson is such a "person" and that the enforcement provision therefore applies. The petition was granted based on the Courts determination that the CMP violated the Administrative Procedure Act ("APA").

- The Court of Appeals ruled that OCR had acted arbitrarily, and its decision was capricious and contrary to law. Many experts are focused on the encryption aspects of the finding. M.D. Anderson had implemented a "*mechanism"* for encryption as early as 2006, however OCR had taken issue with the failure to consistently apply that mechanism. According to the Court, OCR failed to demonstrate that M.D. Anderson had not done enough to secure the ePHI, the Court determined it was only possible to demonstrate that three employees had failed to abide by M.D. Anderson's encryption policies.

- The Court of Appeals also found issue with the impermissible disclosure aspect of the decision. The HIPAA definition of disclosure suggests an affirmative act rather than a passive loss of information, and also that ePHI would need to be disclosed to someone outside the covered entity, when that could not be determined in this case.

- The Court of Appeals also found the decision to fine some covered entities for loss/theft incidents and not others was inconsistent. M.D. Anderson provided examples of other covered entities that similarly violated HHS's interpretation of the "Encryption Rule" and faced no financial penalty. The Court emphasized that "an administrative agency cannot hide behind the fact-intensive nature of penalty adjudications to ignore irrational distinctions between like cases."

- Following the petition to the Court of Appeals, the HHS' Office for Civil Rights conceded that the $4,348,000 financial penalty could not be justified and asked the Court of Appeals to reduce the fine by a factor of ten to $450,000.

- The Court of Appeals concluded that the Government had offered no lawful basis for the civil monetary penalties, vacated the CMP order, and remanded the matter for further proceedings

FEBRUARY

Washington State: On February 26, news reports disclosed that the state of Washington was planning to send notifications to individuals affected by a data security incident at Accellion, a software provider the office uses to transfer large computer files. Accellion is a popular vendor for lawyers and health care organizations because of its ability to transfer large files. The February notice was the first indication of the issue, however several covered entities were affected.

No ransomware was deployed in the incident. At first, it was unclear the motive of the attack. But Clop actors have since posted troves of stolen data online in a mass extortion effort. A number of impacted entities have also received emails from the attackers, adding to the extortion attempts.

The exploit gave the hacker access for a number of days, which resulted in the theft of data from at least 100 Accellion clients, including Centene, Kroger, the Jones Day Law

Firm, Trillum Community Health Plan, and the Southern Illinois University School of Medicine, among others. With regard to Centene:

- In April, the "wall of Shame" the OCR breach reporting tool showed over 1.3 million patients of Centene subsidiaries were impacted by the massive Accellion File Transfer Appliance vulnerability hack and subsequent data exfiltration.

- The incident was reported to HHS in four separate filings, affecting 523,709 Health Net of California patients, 26,637 patients of HealthNet Life Insurance Company, 686,556 patients of Health Net Community Solutions, and 80,138 California Health & Wellness patients. All reported entities are subsidiaries of Centene.

- The notices show the attackers had access to the entities' information from January 7 until January 25. The impacted data included contact details, dates of birth, insurance ID numbers, and health information, such as treatments and medical conditions.

- An SEC filing issued by Centene revealed Accellion notified the entity in January 2021 that an attacker exploited multiple, unpatched zero-days vulnerabilities.

CaptureRx: On February 6, a Texas-based healthcare technology company suffered a ransomware attack during which cyber criminals exfiltrated files containing the personal health information (PHI) of more than 24,000 individuals.

- CaptureRX is a 340B program solution provider (IT vendor) that helps rural health care providers purchase drugs at a discount for needy patients.

- Data exposed and stolen by the ransomware attackers included names, dates of birth, prescription information, and, for a limited number of patients, medical record numbers.

- Although initially reported to HHS on May 5, healthcare systems that were impacted by the business associate breach continued to announce their involvement throughout the summer of 2021. In July, MetroHealth System in Ohio announced that its patient files were accessed during the breach. In August, New York-based Catholic Health said that patient PHI was impacted as a result of the CaptureRx incident.

- The breach impacted patient PHI across multiple healthcare organizations, exposing prescription data, names, and birth dates.

- The breach also impacted Walmart

MAY

DarkSide Ransomware: DarkSide is a Russian ransomware-as-a-service platform that vetted cybercriminals can use to infect companies with ransomware and carry out negotiations and payments with victims. DarkSide exclusively targets large companies

with double extortion – demanding separate large sums for both a digital key to unlock encrypted files and servers, and a separate ransom in exchange for a promise to destroy any data stolen from the victim. In mid-April, DarkSide announced new capability for affiliates to launch distributed denial-of-service (DDoS) attacks against targets whenever added pressure is needed during ransom negotiations.

- On May 7, Colonial Pipeline learned that it had suffered a significant ransomware attack by DarkSide. The breach affected Colonial's business networks, forcing the company to deactivate those systems. To ensure the hackers had not compromised the operational technology systems that monitor the flow of gas for impurities and leaks, control power levels, and perform other automated tasks to keep the pipeline operating, Colonial also took those systems offline. The end result was a total shutdown of Colonial's primary pipeline system, which transports 45 percent of gasoline, jet fuel, and diesel for the East Coast.

- DarkSide Leaks, an extortion website of DarkSide ransomware, published samples of the data stolen from Smile Brands Inc. Smile Brands is a US healthcare provider with over 650 affiliated dental offices. According to the post, the threat actors gained access to finance accounting data, contracts and NDAs, data from the human resources and legal departments, and more. The threat to leak stolen data is a part of the double extortion "name and shame" technique meant to persuade the compromised organizations to pay the ransom.

- DarkSide Leaks made an announcement on April 20, 2021 that they are willing to provide security breach information related to the publicly traded companies on NASDAQ and other stock exchanges to interested parties who can short the stock and monetize the insider information. While other ransomware families have previously discussed how to leverage the effect of publicly disclosed cyberattacks on the stock market, they have never made it an official attack vector. DarkSide is the first ransomware variant to make it formal suggesting that interested parties can use the "Contact Us" page on their website to submit a request for information. The ransomware operators promise to provide detailed information about the uncooperative victims whose data is going to be published in the near future.

    - The announcement also serves as an indirect method to threaten hacked companies that not paying the ransom demand could result in negative press large enough to impact their market listings and enough to push some victims into paying the asked ransom. Once the original ransom demand is declined, ransomware groups start putting additional pressure on victims with the tactics listed below:

        - Cold-calls to threaten victims

        - Personal threats against the executives responsible for approving the ransom payment

- Threats to notify business partners
- DDoS attacks
- Media coverage
- Threats to notify privacy watchdog agencies about a breach
- Emails to victim's clients

Scripps Health: On May 2, 2021, Scripps Health, a nonprofit health care provider, announced that it had suffered a ransomware attack which significantly impacted its operations. Information systems at two of Scripps' four central hospitals were impacted, including backup servers in Arizona. This case is very similar to the issues faced by University of Vermont Medical Center in October 2020.

- First detected on May 1, 2021, the attack sidelined the organization's electronic medical record and other electronic systems used to deliver care in hospitals and medical office buildings, leading to ambulance diversions, canceled procedures and patient surges at other local facilities. The outage also shut down the "My Scripps" smartphone application that provided a tool for messaging their doctors, making appointments and tracking prescriptions.

- Scripps has cancelled the majority of its appointments. It is unclear whether Scripps has access to its patients' medical history records.

JUNE

Colonial Pipeline: No 2021 discussion would be complete without some mention of the Colonial Pipeline Breach which caused a gasoline crisis on the entire east coast. Reports have indicated that hackers gained entry into the networks of Colonial Pipeline on April 29 through a virtual private network account, which allowed employees to remotely access the company's computer network.

- The account was no longer in use at the time of the attack but could still be used to access Colonial's network- another key reason to ensure good process when terminating employees or others with access to networks. The account's password has since been discovered inside a batch of leaked passwords on the dark web. That means the former employee may have used the same password on another account that was previously hacked, but investigators may never know for certain how the credential was obtained.

- The VPN account, which has since been deactivated, didn't use multifactor authentication, a basic cybersecurity tool, allowing the hackers to breach Colonial's network using just a compromised username and password. Apparently, there was no evidence of phishing for the employee whose credentials were used.

- A little more than one week later, on May 7, an employee in Colonial's control room saw a ransom note demanding cryptocurrency payment. The operations team began to start the process of shutting down the pipeline. It was the first time Colonial had shut down the entirety of its gasoline pipeline system in its 57-year history. Colonial began resuming service on May 12.

- Colonial paid the hackers, who were an affiliate of a Russia-linked cybercrime group known as DarkSide, a $4.4 million ransom shortly after the hack. The hackers also stole nearly 100 gigabytes of data from Colonial Pipeline.

JULY

Forefront Dermatology: In July, there were 70 reported data breaches of 500 or more records to the OCR portal, making it the fifth consecutive month where data breaches have been reported at a rate of 2 or more per day. The largest breach that was reported that month was by a Wisconsin-based healthcare provider with locations in 21 states. Forefront Dermatology's breach exposed more than 2.4 million patient records including names, addresses, dates of birth, account numbers, health insurance plan member ID numbers, medical record numbers, dates of service, accession numbers, provider names, and/or medical and clinical treatment information. The investigation reportedly determined that unauthorized parties gained access to Forefront's IT network between May 28 and June 4. Upon discovery in early June, Forefront took its network offline and notified law enforcement. The intrusion resulted in unauthorized access to files on Forefront's IT system containing patient and employee information. "While the investigation found evidence that only a small number of patients' information was specifically involved, Forefront Dermatology could not rule out the possibility that files containing other patients' information may have been subject to unauthorized access," said the company in a press statement.

SEPTEMBER

On September 21 the US Department of Treasury's Office of Foreign Assets Control (OFAC) issued an update highlighting the sanctions risks associated with ransomware payments. That same month OFAC closed down a crypto exchange SUEX, for its transactions related to ransomware payments. OFAC designated numerous malicious cyber actors under its cyber-related sanctions program and other sanctions programs, including perpetrators of ransomware attacks and those who facilitate ransomware transactions.

In September 2021, OFAC designated SUEX OTC, S.R.O. ("SUEX"), a virtual currency exchange, for its part in facilitating financial transactions for ransomware actors, involving illicit proceeds from at least eight ransomware variants. Analysis of known SUEX transactions showed that over 40% of SUEX's known transaction history was associated with illicit actors.10 OFAC has imposed, and will continue to impose, sanctions on these actors and others who materially assist, sponsor, or provide financial,

material, or technological support for these activities.

- This action will have/already has had an impact on how ransom incidents are handled.

OCTOBER

QRS EHR: In October, EHR vendor QRS began notifying its clients of an August cyberattack that exposed the PII and PHI of nearly 320,000 individuals. The attack occurred between August 23 and August 26, 2021, when a hacker accessed one QRS dedicated patient portal servers. QRS said it immediately took the server offline, notified law enforcement, and engaged a forensic security firm to investigate the incident. During the three-day attack window, the hacker accessed and may have acquired files on the server containing PII and PHI.

DOJ – Civil Cyber Fraud Unit: In October the Department of Justice (DOJ) announced a new Civil Cyber Fraud Initiative (the "initiative") designed to remind providers of their obligations to protect their assets, patient information and to target cybersecurity-related fraud by ensuring representations regarding information security controls are accurate through use of False Claims Act (FCA) authorities. Hospitals, nursing homes and other health care providers and organizations should be very careful in this area and their Boards and Officers cannot stay to "high level" and make sure they are comfortable with the cyber program and testing related to cyber controls.

The Initiative will utilize the FCA to target three categories of activities: (1) "providing deficient cybersecurity products or services," (2) "knowingly misrepresenting their cybersecurity practices or protocols," and (3) "knowingly violating obligations to monitor and report cybersecurity incidents and breaches."

An example of one of the many State Law developments: A new Connecticut statute, which became effective on October 1, 2021, provides legal protection from the assessment of punitive damages in cases that allege failure to protect personal and confidential information, provided that reasonable cybersecurity controls are in place.

The Connecticut legislation works to add safeguards and bolster statewide cybersecurity defenses to better protect businesses and consumers from cyber threats, by incentivizing businesses' voluntary adoption of nationally recognized cybersecurity best practices. Programs like the NIST framework or CIS Critical Security Controls have been proven to substantially reduce the risk of cyber-attacks, in some cases by up to 86%.

OCR Alert re: Legacy Systems. In October, OCR issued an alert, one of the many issued in 2021. Many health care providers are "stuck" with certain systems that are no longer supported by their vendor. Legacy systems' lack of vendor support makes them particularly vulnerable to cyberattacks. OCR was clearly concerned that organizations were not adequately considering the risks posed by legacy systems. Providers and their vendors must identify the potential risks and vulnerabilities to ePHI posed by those systems, the security measures the organization will take to reduce those potential risks

and vulnerabilities, and the proposed timeline, including (if possible) the legacy system's ultimate retirement date. OCR further noted the potential strategies to mitigate a legacy system's security risk:

- Upgrade to a supported version or system.
- Contract with the vendor or a third party for extended system support or migrate the system to a supported cloud-based solution.
- Remove or segregate the legacy system from the internet or from the organization's network.
- Maintain the legacy system, but strengthen existing controls or implement compensating controls.

If an organization elects to maintain a legacy system and strengthen its existing controls, or implement compensating controls, those controls should be tailored to the potential risks and vulnerabilities identified with the legacy system. Such controls may include:

- Enhancing system activity reviews and audit logging to detect unauthorized activity, with special attention paid to security configurations, authentication events, and access to ePHI.
- Restricting access to the legacy system to a reduced number of users.
- Strengthening authentication requirements and access controls.
- Restricting the legacy system from performing functions or operations that are not strictly necessary (e.g., by removing or disabling unnecessary software and services).
- Ensuring that the legacy system is backed-up – especially if strengthened or compensating controls impact prior backup solutions.
- Developing contingency plans that contemplate a higher likelihood of failure, especially if the legacy system is providing a critical service.
- Implementing aggressive firewall rules.
- Implementing supported anti-malware solutions.

NOVEMBER

AG Enforcement Activity: Remember, since HITECH state AGs now have enforcement authority. In November the New Jersey Attorney General and the Division of Consumer Affairs announced in November that a settlement had been reached with two New jersey printing firms – Command Marketing Innovations, LLC and Strategic Content Imaging

LLC – to resolve violations of HIPAA and the New Jersey Consumer Fraud Act. The violations were uncovered during an investigation into a data breach involving the PHI of 55,715 New Jersey residents.

- The breach was due to a printing error that saw the last page of one individual's benefit statement being attached to the benefit statement of another individual.

- The Division of Consumer Affairs determined the companies failed to ensure confidentiality of PHI, did not implement sufficient PHI safeguards and failed to review security measures following changes to procedures.

- A financial penalty of $130,000 was imposed on the two firms, and $65,000 was suspended and will not be payable provided the companies address all the security failures identified during the investigation.

DECEMBER

Planned parenthood: A hacker gained access to the personal information of approximately 400,000 patients of the Planned Parenthood in Los Angeles (PPLA) in October, and the breach was reported December 1. Information was compromised when someone gained access to the PPLA network between Oct. 9 and Oct. 17, installed malicious software and exfiltrated files. The PPLA discovered the issue on November 4.

- Notification letters to patients stated that files that contained names and one or more of the following: address, insurance information, date of birth, and clinical information, such as diagnosis, procedure, and/or prescription information.

- The ransomware was the same type of malware behind the Colonial Pipeline shutdown.

F. ONC Information Blocking Rule

Author: Melissa A. Soliz, Coppersmith Brockelman

April 5, 2021 was the applicability date for the start of compliance with the information blocking regulations.

The Office of the National Coordinator for Health Information Technology (ONC) published the ONC Cures Act Final Rule on May 1, 2020. The ONC Cures Act Final Rule consists of two components that implement certain provisions of the 21st Century Cures Act—(1) certification requirements for certified health information technology (CHIT) developers; and (2) implementing regulations for what constitutes impermissible information blocking by health care providers, health IT developers of CHIT, and health information networks/exchanges (HIN/HIE). This section addresses recent developments concerning the Information Blocking Rule (IBR) (collectively, 42 U.S.C. § 300jj-52 and 45 C.F.R. Part 171).

A practice may implicate the IBR if it is done by a health care provider, health IT developer of CHIT (including offerors of CHIT) or HIN/HIE (collectively, "actors") with the requisite level of intent, if it is likely to interfere with the access, exchange or use of electronic health information (EHI). A practice that implicates the IBR will not violate it if the practice is expressly required by law or falls into one or more eight regulatory exceptions (aka safe harbor protections):

- Preventing Harm
- Privacy
- Security
- Infeasibility
- Health IT Performance
- Content and Manner
- Fees
- Licensing

The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) will investigate and enforce compliance with the no Information Blocking Rule. If a practice violates the IBR, a health IT developer of CHIT or HIN/HIE may face up to $1 million in civil monetary penalties (CMPs) per violation. OIG will refer health care providers to the appropriate agency for disincentives.

Actors may limit their compliance with IBR to EHI that is represented by the United State Core Data for Interoperability version 1 (USCDI v.1) data elements, until October 6, 2022. After October 6, 2022, compliance with the full scope of EHI is required. *See* 45 C.F.R. § 171.103(b).

IBR regulatory enforcement is pending finalization of the OIG's CMP proposed rule for information blocking violations committed by health IT developers of CHIT and HIEs/HINs, and the HHS disincentives rule for health care providers, which HHS has not yet proposed.

To learn more about IBR visit the ONC Cures Act Final Rule webpage.

G. ONC Trusted Exchange Framework and Common Agreement (TEFCA)

Author: Melissa A. Soliz, Coppersmith Brockelman

On January 18, 2022, ONC released the Trusted Exchange Framework (TEF): Principals for Trusted Exchange (January 2022); Common Agreement for Nationwide Health Information Interoperability (v1) (January 2022); Qualified Health Information Network (QHIN) Technical Framework (QTF) (v1) (January 2022); and FHIR® Roadmap for TEFCA Exchange (January 2022). The TEF is a set of nonbinding principles intended to facilitate a national data sharing network. The Common Agreement is intended to establish the legal framework for national data exchange, and the QHIN Technical Framework is intended to establish the minimum functional and technical requirements.

Additional TEFCA resources are available on the Recognized Coordinating Entity's (Sequoia Project's) website: TEFCA and RCE Resources.

H. CMS Interoperability Rules

Author: Melissa A. Soliz, Coppersmith Brockelman

1. 2020 CMS Interoperability and Patient Access Final Rule

On May 1, 2020, the Centers for Medicare & Medicaid Services (CMS) published its Interoperability and Patient Access Final Rule. The final rule is an extension of the Trump Administration's MyHealthEData Initiative. The intent is to put patients in control of their health information and to leverage the efficiencies of new technologies, like application programming interfaces (APIs). The rule finalizes 7 different policies with the following applicability dates and some extended enforcement deadlines:

- Patient Access API (applicable January 1, 2021, with enforcement discretion until July 1, 2021)
- Provider Directory API (applicable January 1, 2021, with enforcement discretion until July 1, 2021)
- Payer-to-Payer (P2P) Data Exchange (applicable January 1, 2022, with enforcement discretion until new regulations are finalized)
- Improving the Dually Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges (applicable April 1, 2022)
- CMS Conditions of Participation (CoP), E-Notification Requirements (Admission, Discharge, and Transfer or ADT Alerts) (applicable May 1, 2021)
- Public Reporting about Information Blocking (applicable March 31, 2021)
- Digital Contact Information (public reporting of missing information started in December 2021 and is available here)

Interested parties can learn more on CMS's Health Informatics and Interoperability Group's webpage for Policies and Technology for Interoperability and Burden Reduction, including CMS's decision to delay P2P until future rule making is finalized. *See also* 86 Fed. Reg. 70412 (Dec. 10, 2021).

2. 2021 CMS Interoperability and Prior Authorization Final Rule

On January 15, 2021, CMS released a final rule that purported to significantly expand interoperability and prior authorization requirements for certain CMS-regulated payers. However, the final rule was not published in the Federal Register prior to the Biden Administration's regulatory freeze and thus was withdrawn. It is unclear whether CMS

will reopen the comment period for the proposed rule and/or move to finalize the expansion as proposed.

The proposed rule change would require impacted payers to create, maintain and/or expand the following five APIs:

- An expanded Patient Access API (applicable January 1, 2023);
- A Payer-to-Payer API, which is an enhanced and expanded version of the original Payer-to-Payer Data Exchange (applicable January 1, 2023);
- A new Provider Access API (applicable January 1, 2023);
- A new Document Requirement Lookup Service (DRLS) API (applicable January 1, 2023); and
- A new Prior Authorization Support (PAS) API (applicable January 1, 2023).

The proposed rule also would require impacted payers to include specific denial reasons for prior authorizations, impose shorter prior authorization timeframes, and require reporting of prior authorization metrics. For more details, please see the Coppersmith Brockelman Briefs: CMS Proposed Expansion of Interoperability Requirements for Impacted Payers.

I. Confidentiality of Substance Use Disorder Patient Records, 42 U.S.C. 290dd-2 and 42 CFR Part 2

Author: Melissa A. Soliz, Coppersmith Brockelman

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Section 3221 of the CARES Act changes how health care providers, health plans, and their business associates may share sensitive substance use disorder treatment records protected by 42 U.S.C. § 290dd-2 and its implementing regulations located at 42 C.F.R. Part 2 (collectively, "Part 2"). It also adopts HIPAA's breach notification, enforcement and penalty structure for Part 2 breaches and violations. It further directs the Secretary of the Department of Health and Human Services (HHS) to make changes to the Part 2 regulations to implement and enforce these statutory amendments by March 27, 2021. For more details please see the Coppersmith Brockelman Briefs: The CARES Act—Sweeping Changes to Substance Use Disorder Privacy Law (42 USC 290dd-2).

However, March 27, 2021 has come and gone. In the interim, SAMHSA finalized a 2019 proposed rule change to the Part 2 regulations on July 15, 2020. The 2020 final rule went into effect on August 14, 2020. More details about this rule change are available on HHS's webpage—Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule—and the Coppersmith Brockelman Briefs: Regulatory Changes to Substance Use Disorder Privacy Law.

SAMHSA issued a statement on April 9, 2021, that it is working with HHS Office for Civil Rights (OCR) to address the CARES Act amendments. As part of the 2021 regulatory agenda, HHS announced its intent to release in October of 2021 the regulatory changes that will implement the CARES Act amendments. However, those proposed rule changes were not released, and HHS has not announced a new release date. Until the new regulations are promulgated, the current Part 2 regulations remain in effect.

J. California Consumer Privacy Act and Other State Consumer Privacy Laws

Author: Scott Bennett, Coppersmith Brockelman

1. California Consumer Privacy Act (CCPA)

The California Consumer Privacy Act (CCPA) went into effect on January 1, 2020. It is currently the most comprehensive state privacy law in the nation. The CCPA regulates the collection, use, and disclosure of personal information of California residents. The Act includes requirements for the content of consumer-facing privacy policies. It also gives consumers several rights, including the right to obtain a copy of their personal information held by a business, the right to require a business to delete their personal information, and the right to opt-out of the sale of their information.

Amendments to the CCPA Statutes: Since the original version of the CCPA was approved by the California legislature in June of 2018, the statutes have been amended multiple times. There were amendments in 2020 that are particularly important for health care entities. AB-713, which was signed by the governor of California on September 25, 2020, made the following relevant changes:

- Created an exemption for HIPAA business associates. The original version of the CCPA had an exemption for PHI collected by a business associate, but no exemption for the business associate itself. There is now an exemption for "A business associate of a covered entity governed by the privacy, security, and data breach notification rules [of HIPAA], to the extent that the business associate maintains, uses, and discloses patient information in the same manner as medical information or protected health information . . . ." [Cal. Civil Code § 1798.146(a)(3)]

- Created an exemption for PHI that is deidentified in accordance with the HIPAA deidentification standards in 45 C.F.R. § 164.514. [Cal. Civil Code § 1798.146(a)(4)] The original version of the CCPA includes a definition of deidentification that is different from the HIPAA standards, creating uncertainty about whether PHI identified in accordance with the HIPAA standards was still subject to the CCPA.

- Clarified the exemption for information collected, used, or disclosed in clinical trials or other research. [Cal. Civil Code § 1798.146(a)(5)] The wording of the original exemption created confusion about what types of clinical trials qualified. As amended, the exemption applies to research conducted in accordance with any of the following: HIPAA, the Common Rule, good clinical practice guidelines issued by the

International Council for Harmonisation, or the FDA's regulations on the protection of human subjects.

CCPA Regulations: The California Attorney General has issued regulations under the CCPA. The final regulations went into effect on August 14, 2020. The regulations expand upon multiple provisions in the CCPA statutes, particularly those relating to the information that must be provided to consumers, and the mechanisms for consumers to exercise their rights under the CCPA. Since August of 2020, the state Attorney General has issued two sets of proposed modifications to the regulations, and accepted public comments on the proposals. As of January 15, 2021, the Attorney General had not made any changes to the regulations based on the proposals.

Voter Approval of CPRA: At the general election in November of 2020, California voters approved the California Privacy Rights Act (CPRA). The CPRA expands the privacy protections in the CCPA, and creates a new state agency: the California Privacy Protection Agency. The CPRA will go into effect on January 1, 2023.

The CPRA does **not** modify the CCPA's amended exemptions for HIPAA business associates, PHI deidentified in accordance with HIPAA standards, or research.

For health care entities, one important aspect of the CPRA that it will establish a new subcategory of personal information, called "sensitive personal information." Sensitive personal information (PI) includes genetic, biometric, and health information. The CPRA imposes specific requirements and restrictions relating to sensitive personal information, including:

- New consumer rights to restrict the processing of sensitive PI, and to opt-out of the use or disclosure of sensitive PI;

- A prohibition against using or disclosing sensitive PI for any purpose that is incompatible with the purpose disclosed to the consumer at the time of collection.

Amendments to CCPA Regulations: Amendments to the CCPA regulations went into effect on March 15, 2021. Those amendments made several relatively minor changes:

- The amendments expressly allow businesses to require any authorized agent to provide proof that the consumer gave the agent signed permission to submit an access or deletion request.

- The amendments also made changes relating to consumers opting-out of the sale of their personal information:

    - A business that collects personal information from consumers offline must have an offline method of informing consumers about the right to opt-out of the sale of their information. For example, a brick-and-mortar business could post an opt-out in the same location where it collects personal information.

- In addition to providing the required opt-out notice, any business that sells personal information may also use this optional opt-out icon:

The icon can be downloaded here.

- The opt-out process must be as easy for consumers as opting-in.

Consumer Privacy Interactive Tool. In July of 2021, the California Attorney General launched a consumer privacy interactive tool. In a press release, the Attorney General explained that the tool: "allows consumers to directly notify businesses that do not have a clear and easy-to-find 'Do Not Sell My Personal Information' link on their homepage. As part of the CCPA, businesses are required to have a link to their privacy policy on their website at the bottom of the homepage. Businesses that sell personal information about consumers must also include a 'Do Not Sell My Personal Information' link on their websites or mobile apps. The tool, available here, asks guided questions to walk consumers through the basic elements of the CCPA before generating a notification that the user can then email to the business. This email may trigger the 30-day period for the business to cure their violation of the law, which is a prerequisite to the Attorney General bringing an enforcement action." The interactive tool is available here.

2. Other State Consumer-Privacy Laws

As of May 23, 2021:

- 26 states have introduced consumer privacy bills
- In 12 states, the bills have died (AK, AZ, FL, KY, MN, MD, ND, OK, MS, UT, WA, WV)
- In another 10 states, the bills have been introduced in the legislature, but have not had any significant movement such as a committee hearing or vote (AL, IL, MA, NY, NC, PA, RI, SC, TX, VT)
- In 4 states, the bills have had significant movement, but not yet passed (CO, CT, NV, NJ)

So far, two states have joined California in enacting a comprehensive consumer privacy law: Virginia and Colorado.

On March 2, 2021, the government of Virginia signed the Virginia Consumer Data Protection Act (VCDPA). The law will go into effect on January 1, 2023.

Many of the provisions of the VCDPA are similar to those in California's CCPA. The VCDPA gives consumers a variety of rights in connection with their personal information, including rights of access, correction, deletion, data portability, and opting out of the sale or certain commercial uses of their information. The Virginia law requires business to limit their collection and use of personal information; to implement reasonable administrative, technical, and physical safeguards for data; to conduct data protection assessments; to enter into data processing agreements with individuals or entities that will process data on their behalf; and to have a privacy policy that explains the entity's privacy practices.

But there are a few key differences from the CCPA. First is that the VCDPA does **not** create a private right of action. It can be enforced only by the Virginia attorney general.

Second is that the VCDPA has broader and more complete exceptions for health care entities and health information. The VCDPA does **not** apply to any HIPAA covered entity or business associate. It also does not apply to any of the following types of health-related information:

- Protected health information under HIPAA;
- "Health records" regulated by Virginia law;
- Patient identifying information for purposes of the federal Part 2 law (42 U.S.C. § 290dd-2);
- Identifiable private information for purposes of the federal policy for the protection of human subjects under 45 C.F.R. Part 46; identifiable private information that is otherwise information collected as part of human subjects research pursuant to the good clinical practice guidelines issued by The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; the protection of human subjects under 21 C.F.R. Parts 6, 50, and 56, or personal data used or shared in research conducted in accordance with the requirements set forth in Virginia or federal law;
- Information and documents created for purposes of the federal Health Care Quality Improvement Act of 1986 (42 U.S.C. § 11101 et seq.);
- Patient safety work product for purposes of the federal Patient Safety and Quality Improvement Act (42 U.S.C. § 299b-21 et seq.);
- Information derived from any of the health care-related information listed in this subsection that is de-identified in accordance with the requirements for de-

identification pursuant to HIPAA;

- Information originating from, and intermingled to be indistinguishable with, or information treated in the same manner as information exempt under this subsection that is maintained by a covered entity or business associate as defined by HIPAA or a program or a qualified service organization as defined by 42 U.S.C. § 290dd-2;

- Information used only for public health activities and purposes as authorized by HIPAA.

On June 8, 2021, the Colorado legislature passed Senate Bill 190, the Colorado Privacy Act ("CPA"). The CPA will go into effect July 1, 2023. In the signing statement, Colorado's governor noted that the bill will likely require modifications to ensure that it will "strike the appropriate balance between consumer protection and not stifling innovation."

The CPA will apply to businesses that collect and store data on more than 100,000 individuals, or those earning revenue from the data of more than 25,000 consumers. It includes various data subject rights, a broad opt-out consent model with a universal opt-out mechanism, a right to cure, and attorney general rulemaking and enforcement.

The CPA will have extremely broad exemptions for healthcare entities and health information, including complete exemptions for HIPAA covered entities and business associates.

K. EU General Data Protection Regulation

Author: Scott Bennett, Coppersmith Brockelman

1. Standard Contractual Clauses

On June 4, 2021, the European Commission published the final version of new Standard Contractual Clauses (SCCs). Many entities that handle personal data that originated within the European Economic Area (EEA) will be required to implement these SCCs with customers, suppliers, and affiliates by December of 2022. The new SCCs are available here. Because of the *Schrems II* decision issued in July of 2020 by the Court of Justice of the European Union[73], companies that want to use SCCs as a basis for international data transfers must perform a Transfer Impact Assessment to determine if supplemental measures such as encryption are necessary.

2. COVID-19 Issues

In June of 2021, the EU approved the use of the EU Digital COVID Certificate. The purpose of the Certificate is to " to facilitate safe free movement inside the EU."74 The

[73] *Data Protection Commissioner v. Facebook Ireland Limited and Maximillian Schrems* (case C-311/18).
[74] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en

website of the EU explains that the Certificate "is not a pre-condition to free movement, which is a fundamental right in the EU."[75] Instead, the Certificate creates an exemption from travel-related testing or quarantine for people who are fully vaccinated, have recently recovered from COVID-19, or have a negative test shortly before travel. The Certificate is available to EU citizens and residents, and applies to travel between EU member states. The Certificate program was originally scheduled to stay in effect from July 1, 2021, until July 1, 2022, but the Europoean Commission has indicated that it could propose extending the program based on the state of the pandemic in 2022.

L. Federal Trade Commission Developments

Author: Scott Bennett, Coppersmith Brockelman

1. COVID-19

In April of 2021, the FTC released a report that summarizes the actions it took in the previous year to protect consumers from fraud and deceptive claims relating to the COVID-19 pandemic. As the FTC explained in a press release, the report notes that in the past year the agency:

- Filed 13 enforcement actions against companies that, among other things, failed to deliver personal protective equipment or made deceptive health or earnings claims, including its first action under the new COVID-19 Consumer Protection Act.

- Directed more than 350 companies to remove deceptive claims related to COVID-19 treatments, potential earnings, financial relief for small business and students, and warned companies that it is illegal to assist and facilitate deceptive COVID-19 calls.

- Prioritized privacy enforcement actions addressing the types of conduct that have been exacerbated in the transformation to digital work and schooling, including videoconferencing, ed-tech and health-tech.

- Collected and tracked more than 436,000 reports associated with COVID-19 between January 2020 and April 7, 2021, in which consumers reported $399 million in fraud losses.

- Issued more than 100 consumer and business alerts on COVID-related topics.

- Report

- Press release

[75] *Id.*

2. FTC Enforcement Actions

U.S. v. Nepute & Quickwork LLC (Case No. 4:21-cv-00437, E.D. Mo.). On April 15, 2021, the FTC charged a St. Louis-based chiropractor and his company with violating the FTC Act, and also the newly-enacted COVID-19 Consumer Protection Act. This is the first enforcement action under the COVID-19 Consumer Protection Act, which makes it illegal under the FTC Act to engage in deceptive marketing related to the treatment, cure, prevention, mitigation or diagnosis of COVID-19, among other things. In the case, FTC alleges that the defendants falsely marketed Vitamin D and zinc products as scientifically proven to prevent or treat COVID. The FTC is seeking monetary penalties and an injunction.

- Complaint (filed by the DOJ)
- Warning letter
- Press release

COVID-19 Consumer Protection Act of 2021, Pub. L. No. 116-260, 134 Stat. 1182, Division FF, Title XIV, § 1401

Statement of the Commission on Breaches by Health Apps and Other Connected Devices. On September 15, 2021, the FTC issued a statement to offer guidance on the scope of its Health Breach Notification Rule (16 C.F.R. Part 318). The FTC said it was issuing the statement in response to "the proliferation of apps and connected devices that capture sensitive health data." In the statement, the FTC acknowledges that it has not previously enforced the Health Breach Notification Rule, but that it intends to start doing so. The statement notes that "When a health app . . . discloses sensitive health information without users' authorization, this is a 'breach of security' under the Rule." In the statement, the FTC takes a very broad view of the types of health apps that are covered by the Rule – any app that draws information from multiple sources. That would include, for example, an app that collects information directly from users and from a fitness tracker (such as an Apple Watch or Fitbit), or an app that collects health information input directly by the user and also draws information from the calendar on the user's phone. The statement notes that the potential civil penalties for violations of the Rule are steep: Up to $43,792 per violation, per day.

Flo Health, Inc. In January of 2021, the FTC brought an enforcement action against the developer of a mobile app used by more than 100 million consumers to track menstrual periods and fertility. The FTC explained in a press release:

> In its complaint, the FTC alleges that Flo promised to keep users' health data private and only use it to provide the app's services to users. In fact, according to the complaint, Flo disclosed health data from millions of users of its Flo Period & Ovulation Tracker app to third parties that provided marketing and analytics services to the

app, including Facebook's analytics division, Google's analytics division, Google's Fabric service, AppsFlyer, and Flurry.
According to the complaint, Flo disclosed sensitive health information, such as the fact of a user's pregnancy, to third parties in the form of "app events," which is app data transferred to third parties for various reasons. In addition, Flo did not limit how third parties could use this health data.
Flo did not stop disclosing this sensitive data until its practices were revealed in a news article in February 2019, which prompted hundreds of complaints from the app's users.

The proposed settlement would require Flo Health to, among other things:

- Obtain an independent review of its privacy practices
- Get users' consent before disclosing their health information
- Notify previously affected users about the disclosures of their health information
- Instruct any third party that received users' health information to destroy it.

In connection with the settlement of the Flo Health matter, the FTC issued guidance to consumers about how to protect their privacy when using mobile health apps.

- FTC press release
- Agreement containing consent order
- Analysis of proposed consent order. Published in Federal Register. Describes both the allegations and the terms of the settlement.

M. Health Information Technology Developments

Author: Gerard Nussbaum, Zarach Associates

1. Artificial Intelligence (AI)

- **AI Spending**. AI spending continued to increase rapidly in 2021, with overall global AI spending of $51.5 billion in 2021; which Gartner predicts will increase by 21.3% to $62.5 billion in 2022.[76] The top major AI uses will include knowledge management, virtual assistants, autonomous vehicles, digital workplace, and crowdsourced data.[77]

[76] https://www.gartner.com/en/newsroom/press-releases/2021-11-22-gartner-forecasts-worldwide-artificial-intelligence-software-market-to-reach-62-billion-in-2022
[77] *Id*.

- **AI Regulation**. Globally, regulators are looking more closely at regulating AI, with a focus on limits on how AI may be used in recruiting/hiring, policing, and banking.[78] New York City has enacted a law relating to the use of AI in employment decisions,[79] building upon laws enacted in some states.[80] These efforts build upon existing limitations regarding use of biometric identification (including facial recognition, fingerprints) already enshrined in state laws.[81] The EEOC is also turning its focus to the use of AI in employment decisions.[82]

- **AI Patents**. South Africa became the first country to award a patent that listed AI as the inventor.[83] The United States Trademark and Patent Office refused to grant this patent as it does not recognize an AI algorithm as a valid inventor; the matter is currently under litigation.[84]

- **AI transcription**. In response to the government lockdown, much of life shifted to video teleconferences (e.g., Zoom, Webex). What many of us learned as that it is hard to pay attention during these online meetings, especially when they were sunrise to sunset, and often into the night. Online meetings also pose challenges to the hearing impaired, who often rely on visual cues to help them understand what is being discussed. AI-powered transcription—both real-time and retrospective—has greatly improved. Many organizations, or individuals within the organization, used AI-based transcription tools (such as Otter and Rewatch) to generate a reasonably accurate transcription of the recorded meetings.[85]

  In the past, the record of a meeting might be noted attendees took, minutes circulated. With these tools, "verbatim" transcripts are created. Attorneys may wish to understand when such tools are used, how the recordings are retained and archived, and whether anyone reviews the transcript to assure that the transcript is accurate. Attorneys may wish to offer guidance to their clients on the best ways to use these services to avoid maintaining records which do not fully reflect the decisions made or the discussions held. Also, the privacy issues, especially if patient or employee, or other private information is discussed, ae appropriate addressed.

- **Discovering New Drugs**. Pattern discovery is a key feature of many AI algorithms. AI often excels at not only finding a needle in a haystack, but in finding new haystacks to search inside massive datasets. Given the growing number of antibiotic resistant bacteria, there is a large need for new antibiotics. Using AI models,

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[78] Sam Schechner and Parmy Olson, Artificial Intelligence, Facial Recognition Face Curbs in New EU Proposal, The Wall Street Journal, 21 April 2021
[79] https://news.bloomberglaw.com/daily-labor-report/nyc-targets-artificial-intelligence-bias-in-hiring-under-new-law
[80] See *Artificial Intelligence Video Interview Act*, Illinois Public Act 101-0260 (2019)
[81] Illinois Biometric Information Privacy Act, 740 ILCS 14/1
[82] https://www.eeoc.gov/newsroom/eeoc-launches-initiative-artificial-intelligence-and-algorithmic-fairness
[83] *Recent Developments in Artificial Intelligence and IP Law: South Africa Grants World's First Patent for AI-Created Invention*, National Law Review, 4 January 2022, https://www.natlawreview.com/article/recent-developments-artificial-intelligence-and-ip-law-south-africa-grants-world-s
[84] *Id*.
[85] https://www.wired.com/story/ai-means-missing-the-meeting-is-no-longer-an-excuse/

researchers have uncovered thousands of potential antibiotic sources from peptides already existing in the human body.[86] What is astounding is the discovery of potentially thousands of peptides that may act as antibiotics. The research team the team used artificial intelligence to screen the entire human proteome—the set of all proteins in the human body to find molecules that might be the basis for effective antibiotics.[87] Of note is that the identified peptides did not give rise of antibiotic resistant bacteria strains.[88] While this is preliminary research, to does show the power of AI to help us look and find in unexpected places new drugs.

2. Acquisitions

Healthcare continues to be a major target for acquisitions. The rapid growth in the use of telehealth during the government lockdowns and the greater awareness of challenges in sharing data, which, while definitely not new, were highlighted by the pandemic, are among the factors that renewed focus on the healthcare market. Among notable transactions during 2021:

- **Cerner**. In December 2021, Oracle and Cerner entered an agreement for the acquisition by Oracle of Cerner in a deal worth approximately $28.3 billion (all cash tender offer at $95 per share).[89] The combined company may assist healthcare in moving data interoperability forward.[90] Though, in the short-term, the disruption of the acquisition and loss of staff from Cerner may adversely affect customers.

- **Athenahealth**. Athenahealth, which went private in 2018, was sold, in November 2021, to a consortium of Bain Capital and Hellman & Friedman for approximately 17 billion.[91] Earlier in 2021, Athenahealth settled, for $18.25 million, False Claims Act violations for illegal kickbacks –including inviting prospects and customers to all-expense-paid sporting and entertainment events – to generate sales of its EHR product-- and causing healthcare providers to submit false claims to the federal government related to incentive payments for adoption and "meaningful use" of Athena's EHR technology.[92]

- **Medline**. Blackstone, Carlyle and Hellman & Friedman paid about $30 million for the privately held medical supply company.

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[86] https://doi.org/10.1038/s41551-021-00801-1, https://www.nature.com/articles/s41551-021-00801-1#article-info
[87] https://www.nih.gov/news-events/nih-research-matters/searching-new-antibiotics-human-body
[88] https://bioengineeringcommunity.nature.com/posts/mining-for-encrypted-peptide-antibiotics-in-the-human-proteome
[89] https://www.oracle.com/news/announcement/oracle-buys-cerner-2021-12-20/
[90] https://www.wsj.com/articles/oracle-cerner-deal-could-help-healthcare-systems-share-data-11640084403?reflink=desktopwebshare_permalink
[91] https://www.wsj.com/articles/bain-h-f-near-deal-to-buy-athenahealth-for-about-17b-including-debt-sources-say-11637361200?reflink=desktopwebshare_permalink
[92] https://www.justice.gov/usao-ma/pr/athenahealth-agrees-pay-1825-million-resolve-allegations-it-paid-illegal-kickbacks

3. Privacy

- **DNA Privacy.** Florida passed the toughest criminal penalties for misuse of an individual's DNA.[93] The law makes it a misdemeanor to collect or retain another individual's DNA sample with the intent to perform DNA analysis without express consent and a felony to analyze, submit for analysis, or procure the analysis of another individual's DNA sample without consent.[94] There are exceptions for medical diagnosis and treatment, certain research, and criminal investigations and prosecution.[95] The law also proclaims that the genetic information of the person from whom it is extracted to be the "exclusive property" of that person to control (previously Florida Supreme Court holdings took the opposite position for samples voluntarily given to a third party).[96]

- **Melding human and machine.** Restoring the capacity to communicate has taken significant steps in recent years. In part, this research relies upon the body's retained knowledge for gross motor skills, such as reaching, grasping or moving a computer cursor, after paralysis.[97] Among the promising developments in this area are:

- **Returning Speech to Paralyzed Individuals**. UC San Francisco researchers have developed a "speech neuroprosthesis" that has enabled a man with severe paralysis to communicate in sentences, translating signals from his brain to the vocal tract directly into words that appear as text on a screen.[98] This is a significant improvement over the current approach of word spelling. The ability to directly decode full words from the brain activity of a paralyzed individual, who cannot speak, holds out the promise of tapping into the brain's natural speech machinery to restore communication.[99]

- **High speed brain to text handwriting**. Stanford researchers have developed a brain to computer interfaces that results in high speed typing for an individual whose hand was paralyzed from a spinal cord injury.[100] Remarkably, the individual achieved typing speeds of 90 characters per minute with 94.1% raw accuracy online, and greater than 99% accuracy offline with a general-purpose autocorrect. By comparison smartphone typing speeds are on the order of 115 characters per minute. The implications of this study may be more broadly applicable beyond typing tasks.

- **Elon Musk**. Elon Musk's neuroscience startup Neuralink Corp, seeks to start testing its technology that connects human brains and machines. The goal is to connect a neural lace, consisting of connections to thousands of neurons in the brain; thus more precisely read brain activity.[101] In addition to reading brain signals, the research

[9393] http://laws.flrules.org/2021/216
[94] https://www.natlawreview.com/article/florida-s-protecting-dna-privacy-act-goes-effect
[95] *Id*.
[96] https://lawreview.law.miami.edu/florida-protecting-dna-privacy-rights-didnt-protection/
[97] https://web.stanford.edu/~shenoy/GroupPublications/WillettEtAlNature2021.pdf
[98] https://www.nejm.org/doi/full/10.1056/NEJMoa2027540
[99] https://www.ucsf.edu/news/2021/07/420946/neuroprosthesis-restores-words-man-paralysis
[100] https://web.stanford.edu/~shenoy/GroupPublications/WillettEtAlNature2021.pdf
[101] https://www.biorxiv.org/content/10.1101/578542v1.full.pdf

includes direct brain simulation. Beyond clinical applications, such as helping individuals with disease or effects of stroke, Neuralink also is looking toward potential elective procedures not tied to disease states.[102]

- **FDA Guidance.** In May 2021, the FDA issued a guidance document, Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations.[103] This guidance provides addresses clinical and non-clinical testing considerations for implanted brain-computer interface (BCI) devices. The focus of the guidance is for patients who have suffered paralysis or amputation where brain-computer interface devices have the "potential to bring benefit to people with severe disabilities by increasing their ability to interact with their environment, and consequently, providing new independence in daily life."[104] The covered devices are "neuroprostheses that interface with the central or peripheral nervous system to restore lost motor and/or sensory capabilities in patients with paralysis or amputation."[105]

VIII. LABOR AND EMPLOYMENT

Authors: Jennifer L. Curry, Baker Donelson, Ajente Kamalanathan, Ogletree Deakins, and Gillian Murphy, Davis Wright Tremaine
(As of June 2021)

A. The Temporary 100% COBRA Subsidy In Effect Until September 30, 2021

The American Rescue Plan Act (ARPA) provides a 100 percent COBRA subsidy to eligible individuals from April 1, 2021, through September 30, 2021 (Assistance Period). Eligible individuals pay nothing, and employers receive a tax credit through quarterly payroll tax returns. There are no financial restrictions regarding eligibility.

Employers subject to COBRA must act soon to compile lists of eligible individuals and comply with notice requirements to inform those eligible of the right to the subsidy (by May 31, 2021) and later that the subsidy is coming to an end. In addition, employers must understand the interplay of COBRA tolling relief.

The U.S. Department of Labor (DOL) has issued model notices and Frequently Asked Questions (FAQs) regarding the COBRA subsidy (see https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/cobra/premium-subsidy) made available under the American Rescue Plan Act of 2021 (ARPA).

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[102] https://www.wsj.com/articles/elon-musks-neuralink-advances-brain-computer-interface-11563334987?reflink=desktopwebshare_permalink
[103] https://www.fda.gov/media/120362/download
[104] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/implanted-brain-computer-interface-bci-devices-patients-paralysis-or-amputation-non-clinical-testing
[105] *Id.*

1. Eligibility for COBRA subsidy

Any individual who is on COBRA continuation coverage during the Assistance Period because of an employee's involuntary termination of employment or reduction of hours for any reason (i.e., it does not have to be COVID-related) gets free COBRA during that time. Voluntary terminations of employment are not covered, and neither are other COBRA qualifying events (e.g., death or dependent aging out of coverage).

There are two additional situations giving individuals the chance to elect coverage where they could otherwise have been covered by COBRA during the Assistance Period because of the employee's involuntary termination of employment or reduction of hours:

- If the qualified beneficiary did not elect COBRA, the employer must give them a second chance to elect it now (this might have limited impact because of the tolling relief, but it does mean qualified beneficiaries who declined COBRA in, say, November or December 2019 could elect it now, even though they do not benefit from the tolling relief).

- If the qualified beneficiary elected COBRA but discontinued it, they can elect it again now.

These qualified beneficiaries must elect COBRA no earlier than April 1, 2021, and no later than 60 days after the employer provides the notice. The COBRA coverage is prospective (unless the individual elects it retroactively and pays for coverage, subject to tolling relief), and the COBRA coverage period will not extend beyond what would have been a qualified beneficiary's regular COBRA period.

Example: An employee was laid off and lost coverage May 31, 2020. The employee could elect and pay for COBRA retroactively, but that could be burdensome. The new law gives the employee the option to enroll from April 1, 2021, with a 100 percent subsidy. After the subsidy ends on September 30, 2021, the employee could continue to pay for coverage until November 30, 2021 (the end of the original COBRA 18-month period).

2. Early Termination of Subsidy

An individual will lose the subsidy (i.e., need to pay the full cost of COBRA) for months of coverage beginning on or after the earlier of:

- Eligibility for coverage under any other group health plan (GHP) (other than a plan consisting of only excepted benefits, a qualified small employer health reimbursement arrangement (QSEHRA) or flexible spending arrangement (FSA));

- Eligibility for Medicare; or

- End of the COBRA maximum coverage period applicable to the individual.

The individual must notify the plan administrator if he or she loses subsidy eligibility because of eligibility for coverage under a GHP or Medicare and may face a $250 penalty for failure to notify. The penalty can increase to 110 percent of the subsidy received if the failure to notify was fraudulent. There are penalty exceptions for reasonable cause.

3. Option to Allow Change in Medical Plan

Plan sponsors may also offer those who lose coverage because of the employee's involuntary termination of employment or reduction of hours the chance to enroll in an alternative medical plan option not later than 90 days after the date of the notice from the employer. The premium for the alternative coverage cannot exceed the premium for the coverage in which the individual was enrolled at the time of the COBRA qualifying event.

In addition, the alternative coverage must also be available to similarly situated active employees at the time the election is made, cannot provide only excepted benefits, and cannot be a QSEHRA or FSA. In effect, this allows the option of a new open enrollment period for those eligible for the subsidy.

4. Plan Administrators Must Amend COBRA Notices and Send by May 31

Plan administrators must amend their COBRA notices to explain subsidy availability and the option to enroll in alternative coverage (if applicable), and distribute that notice no later than May 31, 2021. Failure to meet the deadline is treated as a failure to meet COBRA notice deadlines. The DOL) issued model notices and Frequently Asked Questions (FAQs) regarding the COBRA subsidy (see COBRA Premium Subsidy guidance) made available under the American Rescue Plan Act of 2021 (ARPA).

In practice, to determine who should be sent the notice, employers need to go back to November 2019 (because the 18-month period for such individuals would end April 30, 2021, allowing one month of subsidized coverage).

The notice must also include:

- The forms necessary for establishing subsidy eligibility;
- Name, address and telephone number for the plan administrator or COBRA administrator;
- A description of the extended election period;
- A description of the qualified beneficiary's obligation to notify the plan administrator if he or she becomes eligible under another GHP or Medicare, and the penalties for failing to comply;

- A prominent explanation of the qualified beneficiary's right to a subsidized premium and any conditions on entitlement; and

- A description of the option to enroll in alternative coverage, if permitted by the employer.

5. It's Not Over Yet – Employers Also Required to Send Notice When Subsidy Expires

The plan administrator must also provide a clear and understandable notice explaining that the subsidy will end soon (including prominent identification of the expiry date), but that coverage may continue without the subsidy through COBRA or a GHP. However, the notice is not required if the individual loses subsidy eligibility because he or she became eligible for another GHP or Medicare.

This notice must be furnished no earlier than 45 days but no later than 15 days before the subsidy expires. DOL will provide model notices within 45 days of ARPA's enactment.

6. Employers Are Paid the Subsidy Through a Payroll Tax Credit

Employers decide who is eligible and, if self-insured or subject to federal COBRA, claim a tax credit against their quarterly payroll tax returns (insurance carriers receive the subsidy directly in other cases, and there are special rules for multiemployer plans). The credit is refundable if it exceeds payroll taxes and may even be advanced. If a qualified beneficiary inadvertently pays when eligible for a subsidy, the employer must refund the premium.

7. Summary of Action Items for Employers

- Identify all potential COBRA qualified beneficiaries who might benefit from the subsidy and send them a notice no later than May 31, 2021.

- Decide whether to offer alternative coverage.

- Amend COBRA notices. COBRA notices are already required to note that the individual Marketplace is an alternative, for which open enrollment is again available through May 15, 2021.

- Notify those receiving the subsidy when it will end.

B. Understanding OSHA's New Workplace Guidance

For employers still working to manage COVID-19 in the workplace, the Occupational Safety and Health Administration (OSHA) has provided some guidelines to help strengthen your policies and procedures. The guidance, *Protecting Workers: Guidance on*

Mitigating and Preventing the Spread of COVID-19 in the Workplace, reiterates that employers should implement a COVID-19 Prevention Program. If you are creating a COVID-19 prevention program, or beefing up the one you have, OSHA suggests you include these key elements:

Make A Plan: As OSHA notes, the most effective programs will engage workers and their representatives in both the development and implementation of the program. If you don't have one already, assign a workplace coordinator, who is responsible for COVID-19 issues.

Also, once you have a plan in place, train workers on COVID-19 policies and procedures, including an effective communication system (for both reporting and notifying workers of exposures). Further, provide guidance on screening and testing. Your plan also needs to protect workers from retaliation. To that end, do not distinguish between workers who are vaccinated and those who are not.

Of course, make sure you stay on top of recording and reporting COVID-19 infections and deaths. See our previous alert. Finally, don't forget to consider application of other OSHA standards.

Identify Exposure Points and Limit Spread: Identify where and how workers might be exposed to COVID-19 at work. Identify specific measures to limit the spread of COVID-19 in the workplace, such as isolating and sending home infected or potentially infected employees, physical distancing, physical barriers, face coverings or other personal protective equipment (PPE), improving ventilation, encouraging good hygiene, and routine cleaning and disinfecting. Note that these decisions should be in line with the hierarchy of controls: engineering controls, administrative policies, and PPE.

Be sure to instruct infected or potentially infected workers to stay home. Moreover, perform enhanced cleaning and disinfecting when infected or potentially infected persons have been in the facility. Also, consider additional protections for higher risk workers. If possible, make the vaccine available at no cost to employees.

In all decisions, minimize the negative impact of quarantine or isolation on workers. For instance, where possible, allow telework or work in an isolated area, or allow use of paid sick leave.

As a reminder, OSHA also suggests implementing the following key measures for limiting the spread of COVID-19 in the workplace:

1. Eliminate the hazard by separating and sending home infected or potentially infected people.

2. Implement physical distancing in all communal work areas.

3. Install barriers where physical distancing cannot be maintained.

4. Require the use of face coverings.

5. Improve ventilation, where possible.

6. Use other PPE when necessary.

7. Provide the supplies necessary for good hygiene.

8. Perform routine cleaning and disinfection.

C. The DOL's Proposed Joint Employer Rule Is Short On Details, But Not Short On Potential Impact For Employers

In a surprisingly fast move for the new Biden administration, the Department of Labor (DOL) sent a proposed rule to the White House on Wednesday, February 24 that may drastically change the joint employer analysis. The proposal's title, "Joint employer status under the Fair Labor Standards Act," is essentially the only thing known about the proposal at this time. In fact, even days later there is still nothing on the DOL's website about this new regulation. However, we would like to offer insights regarding speculated substance and the potential implications it will have on business and franchising.

The DOL's action shows the agency likely wants to quickly roll back the standards set during the Trump era. The Trump administration's rule took effect in March 2020 and narrowed circumstances by which businesses can be deemed joint employers. The rule adopted a four-factor balancing test to assess whether a purported employer: (1) hires or fires the employee; (2) supervises and controls the employee's work schedule or conditions of employment to a substantial degree; (3) determines the employee's rate and method of payment; and (4) maintains the employee's employment records. No single factor is dispositive in determining joint employer status, and the weight given to each factor varies depending on the circumstances. However, the rule was not without issues of its own and a federal Judge in New York ruled that the regulation was illegal, inconsistent with the FLSA, and "arbitrary and capricious." While the Second Circuit reversed the decision days after Biden was sworn in, the future landscape is still unclear.

It appears that the Trump administration's rule may be coming to a quick end. While there is little information about the substance of the proposal, the regulation will likely return to the Obama administration's broader rule that often saw corporations held accountable for the labor standards of their affiliates, franchisees, and subcontractors. While a new proposal is not unexpected given the vast differences between the Trump and Biden administrations, the swift moves likely mean businesses should prepare sooner rather than later for changes to their business models.

D. What ALL Employers Need to Know about the American Rescue Plan Act of 2021

President Biden signed the American Rescue Plan Act of 2021 (ARPA) into law on March 11, 2021. ARPA provides $1.9 trillion in federal stimulus, which includes, in addition to subsidies for employer-provided benefit plans, a handful of items directly affecting employers and their employees, most notably extension of tax credits under the Families First Coronavirus Response Act (FFCRA) and Payroll Protection Plan (PPP) loan eligibility.

What Is Included in ARPA Affecting Employers and Employees?

E. Extension of Tax Credits for Employers That Voluntarily Continue to Allow FFCRA Leave

Employers with 500 or fewer employees should decide now whether they wish to claim tax credits for employee leave taken in the next two quarters of 2021 for reasons related to COVID-19, and update their policies accordingly.

The FFCRA's requirement that employers with fewer than 500 employees to extend paid leave benefits to employees expired on December 31, 2020. However, the tax credits continued to be available for covered employers who provided paid leave to employees for FFCRA-qualifying reasons through the first quarter of 2021.

ARPA provides employers with the opportunity to obtain tax credit for offering an additional 10 days' worth of paid sick leave to eligible employees during the second and third quarters of 2021, i.e., April 1, 2021 through September 31, 2021. In addition, ARPA expands the coverage of the type of sick leave that qualifies for tax credit.

Under one prong of the FFCRA's Emergency Paid Sick Leave Act (EPSLA), an employee was entitled to paid leave only if he or she was "experiencing symptoms consistent with COVID-19 and seeking a diagnosis." ARPA modifies this eligibility category to eliminate the reference to COVID-19 symptoms (presumably in light of the fact that carriers of the virus may be asymptomatic), but imposes the condition that "such employee has been exposed to COVID-19 or the employee's employer has requested such test or diagnosis."

In addition to the other four qualifying reasons for taking paid sick leave under the EPSLA, ARPA makes the tax credit available "if the employee is [taking paid leave in connection with] obtaining immunization related to COVID-19 or recovering from any injury, disability, illness or condition related to such immunization."

The tax credit for leave in connection with an individual's own health condition (including vaccine-related leave) remains equal to the employee's regular rate of pay, up to a maximum of $511 per day, and the tax credit for other forms of sick leave remains capped at two-thirds the regular rate of pay, up to $200 per day.

ARPA also provides tax credit for up to an additional 12 weeks of partially paid leave under the FFCRA's Emergency Family and Medical Leave Expansion Act (EFMLEA), with a significant expansion of qualifying reasons. Under the FFCRA, EFMLEA leave was available only in connection with an employee's inability to work or telework due to a COVID-19-related closure of a son or daughter's school or place of care. ARPA expands the list of qualifying reasons so that they are coextensive with the EPSLA.

What's more, ARPA eliminates the FFCRA's initial two-week period of unpaid EFMLEA leave (but keeps the maximum tax credit equal to two-thirds the employee's regular rate of pay—regardless of qualifying condition—up to a maximum of $200 per day). Accordingly, the maximum amount of tax credit available to an employer under this provision of ARPA has been increased from $10,000 (10 weeks of leave, with a $200-per-day cap) to $12,000.

ARPA prevents an employer from cherry-picking which of the qualifying reasons under the FFCRA it wishes to recognize, or to which employees it wishes to extend them, and takes an all-or-nothing approach to the leave entitlement. Specifically, "[i]f an employer fails to comply with any requirement" of the EPSLA or EFMLEA, "amounts paid by such employer with respect to such paid sick [or family] time shall not be taken into account as qualified sick [or family] leave wages." Moreover, no credit is available if an employer "discriminates in favor of highly compensated employees … full time employees, or employees on the basis of employment tenure with such employer."

While extension of ARPA tax creditable leaves is voluntary, several states impose paid leave requirements on employers in connection with circumstances related to COVID-19. New York, for example, requires certain employers to provide up to 14 days of paid leave to employees under an order of quarantine, and up to four hours of paid leave to employees so that they can get vaccinated. ARPA provides these employers with an opportunity to offset some of those costs, provided they comply with the other expanded provisions of the FFCRA.

1. Extension of PPP Loans and Other Benefits for Small Businesses

ARPA adds $7.25 billion to the popular Paycheck Protection Program (PPP) and expands eligibility to internet-only news publishers (500 employees or fewer), some tax-exempt groups (labor organizations, social and recreational clubs, fraternal benefit societies and religious educational groups) with no more than 300 employees and which meet specific limitations on lobbying activities, and many larger nonprofits (e.g., 501(c)(3) organizations) with no more than 500 employees.

The initial deadline to apply for PPP loans was March 31, 2021. However, President Biden signed a bill that extended the deadline to May 31, 2021.

ARPA establishes other notable benefits aimed at assisting small businesses as well. These include, for example, the Restaurant Revitalization Fund—a $28.6 billion fund that provides grants to eligible entities for pandemic-related revenue loss. (See our Restaurant

Revitalization Fund FAQs.) ARPA also sets aside substantial sums for other small business loans, to support vaccination efforts, school re-openings, health insurance and other similar endeavors responsive to the pandemic and its far-reaching consequences.

2. Extension of Unemployment Benefits for Certain Individuals

ARPA extends unemployment benefits in three key ways:

(1) ARPA adds $300 per week for individuals collecting any form of unemployment compensation benefits (including, *inter alia*, traditional unemployment compensation and PEUC and PUA benefits described below) through September 6, 2021. This $300 addition extends a benefit previously scheduled to expire on March 14, 2021, under the Continued Assistance for Unemployed Workers Act of 2020.

(2) Pandemic Emergency Unemployment Compensation (PEUC) benefits originally extended under the CARES Act—which may become available once an individual exhausts traditional unemployment compensation—are extended until September 6, 2021.

(3) Pandemic Unemployment Assistance (PUA) benefits, which were also part of the CARES Act and which may become available once an individual exhausts extended unemployment compensation benefits (or, if the state in which the individual lives has not triggered "on" to extended benefits, exhausts traditional unemployment compensation and PEUC benefits), are extended to September 6, 2021. PUA also applies to individuals who are self-employed or who otherwise are seeking employment but are not eligible for traditional unemployment compensation benefits, and benefits for those individuals are likewise extended to September 6, 2021.

In addition to extending unemployment compensation benefits (in various forms), ARPA permits an individual or each spouse to exclude $10,200 in unemployment benefits from federal income tax, as long as the household income is under $150,000. This means that if ***both*** spouses receive unemployment compensation and their total household income is under $150,000, up to $20,400 may be excluded from federal income tax.

F. What Is Not Included in ARPA?

The ARPA, as finally adopted, did not include certain controversial proposals that would have had a significant impact on employers, including:

- **No Increase to Federal Minimum Wage:** The bill did not ultimately adopt President Biden's push to bump up the federal minimum wage from $7.25 per hour (the hourly rate in place since 2009) to $15 per hour. Of course, many states and local jurisdictions have minimum wage requirements that already are far in excess of the federal minimum wage.

- **No Elimination of Tip Credit:** A provision to phase out the existing federal tip credit **allowance** was eliminated from the final Act. Currently, many states do not allow a tip credit toward state minimum wage obligation for tipped employees, but for those states that permit a tip credit, ARPA does not alter the status quo. Employers in the hospitality industry may breathe a sigh of relief that this was ultimately removed from the final bill.

- **No Paid Leave Entitlement:** ARPA does not expand obligations for employers in the private sector to provide employees with paid leave. Instead, as described above, ARPA **incentivizes**—but does not require—employers to provide additional paid leave under the FFCRA through September 2021.

G. NLRB Knocks Down Employer's Mandatory Arbitration

Employers received updated guidance from the National Labor Relations Board (NLRB) regarding mandatory arbitration agreements in the Board's most recent decision addressing this issue, *Alexandria Care Center, LLC*, 31-CA-140383; 369 NLRB (June 2, 2020).

In *Alexandria Care Center, LLC*, the Administrative Law Judge held it was unlawful for Alexandria Care Center, LLC's Employment Dispute Resolution Program ("EDR Program") to require employees not covered by a collective-bargaining agreement to be subject to arbitration for employment-related disputes. The EDR Program contained a savings clause that provided that the program did "not constitute a waiver of your rights under the National Labor Relations Act." The Administrative Law Judge originally found that employees would read the EDR Program to interfere with their rights to file unfair labor practice charges. However, the National Labor Relations Board ("the Board") reversed the Administrative Law Judge's decision and held that the savings clause would be interpreted by an employee to mean that he or she is able to file an unfair labor practice charge.

H. Castro v. Yale University: Employees Can Sue For Sex Discrimination Under Title IX

In March 2020, six female physicians filed suit against Yale University, Yale New Haven Hospital, Inc., and an individual defendant, alleging that they were subject to sexual harassment by their supervisor.

Defendants' filed respective Motions to Dismiss. Yale New Haven Hospital, Inc. ("YNHH") alleged amongst other issues, that Title IX did not apply because it is not an entity principally engaged in the business of education and that Title IX did not provide a private remedy for employment discrimination based on sex.

The Court analyzed whether YNHH was subject to Title IX, and determined that because the teaching hospital received federal funding for its residency program, it would be

subject to the requirements of Title IX.

The Court further ruled that employees of education institutions may bring suit for sex-based discrimination under Title IX, rejecting Yale University and YNNH claim that Title IX does not provide a private right of action for employment discrimination based on sex. While the Court acknowledged that the Supreme Court had not yet directly decided the issue, it ruled that it "construes Title IX with the breadth intended by Congress and recognized by the Supreme Court, concluding that employees of educational programs may bring suit against their federally-funded employers for sex-based discrimination..."

The Court therefore denied Yale University and YNHH's respective Motion to Dismiss on these claims and others.

IX. LIFE SCIENCES AND CLINICAL RESEARCH

(Updated January 2022)

A. Research Integrity and Misconduct

Author: Kate Gallin Heffernan, Epstein, Becker, Green

1. ORI Leadership

With respect to the regulation of research misconduct in the United States, the Office of Research Integrity (ORI), responsible for the enforcement of integrity in the context of research supported by Public Health Service funds, has attempted to rebuild its leadership in recent years. The leadership at ORI has come under scrutiny, with reports of internal turmoil leading to the departure of key staff and leadership turnover.

In March 2020, the Office of the Assistant Secretary for Health (OASH) appointed Elisabeth Handley permanent Director of ORI, following her service as interim Director since August 2019. Dr. Wanda Jones, who had served as interim Director in between Kathy Partin and Ms. Handley, was also appointed associate director of research and scientific integrity. In June, 2021, Ms. Handley was appointed the Principal Deputy Assistant Secretary for Health ("PDASH") within the Office of the Assistant Secretary for Health ("OASH"). Dr. Jones has since been serving as Acting Director of ORI.

2. Misconduct Findings by ORI

ORI reported three cases during 2021 in which administrative actions were imposed by the government due to findings of research misconduct. Two of these resulted in Voluntary Exclusion Agreements; one resulted in a Voluntary Settlement Agreement.

3. Request for Information Regarding Activities that Foster Research Integrity

On October 19, 2020, ORI published a request for information (RFI) regarding activities that "foster research integrity and promote the responsible conduct of research under 42 CFR Part 93." The stated purpose of this RFI is to assist ORI in conducting outreach and developing educational resources for the grantee community. Responses were due on December 18, 2020. There have not been any updates related to this RFI in 2021.

On June 28, 2021, the White House Office of Science and Technology Policy ("OSTP") published a notice of request for information "to help improve the effectiveness of Federal scientific integrity policies to enhance public trust in science," in response to the January 27, 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking (Memorandum). Responses were due on July 28, 2021. The primary goal of this RFI is to evaluate "the effectiveness of policies developed since the issuance of the Presidential Memorandum on scientific integrity issued on March 9, 2009 in preventing improper political interference in the conduct of scientific research and the collection of data; preventing the suppression or distortion of findings, data, information, conclusions, or technical results; supporting scientists and researchers of all genders, races, ethnicities, and backgrounds; and advancing the equitable delivery of the Federal Government's programs."

4. Notice of Information about Scope of Research Misconduct in Institutional Proceedings

On May 27, 2021, ORI issued an informal notice on its website related to grantee institutions' responsibility to define correctly the scope of any research misconduct proceeding in order to meet their obligations to pursue diligently all significant leads relevant to an investigation pursuant to 42 C.F.R. § 93.310(h). ORI directed the regulated community to specific case studies and clarifying guidance it developed to highlight institutional responsibilities related to defining the appropriate scope of any misconduct proceeding.

B. Conflicts of Interest and Undue Foreign Influence in Research

Authors: Kate Gallin Heffernan and Marylana Saadeh Helou, Epstein, Becker, Green

2021 saw continued focus by the NIH, DOJ, FBI and other federal agencies on combatting the threat of foreign undue influence to U.S. research efforts. As a reminder, this focus intensified after the Trump administration began its 'China Initiative' in 2018, an initiative aimed at (i) identifying and prosecuting those engaged in trade secret theft, hacking, and economic espionage, and (ii) developing an enforcement strategy concerning non-traditional collectors (e.g., researchers in labs, universities) that are being coopted into transferring technology contrary to U.S. interests. In March 2018, the NIH issued a notice reminding the researcher community that *all* financial interests received by a U.S. investigator from a foreign institution of higher education or foreign

government must be disclosed to NIH in accordance with the Public Health Service financial conflicts of interest regulations, 42 CFR Part 50, Subpart F, which require disclosure of investigator significant financial conflicts of interest. This was followed by a statement by Francis Collins, Director of NIH, in August 2018 on the NIH's commitment to protecting U.S. research from undue foreign influence, during which time the NIH-grantee community also began to receive "Dear Colleague" letters alerting the regulated community to the NIH's concerns and anticipating follow-up inquiries from the Office of Extramural Research related to specific researchers or submissions. The ACD Working Group on Foreign Influences on Research Integrity was formed, issuing its first report in December 2018. On July 10, 2019, the NIH issued NOT-OD-19-114 to remind grantees of the obligation "to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap." The U.S. Senate Permanent Subcommittee on Investigations subsequently issued a report in November 2019 exploring the specific threats to U.S. research posed by China's talent recruitment programs.

The specific concerns related to undue foreign influence on U.S. researchers and the potential theft of U.S. intellectual property have revitalized institutions' focus on how their existing conflicts of interest and policies and disclosure processes address the topic of foreign interests. Highlighted legislative developments, agency-specific updates, and cases of note are discussed below. In response to the government's enforcement efforts, the regulated community continues to be engaged in the development of best practices related to its education of the researcher community and implementation of compliance programs and processes to identify potential instances of undue foreign influence in a timely manner.

- *Trump Administration Publishes "Presidential Memorandum on United States Government-Supported Research and Development National Security Policy"*

On January 14, 2021, the outgoing Trump administration published the National Security Presidential Memorandum (NSPM)-33, which outlined the steps the U.S. can take to protect intellectual capital, discourage research misappropriation, and ensure responsible management of taxpayer dollars while maintaining an open environment to foster research discoveries and innovation. These steps include:

  - Prohibiting federal personnel from participating in foreign government-sponsored talent recruitment programs, directing departments and agencies to control access to and utilization of federal government research facilities, and requiring that federal agency personnel who allocate R&D funding receive training on research security.

  - Requiring research institutions to establish and operate research security programs.

  - Directing federal departments and agencies to share information about individuals whose activities demonstrate an intent to threaten research security and integrity.

- Directing the Secretary of State and the Secretary of Homeland Security to ensure that vetting processes for foreign students and researchers reflect the changing nature of the risks to the U.S. research enterprise while also promoting and protecting international R&D collaboration with foreign allies and partners.

- Directing departments and agencies to standardize disclosure processes, definitions, and forms related to research security across funding agencies to the maximum extent practicable.

- Directing departments and agencies to establish policies regarding the use of digital persistent identifiers (DPIs) for researchers supported by or working on federal research. DPIs can streamline grant application processes and enhance research rigor by linking researchers to their awards, publications, and other research outputs.

The Biden administration's endorsement of NSPM-33 was confirmed by an OSTP official at the March 2021 meeting of the National Science, Technology, and Security Roundtable, an advisory body created by Congress to provide a neutral venue where individuals from the national intelligence and law enforcement communities meet with representatives from industry and the academic research community to discuss current threats, benefits, and potential risks. The OSTP official stressed that the recommendations are not mandatory and welcomed feedback on aspects of the recommendations where the implementation cost for institutions could outweigh the benefit.

- *The National Science and Technology Council Releases Recommendations for Strengthening Research Security*

On January 19, 2021, the Subcommittee on Research Security, in coordination with the National Security Council (NSTC) staff, and the Joint Committee on the Research Environment (JCORE) published a report titled, "Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise." The report offered recommendations for research organizations (e.g., universities, private companies, independent research institutes) to better protect the security and integrity of America's research enterprise and focused on five high-level objectives:

- Demonstrating organizational leadership and oversight

- Establishing an expectation of openness and transparency

- Providing and sharing training, support, and information

- Ensuring effective mechanisms for compliance with organizational policies

- Managing potential risks associated with collaborations and data

- *NIH Announces Changes to Biographical Sketch and Other Support Format Page*

On March 12, 2021, NIH issued Guide Notice NOT-OD-21-073 titled "Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021" and updated its related Frequently Asked Questions (FAQs). NIH explained that the purpose of the changes is to "to support the need for applicants and recipients to provide full transparency and disclosure of all research activities, foreign and domestic." The changes to the forms include:

- ***Requiring researchers to attest to the accuracy and completion of the other support submission***. The new other support form includes a signature block for all principal investigators and other senior/key personnel and requires these individuals to electronically sign the form, prior to its submission to NIH and to certify that the information is accurate and complete.

- ***Submission of supporting documentation for foreign appointments and/or employment with a foreign institution***. Other support submissions that include foreign activities and resources must include copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation (note that if these agreements are not in English, the recipients must provide translated copies).

- ***Clarification of which consulting agreements qualify as other support***. Principal investigators and other senior/key personnel that are conducting research *as part of the consulting activities*, must disclose such activities on the updated other support form (i.e., non-research consulting activities are not considered other support).

- ***Immediate notification of undisclosed other support***. If a recipient organization discovers that a principal investigator or a senior/key personnel on an active NIH grant failed to disclose other support information outside of the Just-in-Time (JIT) or the Research Performance Progress Reports (RPPR), the recipient must submit an updated other support form to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

- ***Inclusion of scientific appointments in biosketch***. Recipients must include titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

NIH expects applicants and recipients to use the updated biosketch and other support forms for applications, JIT reports, and RPPRs as of May 25, 2021. However, NIH will *require* the use of the updated forms on and after January 25, 2022. That said, applicants

and recipients remain responsible for disclosing all research endeavors regardless of the version of the forms used. Therefore, if applicants and recipients choose not to use the updated format pages before they are required, applicants and recipients must still capture all the necessary information. The failure to use the appropriate formats on or after January 25, 2022 may cause NIH to withdraw applications from or delay consideration of funding.

- *Senate Passes "Endless Frontier Act," Including Ban on U.S. Researchers' Participation in Foreign Talent Programs*

On June 8, 2021, the U.S. Senate voted to pass S. 1260, the "Endless Frontier Act" (EFA), a bipartisan legislation which, among other things, would create a new Directorate for Technology and Innovation at the National Science Foundation (NSF) and authorize a budget increase for the NSF. Although the bill focuses mostly on changes to the NSF, Section 2303 "Foreign Government Talent Recruitment Program Prohibition" requires OSTP to "publish and widely distribute a uniform set of guidelines for Federal science agencies regarding foreign government talent recruitment programs." OSTP's new guidelines under the bill would "prohibit awards from being made for any proposal in which the principal investigator, any individual listed on the application for the award with direct involvement in the proposal, or co-principal investigator is participating in a foreign government talent recruitment program of the People's Republic of China, the Democratic People's Republic of Korea, the Russian Federation, or the Islamic Republic of Iran; and … to the extent practicable, require institutions receiving funding to prohibit awards from being used by any individuals participating in a foreign government talent recruitment program" operated by those four countries.

- *EFA is Expanded and Renamed "United States Innovation and Competition Act;" House and Senate Go to Conference on USICA*

After passing the Senate, the EFA was expanded to include various proposals addressing U.S. competitiveness and China and became known as the "United States Innovation and Competition Act" (USICA). On June 28, 2021, the House of Representatives passed its own pieces of legislation that address investing in research and infrastructure to spur scientific innovation (including H.R.2225 - National Science Foundation for the Future Act, which requires that "each covered individual listed on [an] application for a [NSF] research and development award certify that they are not an active participant of a malign foreign talent recruitment program from a foreign country of concern and will not be a participant in such a program for the duration of the award"). On November 17, 2021, House Speaker Nancy Pelosi and Senate Majority Leader Chuck Schumer announced that the House and Senate agreed to immediately begin a bipartisan process of reconciling the two chambers' legislative proposals to deliver a final piece of legislation to President Biden that would "bolster American manufacturing, fix [the] supply chains, and invest in the next generation of cutting-edge technology research." The announcement recognized that "[w]hile there are many areas of agreement on these legislative proposals between the two chambers, there are still a number of important unresolved issues."

As of the writing of this AHLA update, no such legislation has been issued.

- *NIH Publishes Cumulative Summary of Findings Regarding Foreign Interference in NIH Funding and Grant Making Processes*

On July 30, 2021, Dr. Michael Lauer, NIH's Deputy Director for Extramural Research published a summary of findings from 2016 to 2021 regarding foreign interference in NIH funding and grant making processes. Dr. Lauer reported that as of early July 2021, the NIH had contacted 93 institutions about 214 scientists (over 90% of these cases involved activities based in China). Of these scientists, 147 had failed to disclose foreign grant support and 119 had failed to disclose participation in foreign talents programs. The NIH was made aware of these concerns either through self-disclosures from institutions, referrals from law enforcement, or via other routes such as anonymous tips and NIH staff noticing discrepancies in publications and grants records. Thus far, institutions have executed or enabled employee separations (e.g., terminations, resignations, or early retirements) in 79 cases and removed scientists from NIH grants without employment actions in 39 other cases (i.e., in total, institutions have removed 118 scientists from NIH-funding support). Dr. Lauer reiterated that individuals violating laws and policies represent a small proportion of scientists working at U.S. institutions and emphasized the NIH's commitment to ensure that its responses to this issue do not create a hostile environment for colleagues who are dedicated to advancing human health.

- *GAO Reiterates Need for Agency Actions to Address Foreign Influence*

On October 5, 2021, Candice Wright, the Director of Science, Technology Assessment, and Analytics at the Government Accountability Office (GAO) testified before the U.S. House of Representatives Committee on Science, Space, and Technology and the Subcommittees on Investigations and Oversight and Research and Technology about agency actions needed to address the growing concern of foreign influence in federally funded research. Ms. Wright's testimony was based on a GAO report issued in December 2020 (GAO-21-130) that identified gaps in select U.S. agencies[106] and institutional policies on foreign influence in research and made recommendations on how funding agencies should address this issue. In addition to discussing the opportunities identified by stakeholders to improve such agencies' responses to foreign influence (e.g., harmonizing and standardizing disclosure requirements across agencies), Ms. Wright reiterated GAO's recommendation that the agencies address *non-financial* conflicts of interest in their COI policies and develop written procedures for addressing cases of failure to disclose required information. Ms. Wright noted that although the agencies have recently taken steps to improve their conflict of interest policies, they have yet to fully implement GAO's recommendations, a step that could improve their own ability as well as "enhance universities' capacity to identify and mitigate conflicts and ensure consistency in enforcement."

[106] The Department of Defense (DOD), DOE, the National Aeronautics and Space Administration (NASA), NIH, and NSF.

- *OSTP Issues Agency Guidance to Implement NSPM-33*

On August 10, 2021, OSTP announced that it was in the process of creating guidance for federal agencies to implement NSPM-33 "effectively, rigorously, and uniformly … in a way that protects the nation's interests in both security and openness." In an OSTP blog post, Dr. Eric Lander, OSTP's Director and the President Biden's Science Advisor, stated that within 90 days, the office would issue a "clear and effective implementation guidance for NSPM-33" and that the guidance would address three major areas:

  - "Disclosure Policy — ensuring that federally-funded researchers provide their funding agencies and research organizations with appropriate information concerning external involvements that may bear on potential conflicts of interest and commitment;

  - Oversight and Enforcement — ensuring that federal agencies have clear and appropriate policies concerning consequences for violations of disclosure requirements and interagency sharing of information about such violations; and,

  - Research Security Programs — ensuring that research organizations that receive substantial federal R&D funding (greater than $50 million annually) maintain appropriate research security programs."

Dr. Lander stressed the importance of ensuring that policies or processes do not fuel xenophobia or prejudice and stated that "it should never be acceptable to target scientists for investigation based on their race or ethnicity." In an interview earlier this year, Dr. Lander acknowledged the difficulty researchers are facing today in trying to comply with the various disclosure requirements across agencies and suggested that researchers would be happy to comply with a simpler system of disclosure (e.g., an electronic CV that contains their grants, papers, collaborations, and stock holdings, etc. and is updated on a quarterly basis).

On September 30, 2021, AAMC along with multiple other higher education associations sent a letter to OSTP in response to Dr. Lander's blog post. In the letter, the associations stressed the need to safeguard the integrity of federally funded research while also maintaining meaningful international scientific collaboration. The letter provided several recommendations for OSTP, including:

  - Building on existing policies created by institutions to address research security

  - Recognizing that the vast majority of university research is open and unrestricted and should not be subject to research standards from the commercial sector

  - Incorporating the use of pilot programs and continued community engagement as any new policies are implemented

On January 4, 2022, OSTP issued its long-awaited guidance. The memorandum included

general guidance that agencies should apply across their implementation efforts and included more detailed guidance in five key areas addressed in NSPM-33:

- Disclosure Requirements and Standardization
- Digital Persistent Identifiers
- Consequences for Violation of Disclosure Requirements
- Information Sharing
- Research Security Programs

In a foreword by Dr. Lander published with the guidance, he directed federal research agencies to work together within the next 120 days to develop model award proposal disclosure forms and instructions that can be used (and adapted where required) by any federal research funding agency. Dr. Lander reiterated the goal for the government to "clearly describe what it needs to know and for researchers to be able to report the same information in the same way to the greatest extent possible, regardless of which funding agency they're applying to." Next steps also include efforts by the Subcommittee on Research Security to "develop common standards for research security program requirements for use by Federal agencies, as well as a standard and centralized research security program certification process for use by research organizations."

- *Enforcement Actions, Convictions, and Dismissals of Note*

    - *MIT Professor, Gang Chen, Arrested and Charged with Grant Fraud (January 14, 2021)*

    Gang Chen, a professor and researcher at the Massachusetts Institute of Technology (MIT) where he serves as Director of the MIT Pappalardo Micro/Nano Engineering Laboratory and Director of the Solid-State Solar Thermal Energy Conversion Center, was arrested and criminally charged with wire fraud, failing to file a foreign bank account report (FBAR), and making a false statement in a tax return. Since approximately 2013, Chen's research at MIT has been funded by more than $19 million in grants awarded by various U.S. federal agencies. Chen allegedly failed to disclose contracts, appointments, and awards from various entities in China to the U.S. Department of Energy (DOE) in connection with his application for, and receipt of, at least one federal research grant. Within days of his arrest, an open letter in support of Chen was circulated and signed by more than 100 faculty colleagues who characterized the case as "a deep misunderstanding of how research is conducted or funded at a place like MIT."

    - *Former University of Florida Researcher Indicted for Scheme to Defraud National Institutes of Health and University of Florida (February 3, 2021)*

A former University of Florida (UF) professor and researcher, Lin Yang, was indicted for fraudulently obtaining $1.75 million in federal grant money from the NIH by concealing support he received from the Chinese government and a company that he founded in China to profit from that research. Yang was charged with six counts of wire fraud and four counts of making false statements to an agency of the United States. According to the indictment, Yang "intentionally deceived both his employer and the federal government in order to obtain more than a million dollars in research funding." Allegedly, Yang, on multiple occasions, submitted disclosures to NIH containing false statements and material omissions concerning his affiliations and research endeavors with a foreign government and company. The indictment also alleges that Yang provided UF with a written response that falsely stated he had no affiliation with any business, entity, or university in China.

- *Mathematics Professor and University Researcher Indicted for Grant Fraud (April 21, 2021)*

A federal grand jury in Illinois returned an indictment charging a mathematics professor and researcher at Southern Illinois University – Carbondale, Mingqing Xiao, with two counts of wire fraud and one count of making a false statement. According to court documents, Xiao fraudulently obtained $151,099 in federal grant money from the NSF by concealing support he was receiving from the Chinese government and a Chinese university.

- *Researcher Song Guo Zheng Sentenced to Prison for Lying on Grant Applications to Develop Scientific Expertise for China (May 14, 2021)*

Song Guo Zheng, a former rheumatology professor and researcher at the Ohio State University, was sentenced to 37 months in prison for making false statements to federal authorities as part of an immunology research fraud scheme. As part of his sentence, Zheng was also ordered to pay more than $3.4 million in restitution to the NIH and approximately $413,000 to the Ohio State University. Zheng was charged with using of NIH funds to develop China's expertise in rheumatology and immunology and was arrested while attempting to depart the United States to China with proprietary research information. According to his plea, Zheng caused materially false and misleading statements on NIH grant applications, seeking to hide his participation in Chinese Talent Plans and his affiliation and collaboration with a Chinese university controlled by the Chinese government.

- *DOJ Voluntarily Dismisses Six foreign Influence-Related Cases (July, 2021)*

The DOJ filed motions to dismiss the prosecutions of five foreign researchers who were arrested and charged in 2020 with visa fraud for allegedly concealing their military affiliations. The arrested researchers were (i) Juan Tang, a visiting cancer researcher at the University of California, Davis, (ii) Lei Guan, a visiting artificial intelligence researcher at the University of California, Los Angeles, (iii) Xin Wang, a biomedical researcher at the University of California, San Francisco, (iv) Song Chen,

a visiting neurologist at Stanford University; and (v) Kaikai Zhao, a graduate student in artificial intelligence at Indiana University. A spokesperson for the DOJ, Wyn Hornbuckle, stated in an interview "recent developments … have prompted the department to re-evaluate these prosecutions." He added that although the DOJ has determined that it is now "in the interest of justice" to dismiss these cases, the department "continues to place a very high priority on countering the threat posed to American research security and academic integrity" by China. According to the Wall Street Journal, an April 2021 memorandum by the FBI concluded that the U.S. visa application "potentially lacks clarity" regarding how it determines Chinese military affiliation and found little evidence linking dishonesty on such applications to illegal technology transfer to China. The DOJ had also determined that the maximum sentence for visa fraud charges is a year in prison, and given that these researchers had already been imprisoned (or otherwise had their liberty restricted) for about a year as they awaited trial, they had essentially "served their time."

Without explanation, the DOJ also dismissed all charges alleged in the indictment of Qing Wang, a former Cleveland Clinic Foundation employee and researcher, who was charged in May 2020 with false claims and wire fraud related to more than $3.6 million in grant funding from the NIH.

- *DOJ Reaches Second Settlement With VARI To Resolve Allegations Of Undisclosed Foreign Ties To NIH Grants (September 1, 2021)*

Van Andel Research Institute ("VARI") agreed to pay $1.1 million to resolve allegations that it violated the False Claims Act by failing to disclose a foreign component of a NIH award and by failing to disclose foreign research support for two VARI researchers who served as principal investigators on NIH awards. This was the second settlement with VARI in two years involving allegations of undisclosed foreign influence in federally-funded research.[107] Notably, the NIH also imposed Specific Award Conditions on all of VARI's NIH grants, including by requiring personal, executive-level certifications to the accuracy of NIH submissions, withdrawing certain of VARI's expanded grant authorities, and removing all of VARI's NIH grants from the Streamlined Non-Competing Award Process (SNAP).

- *Federal Judge Acquits Professor Accused of Hiding China Ties (September 9, 2021)*

In February 2021, Anming Hu, an Associate Professor in the Department of Mechanical, Aerospace and Biomedical Engineering at the University of Tennessee at Knoxville (UTK) was arrested and charged with three counts of wire fraud and three counts of making false statements. The indictment alleged that beginning in 2016, Hu engaged in a scheme to defraud NASA by concealing his affiliation with the Beijing University of Technology. In June, after a multi-day trial and a deadlocked

[107] In December 2019, VARI paid $5.5 million to resolve allegations that it violated the False Claims Act by submitting grant applications and progress reports to NIH in which VARI failed to disclose Other Support, including Chinese government grants that funded two VARI researchers.

jury, the Court declared a mistrial. Although the government notified the Court of its intent to retry Hu, federal Judge Varlan granted Hu's motion for an acquittal concluding that no rational jury could have found that (i) Hu acted with a scheme to defraud NASA, or (ii) Hu knew that the certifications he caused UTK to submit with the invoices for disbursement of funds were false. The prosecution of Hu, the first case brought to trial under the China Initiative, drew sharp criticism from advocates who raised concerns that the China Initiative may have become an excuse for racial profiling.

- *Harvard University Professor Convicted of Making False Statements and Tax Offenses (December 21, 2021)*

The former Chair of Harvard University's Chemistry and Chemical Biology Department was convicted by a federal jury in connection with making fraudulent statements to U.S. government officials who were investigating his affiliation with China's Thousand Talents Program and the Wuhan University of Technology (WUT) in Wuhan, China, as well as failing to report income he received from WUT. Following a six-day jury trial, Charles Lieber, was convicted of two counts of making false statements to federal authorities, two counts of making and subscribing a false income tax return and two counts of failing to file reports of FBAR with the Internal Revenue Service (IRS). Lieber will be sentenced at a later date that has not yet been scheduled.

C. FDA: Devices

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The COVID-19 public health emergency has continued to drive the FDA's device oversight activities this year. Throughout 2020 and 2021, the FDA issued Emergency Use Authorizations (EUAs) for various diagnostic tests for the SARS-CoV-2 virus and the presence of antibodies, and in March 2021 granted the first marketing authorization for such a diagnostic test using the traditional premarket review process. In December 2021, the FDA published transition plans for medical devices impacted by COVID-19, as discussed further below.

1. COVID-19 and FDA Device Oversight

- **COVID-19 Transition Plans**

The FDA has issued two draft guidance documents for the transition plans for medical devices commercialized pursuant to either EUAs or the FDA's special enforcement policies during COVID-19 public health emergency. The FDA has provided general recommendations for a phased transition process with respect to such devices, including recommendations regarding submitting a marketing application (e.g., 510(k), De Novo, or PMA), as applicable, and taking other actions with respect to these devices. Specifically, the FDA will provide notice to manufacturers that the transition is beginning which will then be followed by a set period for manufacturers to submit applications for

appropriate marketing authorization. If a marketing authorization is not submitted or approved for applicable devices, marketing of such devices must cease at the close of the transition period.

- **Laboratory Developed Tests**

The FDA's regulation of laboratory developed tests (LDTs) – in vitro diagnostic tests that are designed, manufactured and used within a single laboratory – has been an evolving quagmire over the past decade and 2021 continued to complicate FDA's enforcement approach, which, as recently as 2017, remained under consideration by the FDA as it explored a possible partnership with CMS, the agency responsible for regulating laboratories under the Clinical Laboratory Improvement Amendments (CLIA). The convoluted regulatory framework has been particularly relevant in the last year because many of the diagnostic tests granted EUAs by the FDA for purposes of diagnosing the presence of or antibodies to the SARS-CoV-2 virus have been LDTs. As COVID-19 continued to evolve in 2021, the availability of accurate and reliable COVID-19 tests became all the more necessary.

Back in August 2020, HHS issued a statement that the FDA would no longer review LDTs. This statement was not limited to LDTs being developed in connection with the COVID-19 pandemic; no LDTs require pre-market approval under HSS' new interpretation. Following HHS' statement, FDA took the position in October 2020 that it would no longer be reviewing applications for EUAs for LDTs, and would be prioritizing review of other testing technologies like point of care and home testing. However, this policy soon raised concerns that LDTs not receiving pre-market approval would not receive immunity under the Public Readiness and Emergency Preparedness Act (the "PREP Act"). Consequently, the FDA in November 2020 resumed review of voluntary EUA submissions for LDTs in a "timely" manner, notwithstanding the HHS rescission order.

In November 2021, HHS published a statement rescinding its 2020 policy on FDA's review of LDTs, citing concerns about the accuracy and reliability of LDTs to test for COVID-19 and returning HHS and FDA review of LDTs to pre-2020 framework. The FDA simultaneous published revised guidance on COVID-19 testing. The FDA now generally expects newly offered COVID-19 tests, including LDTs, to have an EUA, or traditional marketing authorization prior to clinical use.

2. Other Guidance Related to FDA Regulated Devices

Beyond COVID-19 related activities, this year the FDA has tackled guidance related to device software functions and the continuous surveillance of certain FDA approved and cleared devices. Such notable guidance includes:

- Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act (Draft Guidance May 2021): This draft guidance is designed to assist manufacturers that are subject to a 522 order (under which the FDA requires

postmarket surveillance for certain Class II and III devices) complete their postmarket surveillance plans.

- Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order (Draft Guidance May 2021): This draft guidance proposes updates to postapproval study guidance, including to require new reporting related to study enrollment.

- Content of Premarket Submissions for Device Software Functions (Draft Guidance November 2021): This draft guidance describes the information that the FDA considers important during its evaluation of the safety and effectiveness for premarket submissions for device software, including both software in a medical device and software as a medical device. When final, this would replace software device guidance that has not been updated since 2005.

- Digital Health Technologies for Remote Data Acquisition in Clinical Investigations; Guidance for Industry, Investigators, and Other Stakeholders (Draft Guidance December 2021): This draft guidance outlines recommendations intended to facilitate the use of digital health technologies in clinical investigations as appropriate for the evaluation of medical products, including drugs and devices.

In October 2021, the FDA, jointly with Health Canada and the United Kingdom's Medicines and Healthcare products Regulatory Agency released ten guiding principles to inform the development of Good Machine Learning Practice (GMLP), available at Good Machine Learning Practice for Medical Device Development: Guiding Principles. These principles are intended to lay the foundation for developing Good Machine Learning Practice that addresses the unique nature of artificial intelligence and machine learning products.

A digest of recent FDA draft medical device guidance can be found here. A digest of recent FDA final medical device guidance can be found here.

D. COVID-19 and Research

Authors: Allison Beattie, Clint Hermes, Whitney Mosey, and Angelique Salib, Bass Berry & sims

1. Single IRB Exception Determination

On October 23, 2020, NIH issued a notice to the extramural research community on the implementation of OHRP's single IRB exception determination during the COVID-19 public health emergency (PHE). For as long as OHRP's exception determination is in place, NIH will not require the use of a single IRB for NIH-funded research that qualifies for an exception and for which NIH also approves the exception. Recipients are required to submit an exception request to NIH, including justification as to why the study meets the exception criteria defined by OHRP. On August 23, 2021, NIH issued its "Reminder of Guidance on Requirement for NIH Single Institutional Review Board (IRB) Plan" to

remind the extramural research community that providing the name of the single IRB of record at Just-in-Time submission fulfils the policy on use of a single IRB for multi-side research.

2. Remote Interactive Evaluations During the COVID-19 Public Health Emergency

In April of 2021 the Food and Drug Administration (FDA) published guidance titled, "Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency." The purpose of the guidance is to describe how FDA will request and conduct voluntary remote interactive evaluations at facilities where drugs are manufactured, processed, packed, or held; facilities covered under FDA's bioresearch monitoring program; and outsourcing facilities registered under section 503B of the federal Food, Drug & Cosmetic (FD&C) Act for the duration of the PHE. Use of remote interactive evaluations is aimed to help FDA operate within normal timeframes despite the PHE. This guidance document details how facilities are to plan for a remote interactive evaluation, technological requirements needed for such evaluation, and procedures at the conclusion of the evaluation.

3. NIH Support for Development and Support of Large-Scale Manufacturing Tests

On October 25, 2021, the U.S. Department of Health and Human Services announced several actions to make more COVID-19 over-the-counter testing available at affordable prices. NIH is to invest $70 million to help with the initiative through its "Independent Test Assessment Program" which creates an accelerated pathway to support FDA evaluation of tests. Priority is given to manufacturers who have the ability to manufacture at significant scale. Relatedly, FDA announced that it would further streamline the regulatory pathway for over-the-counter single-use testing for tests that are currently only authorized as serial testing kits. This change should have the effect of lowering costs of tests as they are sold on an individual basis, rather than as two-packs.

4. FDA Guidance on Clinical Trials Generally

On March 18, 2020, FDA published guidance titled, "Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency, Guidance for Industry, Investigators, and Institutional Review Boards." The purpose of the guidance is to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity for the duration of the PHE. FDA expects sponsors, investigators and institutional review boards (IRB) to document their efforts to maintain the safety of trial participants and study data integrity. FDA also recognizes that protocol modifications may be required and documentation of the same is very important. The FAQs attached to the guidance provide a great deal of helpful information on research implementation challenges caused by the PHE and are updated regularly. This guidance has been updated multiple times since the PHE began and was most recently updated on January 27, 2021.

The updated guidance adds twenty-seven answers to questions FDA received concerning the conduct of trials during the PHE. The questions range from deciding when to suspend, continue or initiate a trial to obtaining informed consent from patients in isolation to using alternative laboratory or imaging centers.

On February 22, 2021, the FDA issued "Policies to Guide Medical Product Developers Addressing Virus Variants." The policies apply to developers of vaccines, diagnostics and therapeutic products.

In May of 2021, the FDA issued nonbinding guidance titled, "COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention." The guidance describes the FDA's current recommendations to sponsors of master protocols, specifically for umbrella and platform trials, in evaluating drugs that treat or prevent COVID-19. The guidance provides recommendations on trial design and conduct, statistical considerations, and administrative and procedural recommendations.

In June of 2020, FDA published nonbinding guidance titled, "Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency, Guidance for Industry." The purpose of the guidance is to recommend statistical considerations to address the impact of COVID-19 on meeting trial objectives for clinical trials during the duration of the PHE. Specifically, the guidance addresses considerations for analyzing primary and key secondary endpoints in a trial affected by COVID-19 (*e.g.*, trial participants not being able to visit clinical sites for endpoint assessments) to help ensure the trial provides interpretable findings with correct statistical quantification of uncertainty.

5. FDA Guidance on the Development of Drugs and Biologic Products

In May of 2020, FDA issued guidance titled, "COVID-19: Developing Drugs and Biological Products for Treatment or Prevention." The purpose of the guidance is to assist sponsors in the clinical development of drugs and biologic products with direct antiviral or immunomodulatory activity for the treatment or prevention of COVID-19. Specifically, the guidance describes FDA's recommendations regarding phase 2 and phase 3 trials, with a focus on populations, trial design, efficacy endpoints, and safety and statistical considerations for such trials. This guidance does not address the development of vaccines or convalescent plasma. In February of 2021, FDA updated this guidance. In the update, FDA expands upon its recommendations for treatment trials. Specifically recommending that trials should include high-risk populations such as elderly, persons with cancer, smokers, and other individuals with health complications. FDA also strongly discouraged disseminating data from ongoing trials as that can adversely affect patient accrual, adherence and retention as well as complicating endpoint assessment and objectivity. Any interim data analyses should be guided by separate FDA guidance. This guidance also elaborates on recommendations for prevention trials.

6. FDA Guidance on the Development and Licensure of COVID-19 Vaccines

In June of 2020, FDA issued guidance titled, "Development and Licensure of Vaccines to Prevent COVID-19." The purpose of this guidance is to describe FDA's recommendations regarding the data needed to facilitate clinical development and licensure of COVID-19 vaccines. Specifically, the guidance outlines an overview of key considerations to satisfy the regulatory requirements set forth in the investigational new drug application (IND) regulations at 21 CFR part 312 and biologics licensing regulations at 21 CFR part 601 for chemistry, manufacturing, and controls, nonclinical and clinical data through development and licensure, and for post-licensure safety evaluation of COVID-19 preventative vaccines. With respect to clinical trials, FDA addresses issues related to trial populations, trial design, efficacy, statistical considerations, and safety considerations. The guidance played a significant role in harmonizing trial design across the major vaccine candidates and platforms.

7. FDA Guidance on Emergency Use Authorization for COVID-19 Vaccines

In October of 2020, FDA issued nonbinding guidance titled, "Emergency Use Authorization for Vaccines to Prevent COVID-19." The purpose of this guidance is to describe FDA's recommendations regarding the data and information needed to support the issuance of an emergency use authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (21 USC 360bbb-3) for an investigational vaccine to prevent COVID-19, including guidance on CMC, nonclinical data and information, clinical data and information, as well as administrative and regulatory information. Additionally, the guidance provides recommendations regarding key information and data that should be submitted to a relevant IND or cross-referenced master file prior to submission of an EUA request. Before an EUA is issued to a sponsor, FDA expects to convene an open session of FDA's Vaccines and Related Biological Products Advisory Committee to discuss whether the available safety and effectiveness data support issuance of an EUA. Further, FDA expects that following the submission of an EUA request and issuance of an EUA, a sponsor would continue to collect blinded, placebo-controlled data in any ongoing trials for as long as feasible and that the sponsor would work towards the submission of a biologics license application as soon as possible. FDA updated this guidance in May of 2021. The updated guidance includes recommendations on the development of vaccines for SARS-CoV-2 variants and required data needed to support an EUA for a modified vaccine. The recommendations are specifically tailored to COVID-19 vaccines that express the S protein and are made under the assumptions that the neutralizing antibody to SARS-CoV-2 is a major component of the vaccine protective response, that an immune marker predictive of protection has not been established and that it is not feasible to conduct clinical diseased endpoint efficacy studies rapidly enough to respond to variants. A request for an EUA amendment for the modified vaccine should address: chemistry, manufacturing and controls, nonclinical studies, clinical data, assays used for immunogenicity endpoint assessment, and other additional considerations. Further, the guidance adds information on how the FDA will prioritize EUA requests for

COVID-19 vaccines, recognizing that the FDA has discretion in issuing such authorizations during an emergency. The FDA intends to prioritize EUA requests with developers who have engaged with the agency on an ongoing manner during their trial program and in the manufacturing process as these requests are more likely to contain the comprehensive data needed to issue an EUA. Also, the FDA intends to decline reviewing any EUA request for which the FDA cannot verify one of these characteristics: product quality, facility standards, conduct of trials, and trial data integrity.

In February of 2021, FDA issued nonbinding guidance titled, "Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID-19 Public Health Emergency." This guidance provides recommendations to sponsors in the development of monoclonal antibody products, specifically on the generation of data to support an EUA, as variants may in some cases result in reduced susceptibility to currently authorized or approved products, which compounds an urgent medical need. The guidance includes development program considerations for chemistry, manufacturing and controls, as well as pharmacology toxicology recommendations, virology, and clinical recommendations. For example, FDA recommends sponsors enroll disproportionately impacted patients (e.g. racial and ethnic minorities) and advises that the size and composition of the safety database needed to support an EUA will depend on factors such as the product's proposed use (e.g. treatment versus prevention). Finally, the FDA notes that sharing information regarding SARS-CoV-2 variants among sponsors, consortia, or other partnerships may help expedite the development of therapeutics for variants.

E. FDA: Drugs and Biologics

Given the widespread effects of the COVID-19 pandemic, the FDA largely focused in 2021 on addressing COVID-19 relief resulting in updated guidance for industry, as well as vaccine development and emergency use authorization for vaccines. It also addressed the use of Real-World Data ("RWD") and Real-World Evidence ("RWE") in regulatory submissions.

The FDA is working to identify safety and effectiveness of FDA-regulated products, including through the use of RWE, meaning clinical evidence on usage and potential benefits or risks of a medical product derived from analyzing real world data such as data from EHRs, claims and billing activities, and data from other sources that may inform health status and RWD, meaning data related to patient health status and/or delivery of health care routinely collected from a variety of sources. The FDA has several initiatives, including Sentinel, the Biologics Effectiveness and Safety System ("BEST") and RWE Program, working to provide insight on how RWE can support evaluation of a product's safety and efficacy. In some cases, product approval may be withdrawn if certain metrics are not satisfied.

On December 8, 2021, the FDA published draft guidance for industry, *Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products*, which (among other things) clarifies the

applicability of 21 CFR Part 312 (investigational new drug applications) to studies utilizing RWD and offers regulatory considerations for non-interventional studies involving RWD. The guidance recognizes the "potential utility" of using RWD in interventional studies, such as identifying participants in randomized trials to ascertain potential outcomes or to serve as a comparison in externally controlled trials.

The FDA published other draft guidance documents for industry related to RWE and RWD: (1) *Real World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products (*Nov. 2021); (2) *Data Standards for Drug and Biological Product Submissions Containing Real World Data* (Oct. 2021); and (3) *Real World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products* (Sept. 2021). These documents provide sponsors and researchers further guidance on utilizing RWE and RWD, including guidelines for the use of registries, data standards for product submissions and documentation of processes to manage RWD, and the use of electronic health care data in clinical studies.

In response to the world-wide focus on drug development resulting from the COVID-19 pandemic throughout 2020 and 2021, the FDA has also provided updated industry guidance for research, inspections, and clinical trials of drugs and biologics.

In June 2021, the FDA issued draft guidance for industry, *Sponsor Responsibilities – Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies*, to assist sponsors in complying with safety reporting requirements under investigational new drug applications ("IND") or as part of exempt bioavailability or bioequivalence studies. The guidance provides an overview of IND safety reporting requirements, discusses an approach for review of safety information and considerations for aggregate data analysis for IND safety reporting. It also addresses other safety reporting issues, including reporting arrangements and the duration of safety reporting. The guidance also addresses technical requirements for submitting safety reports, including where and how to submit reports and reporting time frames.

Also in June 2021, the American Society of Clinical Oncology and Friends of Cancer Research submitted proposed guidance documents to the FDA aimed to reduce exclusion criteria and expand eligibility in cancer trials with recommendations related to treatment "washout periods," concomitant medications, prior therapies, laboratory reference ranges and test intervals, and patient performance status. The guidance document proposes the removal of time-based washout periods, or the period of time between when a patient last received medical treatment and is permitted to begin an investigational treatment as part of a clinical trial, and aimed to exclude patients taking concomitant medications in fewer circumstances, including potential or known drug-drug interactions. The guidance also recommended, among other things, excluding laboratory tests only when scientifically justified and abnormal tests indicate safety concerns.

Janet Woodcock, Acting Commissioner of the FDA, noted at a virtual event[108] in April 2021 the FDA's increased focus on streamlining drug trials so more studies may be performed in settings in the communities where patients commonly receive care. She also placed emphasis on improved informed consent processes and the use of EHRs to substitute for paper forms in clinical trials.

In April 2021, the FDA issued guidance for industry, *Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency*, which provides information on remote tools, timelines, and processes the FDA may use during an inspection, as the FDA is currently limiting unnecessary contact by only conducting in-person inspections when deemed mission critical and for certain domestic facilities. Remote interactive evaluations are outside of the statutory definition of inspections, and the FDA stated it will not issue a Form FDA 482, Notice of Inspection, to announce or begin a remote interactive evaluation but will provide a copy of the final remote interactive evaluation report to the facility. As part of a remote interactive evaluation, the FDA may request and review documents, records and electronic systems; use livestream or pre-recorded video; schedule interviews and meetings; evaluate a facility's corrective actions as necessary; and provide verbal updates. The FDA also clarified that it will not accept requests for the FDA to perform a remote interactive evaluation, as it would be too burdensome to establish a request-based system.

In January 2021, the FDA issued draft guidance for industry, *Human Gene Therapy for Neurodegenerative Diseases*, which addresses considerations for product development, preclinical testing, clinical trial design, and marketing approval pathways to assist sponsors in developing human gene therapy products for neurodegenerative diseases. Industry comments on this guidance have called for clarifications, more specificity, and changes to language regarding clinical trial designs and critical quality attributes.

Throughout 2021, the FDA also issued other guidance related to drugs and biologics research, largely related to addressing the COVID-19 pandemic, as discussed in the section on COVID-19 and research. The FDA has published an ongoing list of emergency use drugs and biologics approved in response to the COVID-19 pandemic. The FDA has also published a list of novel drugs that were approved in 2021.

F. Federal Grants Developments

In November 2021, the HHS Office for Human Research Protections (OHRP) announced the launch of an online incident reporting system for reporting unanticipated problems involving risk to subjects or others, serious or continuing noncompliance with 45 C.F.R. Part 46, or suspension or termination of IRB approval to OHRP. Starting January 2022, institutions must begin using the online system to submit all incident reports.

[108] See Virtual Meeting, Modernizing Eligibility Criteria in Clinical Trials: How We Can Improve Patient Access and Representation, available at https://friendsofcancerresearch.org/events/modernizing-eligibility-criteria.

On October 29, 2021, NIH issued another notification to the extramural research community of the implementation of updated eRA Research Performance Progress Report (RPPR) submission system validations for clinical trial registration and results reporting as of October 1, 2021. The system requires recipients to ensure that their NIH-funded clinical trials are registered at ClinicalTrials.gov for public posting no later than 21 days after enrollment of the first participant, and that results information be submitted to ClinicalTrials.gov no later than one year after primary completion date (with limited exceptions). RPPRs that have associated clinical trials that are non-compliant with these requirements will receive errors preventing submission of the RPPR.

On October 12, 2021, NIH issued a notice informing the research community of its implementation of a provision in the 2018 Requirements for the Federal Policy for the Protection of Human Subjects ("the revised Common Rule") under which public health surveillance activities may be deemed not to be research for the purposes of the regulation (45 CFR 46.102(i)(2)). NIH, as a public health authority, will alone make all determinations as to whether an NIH-supported or -conducted study qualifies as a public health surveillance activity for purposes of the Common Rule's exclusion from the definition of research.

The HHS Secretary's Advisory Committee on Human Research Protections (SACHRP)[109] issued a report on July 22, 2021 recommending that IRBs be tasked with seeking to ensure that duties arising from Justice (as articulated in the *Belmont Report*) are discharged when researchers work with underrepresented or disadvantaged populations. This could include lowering burdens to study participation (such as the number or duration of visits), providing compensation for participation, or selecting study recruitment methods that make the study easier to access. SACHRP further recommended that "IRBs encourage attention to Justice by requiring that research proposals include a discussion of Justice and access."

In May 2021, the U.S. National Science Foundation Office of the Inspector General (NSF OIG) published a series of performance audits of the implementation of OMB Coronavirus Disease 2019 (COVID-19) flexibilities at research universities for the period March 1 to September 30, 2020. The audit objective was to determine if the universities used the administrative COVID-19 flexibilities authorized by OMB and, if so, whether the universities complied with the associated guidelines. On August 3, 2021, the NSF OIG issued a capstone report on the OMB COVID-19 flexibilities, and found that NSF award recipients were "generally prudent" in their stewardship of federal resources. Although the auditors found that recipients generally complied with relevant guidance, recipients might have been more willing to use the flexibilities if the guidance had been clearer and reduced opportunities for inconsistent interpretation, and may have used the flexibilities more effectively if they had been able to implement them in a more timely and consistent manner. Auditors also concluded that recipients could have more effectively monitored federal spending during the pandemic if federal agencies had required recipients to formally track the use of implemented flexibilities as well as

[109] SACHRP is charged with providing advice and recommendations to the Secretary of HHS on issues pertaining to the protection of human subjects in research.

flexibility-related spending.

The U.S. Chief Financial Officers Council issued an FAQ in May 2021 designed to address common questions regarding the Office of Management and Budget's (OMB) implementation of the updates to Title 2 of the Code of Federal Regulations (2 CFR), also referred to as the Uniform Guidance. The Uniform Guidance are the cost principles, audit requirements, and administrative requirements for federal awards.

In April 2021, the Department of Health and Human Services (HHS) rescinded actions taken during the Trump Administration regarding extramural research funded by the NIH involving human fetal tissue obtained from elective abortions. Specifically, HHS reversed its 2019 decision that all applications for NIH grants, contracts, and cooperative agreements proposing to use human fetal tissue from elective abortions be reviewed by an NIH Human Fetal Tissue Research Ethics Advisory Board (EAB). Certain Trump-era NIH policies regarding fetal tissue research were left in place.

The Biden Administration announced a proposal for a new health research agency in April 2021. The proposed Advanced Research Projects Agency for Health (ARPA-H), would be housed at the NIH, and would expand the government's ability to fund the development of new technologies and medicines made possible by the research already done at the NIH. According to a White House press release, the agency would initially focus on innovative treatments in cancer, diabetes, and Alzheimer's disease. In May 2021, lawmakers announced that they would fold the proposal for ARPA-H (and its 2022 budget of $6.5 billion) into the next iteration of the 21st Century Cures Act.

The UNITE initiative was established by the National Institutes of Health (NIH) in March 2021 to identify and address structural racism within the NIH-supported and greater scientific community. UNITE aims to establish an equitable and civil culture within the biomedical research enterprise and reduce barriers to racial equity in the biomedical research workforce. To that end, UNITE is facilitating research to identify opportunities, make recommendations, and develop and implement strategies to increase inclusivity and diversity in science. On March 1, 2021, NIH issued an RFI inviting feedback on the approaches NIH can take to advance racial equity, diversity, and inclusion within all facets of the biomedical research workforce, and expand research to eliminate or lessen health disparities and inequities. As part of the UNITE initiative, on October 13, 2021 NIH announced that eleven grants were awarded through the NIH Common Fund's Transformative Research to Address Health Disparities and Advance Health Equity initiative to researchers focusing on one or more NIH-designated populations that experience health disparities in the U.S. Grant awards totaled $58 million over five years, pending availability of funds.

G. International Research

Many U.S. healthcare and research institutions Many U.S. healthcare and research institutions sponsor or collaborate on research that takes place in whole or in part overseas.

The way clinical trials are conducted in the European Union (EU) will undergo a major change when the Clinical Trials Regulation (Regulation (EU) No 536/2014) goes into effect on January 31, 2022. The Regulation harmonizes the assessment and supervision processes for clinical trials throughout the EU, via a Clinical Trials Information System (CTIS). The CTIS will contain the centralized EU portal and database for clinical trials. The Regulation will repeal the existing EU Clinical Trials Directive (EC) No. 2001/20/EC and national legislation that was put in place to implement the Directive. The Regulation will require Consistent rules for conducting clinical trials throughout the EU and information on the authorization, conduct, and results of each clinical trial carried out in the EU to be publicly available.

On July 31, 2021, Health Canada published a Notice of Intent outlining its plan to amend the Food and Drug Regulations (FDR) and the Medical Devices Regulations in the spring of 2022. The proposed amendments are intended to modernize the Canadian clinical trial regulatory regime. The proposed amendments would authorize the Minister of Health to impose terms and conditions on drug and medical device authorizations and to require a Risk Management Plan; extend flexibilities currently in use for COVID-19 drugs to other drugs in specified circumstances (e.g., rolling submissions); and modernize requirements for biologics.

H. Privacy Law and Regulation and Research

Authors: David Peloquin, Cara Dermody, and Carmen Lam, Ropes & Gray

1. Passage of the Virginia Privacy Law

Since the passage of the California Consumer Privacy Act ("CCPA") and the California Consumer Privacy Rights Act ("CPRA"), which amends the CCPA, many states have proposed or enacted data protection legislation. Virginia Governor Ralph Northam signed the Virginia Consumer Data Protection Act (the "VCDPA") into the law on March 2, 2021. The VCDPA, upon its effective date of January 1, 2023, will provide Virginia consumers new rights to access, correct, delete, and obtain a copy of the personal information held by a covered business, as well as a requirement that consumers provide opt-in consent before a business can process sensitive categories of data.

Notably, the VCDPA exempts from its scope HIPAA covered entities and their business associates. In addition, the law exempts identifying information processed in certain research contexts and any information derived from these exceptions that is de-identified in accordance with HIPAA requirements.

The exempt research contexts include information collected as part of human subjects research conducted pursuant to the Common Rule, the good clinical practices guidelines issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH E6 GCP guidelines"), and data used or shared in research conducted in accordance with FDA requirements applicable to human subjects research. Taken together, these exemptions have the effect of excluding considerable

amounts of medical research from the law's purview.

2. Passage of the Colorado Privacy Law

The Colorado Privacy Act was signed into law on July 8, 2021, and will take effect on July 1, 2023. The new law provides consumers with rights to access, correct, and delete personal data as well as a right to data portability. It also requires that consumers provide opt-in consent before a business can process sensitive categories of data or process personal data for unnecessary or incompatible secondary purposes.

The Colorado Privacy Act exempts protected health information that is collected, processed, or stored by a HIPAA covered entity or its business associate. As with other state privacy laws (*i.e.*, VCDPA and CCPA), the Colorado Privacy Act exempts identifying information that is processed in certain research contexts (*i.e.*, in accordance with the Common Rule, ICH E6 GCP guidelines, and FDA human subjects research regulations). However, unlike CCPA and VCDPA, the Colorado Privacy Act does not provide an exemption for non-profit organizations.

3. China's Personal Information Protection Law

China's Personal Information Protection Law ("PIPL") came into effect on November 1, 2021. It applies to the processing of personal information of individuals located in China both when such data processing activities occur within China and also when such data processing activities take place outside of China but (i) such activities are conducted in relation to processing personal information for the purposes of providing products or services to individuals located in China, or (ii) the processing is for analyzing and evaluating the behavior of individuals located in China. The PIPL also contains a catch-all provision that authorizes the Chinese government further to expand the PIPL's extraterritorial applicability through other laws or regulations.

Any offshore personal information processors must appoint a representative located in China to be responsible for matters related to personal information protection and report the representative's contact information to relevant data protection regulators. Unlike the European Union's GDPR (defined below), the PIPL does not contain exceptions to the representative requirement for occasional processing, certain lower-risk processing, or processing by public authorities or bodies.

Similar to GDPR, entities subject to PIPL must establish a legal basis for each processing activity that they undertake. The legal bases for processing personal information are enumerated in the PIPL and include (1) processing on the basis of consent of the individual concerned, (2) processing necessary to conclude or perform a contract with the individual concerned or to implement human resources management in accordance with labor rules and regulations and collective contracts formulated in accordance with law, (3) processing necessary for the performance of statutory duties or obligations, (4) processing necessary to respond to public health emergencies or for the protection of the life, health, and safety of individuals, (5) processing for news reporting and supervision

of public opinion for the public interest where the processing is reasonable in scope, (6) processing of personal information that has been publicly disclosed by the individual concerned or otherwise lawfully publicly disclosed where the processing is in accordance with the PIPL and is reasonable in scope, and (7) processing conducted in accordance with other circumstances prescribed by laws and administrative regulations.

To transfer personal information outside of China, entities must meet various conditions (*e.g.*, security assessments, obtaining certification, entry into a contract, or fulfilling other conditions required by law or regulations). When transferring data of an individual outside of China, the transferor must also adhere to various notification requirements and the data subject must consent to the transfer.

4. GDPR

The General Data Protection Regulation (the "GDPR") is a far-reaching privacy regulation of the European Union that imposes restrictions and obligations on, among other types of entities, those seeking to transfer certain types of personal data from the European Economic Area ("EEA") (the 27 member states of the European Union plus Iceland, Liechtenstein and Norway) to the United States (and other third countries). One mechanism that was developed to enable cross-border transfers of personal data was the EU-U.S. Privacy Shield Framework ("Privacy Shield"), which allowed participant entities which met certain privacy requirements and self-certified to the Privacy Shield with the U.S. Department of Commerce to engage in cross-border transfer of personal data.

In July 2020, the Court of Justice of the European Union ("CJEU") invalidated the Privacy Shield framework in a decision commonly referred to as the Schrems II decision. This decision eliminated the Privacy Shield as a mechanism to legitimize the cross border transfer of personal data. The CJEU ruled that the Privacy Shield did not provide adequate protections to persons located in the European Union, particularly with respect to the national security surveillance laws and programs of the United States.

Pursuant to the CJEU's opinion in the Schrems II decision, companies may continue to rely on the other data transfer mechanisms set out in GDPR. These include the "standard contractual clauses," which are standard form contracts promulgated by the European Commission that are designed to offer sufficient safeguards for data transfers to comply with GDPR, and alternative bases such as obtaining the explicit consent of the individual to whom the information pertains. Notably, the Schrems II decision required that supplementary measures be taken in some cases, such as when relying on standard contractual clauses, to ensure compliance with the level of protection of data required by EU law in a particular third country. The European Data Protection Board ("EDPB") issued guidance (1, 2) setting out recommendations on supplementary measures that may be required to legally transfer data outside of the EEA, including identifying all transfers, verifying transfer tools, assessing laws and practices in the country to which data are being transferred, adopting supplementary measures to ensure data are protected at the required level of "essential equivalence," and taking any formal procedural steps required

by the transfer tool being used. The Schrems II decision and accompanying EDPB guidance have had significant impacts on research taking place in Europe in collaboration with U.S.-based researchers and sponsors. Companies involved in trans-Atlantic data flows have had to re-evaluate their data sharing practices in light of the EDPB guidance, which has stalled certain multi-national research projects. The U.S. federal government is examining this issue and considering solutions, including in a December 2020 hearing on the invalidation of the EU-U.S. Privacy Shield and the future of transatlantic data flows.

In February 2021, EDPB released new guidance on the application of GDPR to health research in the form of responses to questions posed by the European Commission, the executive branch of the European Union.

First, the guidance acknowledged the challenge of GDPR compliance when conducting clinical trials across multiple European Union Member States ("Member States"). EDPB recognized that researchers may need to rely on different legal bases for exemptions to process personal data in the same clinical trial across different Member States but also stressed a strong preference that researchers maintain consistent rights for data subjects across all Member States when possible.

In addition, the guidance explains that "explicit consent," which is one of the legal bases under GDPR for processing health data, and "informed consent" to participate in research are different concepts. To meet the legal basis of "explicit consent," there must not be a "clear imbalance of power" between the study participants and the investigator or institution.

EDPB also provided further guidance on processing previously-collected health data for research purposes. The guidance clarified that the data must be processed for the same "specified, explicit and legitimate purposes" for which the data were initially collected or for scientific research purposes and with adequate safeguards. If the exemption or basis used initially to collect the data does not apply to the researcher's further processing, the researcher must find a different basis and/or exemption. EDPB acknowledged that further guidance would address other questions, including those concerning data collected from social media platforms or activity trackers (rather than collected from patients directly).

EDPB also clarified that researchers using a broad consent should obtain specific consent to known stages of the research and uses of the data at the start of the research; permit data subjects later to withdraw their consent; "narrow[] down" the research areas that the broad consent covers; "carefully evaluate the rights of the data subject, the sensitivity of the data, the nature and purpose of the research and the relevant ethical standards"; and apply other "additional safeguards" on which the EDPB will elaborate in future guidance. EDPB's comment that it will evaluate broad consent in the future guidance suggests potentially more openness to the concept than the EDPB has shown in its previous guidance.

EDPB also noted that data anonymization is "difficult to achieve" and "should be approached with caution in the context of scientific research," especially for research involving genetic data. EDPB provided that, to determine whether data are anonymous, researchers must consider "all the means reasonably likely to be used" to re-identify the data, which may change as technology advances. While EDPB said that it remains "unresolved" whether "any combination" of measures could make genetic data anonymous, its upcoming guidelines on the processing of personal data for scientific research will address this issue.

The European Commission adopted new standard contractual clauses that replace the existing standard contractual clauses used to legitimize the transfer of personal data from the EEA to third countries outside of the EEA that lack an adequacy decision from the European Commission. The new standard contractual clauses contain four modules: one for use for transfers from controllers to controllers, one for use for transfers from controllers to processors, one for use for transfers from processors to controllers, and one for use for transfers from processors to processors. The new standard contractual clauses were modernized to reflect both the GDPR and the Schrems II judgement. By addressing processor to controller transfers and processor to processor transfers, these new standard contractual clauses address transfer situations that were not addressed by the prior standard contractual clauses. The new standard contractual clause modules for controller to processor transfers also incorporate the elements of a data processing agreement under GDPR Article 28, thus eliminating the need for a separate data processing agreement to satisfy Article 28 requirements. One complication is that the new standard contractual clauses state that they cannot be used for transfers of personal data from the EEA to a data importer located outside the EEA that is directly subject to GDPR. The EDPB has suggested in its guidance on the interplay of GDPR Article 3 and the cross-border transfer requirements that new standard contractual clauses may be issued in the future to address this situation. Starting September 21, 2021, any new contracts that use standard contractual clauses as the mechanism to legitimize cross-border data transfers must use the new standard contractual clauses. Existing contracts that relied on the old standard contractual clauses may continue to be used until December 27, 2022.

Following public consultation, on June 18, 2021 the EDPB adopted finalized recommendations on supplemental transfer tools to ensure compliance when transferring personal data from the EEA to countries that lack an adequacy decision, such as the United States. The recommendations provide for a six-step process to identify the GDPR transfer tools that are relied on, and to adopt, identify, and evaluate supplemental measures to be used. Notably for the research community, the guidelines emphasize that pseudonymisation is a supplementary measure that can be used to safeguard the transfer of personal data.

On November 18, 2021, the EDPB published draft guidelines addressing the interplay between the application of Article 3 on extra-territorial scope of the GDPR and GDPR Chapter V provisions on international data transfers. The draft guidelines aim to assist controllers and processors in the EU with identifying whether a processing activity constitutes a transfer to a third country or to an international organization and thus

whether they must comply with the provisions of Chapter V of the GDPR. The draft guidelines clarified that a basis to legitimize the transfer of personal data is required even when the transfer is made to a party that is directly subject to GDPR under Article 3(2). The draft guidelines also state that a basis to legitimize the transfer of personal data is needed when a processor established in the EEA transfers personal data to a controller located outside the EEA that is not subject to GDPR. The draft guidelines additionally explain that no restricted transfer takes place when a data subject located in the EEA transfers on his or her own volition his or her personal data to a country located outside of the EEA. This is because in such case there is no transfer from a data exporter (*i.e.*, a controller or processor) to a data importer; rather, data are transferred directly from the data subject. The draft guidelines are currently open for comment until January 31, 2022.

5. HHS' Secretary's Advisory Committee on Human Research Protections ("SACHRP") Guidance

SACHRP released recommendations in March 2021 concerning two topics: (1) IRB authority to restrict the use of data collected and developed in an unethical matter, and (2) the interactions among sponsors, clinical trials sites, and study subjects (1, 2).

The first topic addressed the use of results from research that was conducted in an unethical manner and whether such results should be used to contribute to generalizable knowledge. SACHRP recommends that OHRP and FDA issue guidance on institutions and IRBs restricting the use of data collected in violation of the Common Rule and FDA regulations concerning human subjects research, providing that the authority for such restrictions is inherent in IRBs' authority to suspend or terminate research. The recommendations further state that OHRP and FDA may want to include criteria for reviewing these cases to clarify when data should and should not be public. Institutions and IRBs should determine in advance if they plan to maintain authority to restrict the use of knowledge from such studies and should set forth their determination in a written policy that is publicly available. SACHRP provides that institutions and IRBs, when considering the development of such a policy, should carefully weigh the nature and magnitude of the ethical violations and regulatory non-compliance with other circumstances, including the applicable principal investigator's record.

On the second topic, SACHRP's recommendations address three common scenarios that may give rise to legal and ethical challenges: (1) interactions between sponsors and potential study subjects for clinical trial recruitment; (2) programs through which sponsors engage current or former subjects to produce testimonials for the sponsor's own use; and (3) sponsor engagement of vendors to perform recruitment services on behalf of study sites.

First, regarding the interaction between sponsors and potential study subjects, SACHRP recommends that trial-specific recruitment activities performed by sponsors be subjected to the same IRB oversight as recruitment activities conducted by investigators and study sites. SACHRP also introduces key principles derived from existing FDA and OHRP guidance on recruitment of human subjects to inform such interactions. Second,

SACHRP acknowledges the interest in contacting subjects to obtain information regarding their experiences with the condition under investigation. SACHRP recommends that the investigator, as opposed to the sponsor, should be responsible for making any initial proactive contact with the study subject, sponsors should ensure that any of their contact with study subjects is reviewed by an IRB, and that IRBs should consider whether the study likely will suffer bias as a result of the sponsor's initiating and maintaining direct contact with subjects, among other key principles. Lastly, SACHRP acknowledges that the increased use of vendors to perform services on behalf of clinical trial sites underscores the importance of adhering to privacy laws. SACHRP notes that study sites and investigators typically are covered entities under HIPAA and may not share protected health information ("PHI") without an authorization (unless an exception to the authorization requirement applies), study sites and investigators are bound by the disclosure obligations made during the informed consent process, and that sponsors and vendors may have privacy obligations outside of HIPAA, including those based on common law principles, state law, and prior promises made by either party.

I. Big Data and Research

Authors: David Peloquin, Cara Dermody, and Carmen Lam, Ropes & Gray

1. FDA Draft Guidance on Real-Word Data and Real-World Evidence

In the last six months, the FDA published a series of draft guidance documents regarding the use of real-world data and real-world evidence in an effort to further the FDA's Real-World Evidence program. A draft guidance was published in September 2021 and pertains to accessing electronic health records and medical claims data to support approval of a new indication for drugs that were previously approved for marketing. This draft guidance complements a previous guidance on best practices for real-world data and real-world evidence, and it focuses on issues associated with data selection, study design, and quality assurance/control considerations. In November 2021, The FDA published a draft guidance on use of registry data to support regulatory decision-making. In this guidance, the FDA discusses the attributes and limitations of registry data to support regulatory decisions. The guidance also notes that in addition to considering validation and processes used for the registry, Sponsors should also consider whether a given registry adheres to the requirements for electronic records found in 21 C.F.R. part 11 (including maintenance of access and audit trails).

In December 2021, the FDA published yet another draft guidance concerning real-world data and real-world evidence, this time addressing the use of such data to support regulatory decision-making for drug and biological products. The FDA clarified that interventional studies involving drugs generally meet the definition of a "clinical investigation" and are therefore subject to 21 C.F.R. part 312 (the FDA's investigational new drug regulations). However, non-interventional studies that do not involve randomization of study subjects (*e.g.*, studies that are limited to data analysis) generally do not meet the definition of a "clinical investigation" under 21 C.F.R. part 312 and do not need to be conducted under an IND. Nevertheless, such non-interventional studies may still be subject to the IRB review, informed consent, and other regulatory

requirements articulated in 21 C.F.R. parts 50 and 56, especially when they involve ancillary protocol-specified activities or procedures (*e.g.*, questionnaires, laboratory tests, and imaging studies). This guidance further encourages Sponsors to engage with the FDA early in the study design process when designing a non-interventional study to support a marketing application. The guidance additionally provides recommendations on data integrity and study oversight, safety-reporting obligations, and other Sponsor obligations (*e.g.*, ensuring records comply with 21 C.F.R. part 11, study oversight, and requirements to maintain proper records).

2. National COVID Cohort Collaborative

COVID-19 has continued the pre-pandemic trend of the growth of "big data" research projects. In response to the COVID-19 pandemic, the NIH launched the National COVID Cohort Collaborative ("N3C"), a centralized national data resource available to the research community to study COVID-19 and identify potential treatments. Under N3C, hospitals and health plans submit clinical, laboratory, and diagnostic data in the form of a limited data set to the NIH for inclusion in the centralized platform. Participation in N3C, and other similar initiatives, generally requires entering into data use agreements, the terms of which become more complex when institutions leverage regional data collaboratives to facilitate such participation. Lawyers must navigate the limitations of existing collaborative participation agreements and data use agreements to enable the release of important COVID-19 data to N3C, a challenge that may be addressed in future agreements by incorporating provisions that contemplate the potential for regional collaboratives to coordinate with national programs, especially during public health emergencies. Thus, N3C may assist with determining how to structure relationships between hospitals, health plans, and regional and national collaboratives to better address future public health emergencies.

3. COVID-19 Diagnostics Evidence Accelerator

In June 2020, the FDA announced its participation in the COVID-19 Diagnostics Evidence Accelerator, a collaborative that allows for the analysis of both diagnostic and clinical data in real-time by convening experts in data aggregation and analytics to compare results and answer key question to inform the COVID-19 response. The Diagnostic Evidence Accelerator evaluates the performance of COVID-19 diagnostic tests and antibody tests, focusing on determining whether the presence of antibodies indicates future immunity, and which specific antibodies may contribute to such protection. The collaborative demonstrates the growing importance of coordination among experts in data aggregation to determine how to leverage big data to address the COVID-19 pandemic.

4. Information Blocking

Information blocking is a practice through which health care providers or other holders of electronic health information impose barriers to the access, exchange, or use of such electronic health information by another party. Pursuant to the 21st Century Cures Act,

the Office of the National Coordinator ("ONC") of HHS issued a series of regulations which prohibited health care providers or health IT developers from interfering with access, exchange or use of electronic health information, with certain defined exceptions. This rule had an effective date of November 2, 2020. However, an interim final rule with comment period was released in October 2020, delaying the compliance date for the information blocking rules until April 5, 2021.

Under the rule, to constitute prohibited information blocking, the interference must be known to the provider to be unreasonable and likely to interfere with access to information. One implication of these rules for the research community is that when patients have executed a HIPAA authorization permitting researchers to access their existing electronic health information held by covered entity health care providers, researchers will likely be able to invoke the information blocking rules (once effective) to require the covered entity health care provider to disclose information for research in response to the authorization. This should prove a helpful development for researchers given that authorizations have historically been seen as a "permissive" basis for disclosure of PHI, and thus some health care providers have refused to disclose PHI to researchers in response to broad authorizations. Providers may impose cost-based fees on researchers or others requesting the information to compensate for the time and effort involved in transferring such information.

Similarly, the rule also makes it more difficult for non-provider actors, including health IT developers of certified health IT and health information exchanges, to decline a researcher's legally permissible request for a patient's electronic health information when not otherwise prohibited under the applicable business associate agreements. Therefore, the rule also creates a new approach for researchers to gain access to electronic health information from certain non-provider actors.

5. Access to Information under HIPAA Notice of Proposed Rulemaking

On December 10, 2020, OCR released a notice of proposed rulemaking that proposed changes to the HIPAA Privacy Rule to support care coordination and the delivery of value-based care. The proposed rule would compel covered entities to adopt policies and procedures that allow for better access by individuals to their own PHI, would clarify when disclosures for care coordination and case management are permitted, and would loosen the requirements relating to the provision of a notice of privacy practices. In addition, the proposed rule would clarify the right for individuals to direct the sharing of PHI in an electronic health record used among covered entities by allowing individuals to request that covered entities share their PHI. The proposed rule permits reasonable fees in connection with the labor and expenses associated with these requests. The provision of the proposed rule clarifying the rights of individuals to direct sharing of their PHI, if ultimately adopted, could prove useful in a research setting where the transfer of PHI between covered entities regarding a research subject may be necessary.

The comment period for the proposed rule closed on May 6, 2021. Commenters generally expressed support for the proposed rules but also noted concerns with the

complex regulatory framework and overlapping regulatory schemes (*e.g.*, interoperability regulations under the 21st Century Cures Act and the CARES Act). Commenters requested that HHS acknowledge and clarify the overlapping regulations and not implement any changes that would be enforced before technologies essential to respond to patient requests are available. As of December 2021 HHS has yet to publish a final rule.

J. Clinical Trial Registration and Data Transparency

Authors: David Peloquin, Cara Dermody, and Carmen Lam, Ropes & Gray

1. Enforcement of ClinicalTrials.gov Submission Requirements

Under section 402(j) of the Public Health Services Act ("PHS Act") and its implementing regulations at 42 C.F.R. part 11, sponsors (or other "responsible parties") of most clinical trials must register such trials and post summary results from such trials on ClinicalTrials.gov. The website serves as a public resource for the identification and matching of trials with potential participants as well as for reviewing summary results of clinical trials.

In August 2020, FDA issued a guidance document (the "Guidance") describing how FDA will identify noncompliance, initiate enforcement actions, and assess civil monetary penalties ("CMPs") for noncompliance with ClinicalTrials.gov requirements. Specifically, the FDA will focus its compliance efforts on parties who fail to submit data for clinical trials of high-risk products and on those who exhibit a pattern of noncompliance. If a party is not in compliance, FDA will issue a Preliminary Notice of Noncompliance, to which the party has 30 days to take corrective action. If the party fails to take such action, FDA will issue a public Notice of Noncompliance, to which the party has an additional 30 days to address its noncompliance. The Notice of Noncompliance is posted on FDA's website and provided to NIH to be posted on ClinicalTrials.gov. If the noncompliant party again fails to take adequate corrective action, FDA will seek CMPs.

Under the CMP proceeding process, FDA presents a formal complaint with sign-off by the FDA Office of Chief Counsel, and the responsible party may submit an answer, including any objections, to such complaint within 30 days of the date of service. Parties who file objections within those 30 days are entitled to a hearing. Such parties also may seek to settle claims for a lower penalty. If FDA and the party do not reach a settlement, the claims will be adjudicated before an administrative law judge ("ALJ"), and either party may appeal the ALJ's decision to the HHS Departmental Appeals Board ("DAB"). The respondent may appeal adverse DAB decisions to the U.S. Court of Appeals for the District of Columbia or another circuit court where the respondent resides or does business.

The Guidance provides that FDA will consider "the nature, circumstances, extent, and gravity" of the violation, the violator's compliance history and ability to pay, its degree of culpability, and "such other matters as justice may require." The Federal Food, Drug,

and Cosmetic Act caps the CMPs at $10,000 (inflation adjusted to $12,316 for 2020) for violations adjudicated within a single proceeding or, if a responsible party fails to remedy its noncompliance within the notice period, $10,000 per day of continuing noncompliance.

After facing criticism for not enforcing these requirements, the FDA issued its first Notice of Noncompliance to Acceleron Pharma, Inc. ("Acceleron") on April 27, 2021 for failing to submit required summary results information to ClinicalTrials.gov. According to ClinicalTrials.gov, Acceleron first submitted results on April 28, 2021, and the results were posted on ClinicalTrials.gov on May 24, 2021. The FDA's second Notice of Noncompliance was issued on June 26, 2021 to Accuitis, Inc., for a failure to submit results information, in addition to a failure to update the primary completion date for a clinical trial. According to ClinicalTrials.gov Accuitis subsequently submitted its results on April 17, 2021.

Most notably, the FDA's third Notice of Noncompliance was issued to an individual, a sponsor-investigator, Dr. Andrey Petrikovets, M.D. According to the Notice, Dr. Petrikovets previously responded to the FDA with a copy of the published manuscript. The FDA noted that scientific manuscripts are insufficient to meet the requirements for submitting clinical trial results to ClinicalTrial.gov. According to ClinicalTrials.gov, Dr. Petrikovets submitted his results on September 1, 2021, one day after the Notice of Noncompliance was issued.

In each of the three Notices of Noncompliance, the FDA gave the responsible party 30 days to submit the required results and submit a written response to the FDA. In each case, according to ClinicalTrials.gov, the responsible party submitted their results within the required time frame.

2. EMA Policy 0070

The European Medicines Agency ("EMA") Policy 0070 generally requires the publication of anonymized clinical study data regarding medicinal products for human use submitted under the EMA's centralized marketing authorization procedure. In December 2018, the EMA suspended the publication of clinical data as a result of the implementation of the third phase of EMA's business continuity plan, and the publication remains suspended due to "ongoing business continuity linked to the COVID-19 pandemic." EMA has not provided a timeframe yet for when the suspension will be lifted but confirmed that it will publish clinical trial data submitted concerning the marketing authorization application of a medicine intended to prevent or treat COVID-19. This commitment is part of EMA's efforts to support global research that may help to address the COVID-19 pandemic through greater information-sharing.

K. Biorepositories and Specimen Research

Authors: David Peloquin, Cara Dermody, and Carmen Lam, Ropes & Gray

1. FDA Reminder Regarding Research Involving Leftover, De-identified Specimens

On October 18, 2021, the FDA published a reminder letter to the diagnostic device industry noting that all FDA-regulated clinical investigations of devices involving leftover, de-identified human specimens must be reviewed by an IRB if the research data will be used to support the application for an investigational device exemption, device marketing application, or other submission to the FDA. While such investigations must be reviewed by an IRB, the FDA cites to its 2006 guidance and reaffirmed that it intends to exercise enforcement discretion as to the requirements for informed consent when such human specimens are used in research.

2. State Laws on Genetic Privacy

The federal Genetic Information Nondiscrimination Act ("GINA"), passed in 2008, bans discrimination based on genetic information in the health insurance and employment settings, but it does not address the life, long-term care and disability insurance context. However, many states have taken legislative steps to provide additional protection to individuals from genetic information discrimination beyond that provided by GINA. Given the broad use of genetic information in research, the recent action by state legislatures in this area may carry important implications for clinical research.

In spring 2021, Utah enacted the Genetic Information Privacy Act, which protects genetic data collected from direct-to-consumer genetic testing by imposing obligations on the companies conducting the tests concerning notice, data use, data security, and consumer rights.

In summer 2020, Florida passed a bill prohibiting life, disability and long-term care insurance companies from using genetic tests to make coverage and rate setting decisions. Although insurers are prohibited from using genetic information for these purposes, or soliciting applicants or covered individuals for their genetic information, individuals are still permitted to volunteer their information. Florida additionally passed the "Protecting DNA Privacy Act," which took effect on October 1, 2021. It applies to the collection, use, retention, maintenance and disclosure of a DNA sample collected from an individual in Florida and the results of any subsequent DNA analysis. The Act clarifies the extent to which individuals own their genetic information, and it creates new crimes for the unlawful collection, retention, analysis, disclosure or sale of an individual's DNA sample and the results of a DNA analysis, subject to certain limited exemptions. The Act also has important implications for secondary uses of data by health care providers and others that perform genetic testing and analyze genetic information, particularly because it lacks a blanket exemption for de-identified data.

The California legislature passed legislation in 2020 to regulate the privacy practices of direct-to-consumer genetic testing companies. This bill was vetoed by Governor Gavin Newsom in September 2020 due to concerns that the bill would inhibit the sharing of COVID-19 test results by clinical laboratories for public health purposes. In October 2021, Governor Newsom signed SB 41 into law, which regulates direct-to-consumer genetic testing companies. This bill requires that direct-to-consumer genetic testing companies provide consumers with certain information regarding their policies and procedures, collect express consent, and honor a consumer's revocation of consent. The bill does not apply to medical information governed by the California Confidentiality of Medical Information Act or protected health information governed by HIPAA. It also does not apply to certain research or educational activities conducted by post-secondary institutions that hold an HHS federalwide assurance provided that the institution complies with laws and regulations for the protection of human subjects in research (*e.g.*, the Common Rule, the FDA regulations on human subjects research, the federal Family Educational Rights and Privacy Act, and California's Protection of Human Subjects in Medical Experimentation Act). Furthermore, the bill also excludes "[t]ests conducted exclusively to diagnose whether an individual has a specific disease."

As of 2021, a number of other states are considering laws that would provide additional rights to consumers and further protections against genetic information discrimination, including: Alaska, Delaware, Hawaii, Massachusetts, Minnesota, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, South Carolina, Vermont, Virginia, and Washington. This is an area that continues to evolve and that should be monitored by those engaging in genetic research on humans or human-derived specimens.

3. Banking of COVID Samples

Although there has not been a specific legal or regulatory development to note, the COVID pandemic has emphasized the need for the use of banked biospecimens for public health and research purposes. Those engaged in COVID research frequently wish to access saliva, blood and other specimens collected in the course of routine COVID testing, and many entities have been banking residual COVID testing samples for this purpose. There are several regulatory considerations that should be addressed when collecting or using these banked specimens. CDC has issued COVID-specific biospecimens handling guidelines that are intended to ensure safety for personnel involved in these activities. Those conducting research need to consider whether research conducted on banked specimens constitutes human subjects research, and if so, should assess the need to comply with the Common Rule (as recently revised), OHRP guidance and other applicable research regulations and guidance, including with respect to informed consent and identifiability of samples. If banked samples will be used in support of an FDA submission, the researchers will need to consider the applicability of the FDA's regulations on clinical investigations. Additionally, depending on the types of personal information associated with the specimens, researchers will need to consider the application of HIPAA, the Family Educational Rights and Privacy Act and other privacy laws to the research activity.

L. Pharmacy Benefits Management Litigation

Authors: Theresa Carnegie, Hassan Shaikh, Bridgette A. Keller, and Pat Ouellette, Mintz Levin

1. Pharmacy Benefits Management Regulation in the wake of Rutledge v. Pharmaceutical Care Management Association (PCMA)

As was predicted in early 2021, the Supreme Court's decision in *Rutledge v. Pharm. Care Mgmt. Ass'n*, No. 18–540 (U.S. Dec. 10, 2020) continues to have far-reaching ramifications for the state regulation of PBMs. Most prominently, the Eighth Circuit in *Pharm. Care Mgmt. Ass'n v. Wehbi* (formerly *Pharm. Care Mgmt. Ass'n v. Wilke* prior to being vacated and remanded by the U.S. Supreme Court to the Eighth Circuit in light of *Rutledge*) concluded in November 2021 that ERISA did not preempt two North Dakota laws that regulate certain PBM practices. The court determined that the state laws did not have an "impermissible connection with" an ERISA plan and that the provisions at the heart of PCMA's challenge were, "at most, a regulation of a noncentral 'matter of plan administration' with de minimis economic effects and impact on the uniformity of plan administration across states." However, the court determined that some North Dakota law provisions, including those that prohibit PBMs from preventing pharmacies from disclosing certain information to patients, are preempted by Medicare Part D. It added that Medicare Part D plans can preempt state law only if they either "(1) regulate the same subject matter as a federal Medicare Part D standard (in which case they are expressly preempted), or (2) otherwise frustrate the purpose of a federal Medicare Part D standard (in which case they are impliedly preempted)." *Wehbi* was the first case to touch upon the subject matter of *Rutledge* in the federal appellate courts since the Supreme Court's decision in *Rutledge*. The cascading effects of *Rutledge* and *Wehbi* on state PBM regulation will be worth continuing to monitor in 2022.

M. Federal Drug Pricing

Authors: Theresa Carnegie and Pat Ouellette, Mintz Levin

1. Build Back Better Prescription Drug Price Proposals

H.R. 5376, the Build Back Better Act ("BBBA") passed through the House of Representatives on November 19, 2021 and will go through the Senate in early 2022. Among many other proposals, the BBBA would alter the drug pricing landscape in the following areas:

- Allow Medicare to negotiate prices for high-cost, single-source brand-name prescription drugs, including drugs seniors get at the pharmacy counter (through Medicare Part D), and drugs that are administered in a doctor's office (through Medicare Part B). Beginning in 2023, Medicare would be able to begin negotiate pricing for a small number (no more than 10) of the costliest drugs and those prices would go into effect in 2025. The number of drugs would scale up to 15 in 2026 and 2027 and 20 beginning in 2028.

- Require drug manufacturers to pay rebates to the government if their prices for single-source drugs and biologicals covered under Medicare Part B (called "Part B rebatable drugs") and those covered under Medicare Part D (excluding those with an average annual cost of less than $100; called "Part D rebatable drugs") increase faster than the rate of inflation (CPI-U). Manufacturers that do not pay their owed rebates would owe the government civil monetary penalties of 125% of the original rebate amount.

- Lower out-of-pocket costs for seniors (maximum of $2,000 a year for their drugs under Medicare Part D)

- Mandate payors such as including Medicare Part D plans and private group or individual health plans to charge patient cost-sharing of no more than $35 per month for insulin products

- Require adult vaccines covered under Part D be covered at no cost (e.g. removal cost-sharing)

- Eliminate the Trump Administration's drug rebate rule (the rule had never gone into effect and was already delayed until 2023 by the Biden Administration) effective in 2026

2. Importation

In July 2021, President Biden issued an Executive Order on Promoting Competition in the American Economy. Among other goals, the order supports state Canadian drug importation programs (see more on states' importation programs below) and directs the FDA to work with states and Indian Tribes that propose to develop Section 804 drug importation programs. The FDA also provided additional information on the Human Drug Imports website for states and tribes interested in developing a Section 804 of the FD&C Act Importation Program in August 2021. The Executive Order followed the Trump Administration's July 2020 Executive Order focused on increasing drug importation to lower drug prices, the Safe Importation Action Plan, and a final rule that implements Section 804 through time-limited Section 804 Importation Programs ("SIPs") and allows importation of certain prescription drugs from Canada.

3. Rebates

- **No Surprises Act and Consolidated Appropriations Act Transparency Requirement Implementation** – Biden Administration released an interim final rule on November 17, 2021 that would require health insurance issuers, employer-based health plans, and other group health plans to report annually on prescription drug and health coverage costs. These entities would need to publish reports to Departments of Health and Human Services (HHS), Labor, and the Treasury on prescription drug pricing trends and rebates, as well as their impact on premiums and consumers' out-

of-pocket costs. The Departments accepted comments on the interim rule through January 24, 2022.

- **42 CFR 1001.952(h)(5) Amendment Effective Date Delay** – On November 30, 2020, the HHS issued a final rule establishing four changes to the regulatory safe harbors to the Federal anti-kickback statute (Social Security Act Section 1128B(b)). Among other actions, the final rule (1) amended 42 CFR 1001.952(h)(5) to remove safe harbor protection for reductions in price for prescription pharmaceutical products provided to plan sponsors under Part D; (2) created a new safe harbor at § 1001.952(cc) for certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations that meet certain criteria; (3) created a new safe harbor at § 1001.952(dd) for fixed fees that manufacturers pay to pharmacy benefit managers (PBMs) for services rendered to the manufacturers that meet specified criteria; and (4) added new paragraphs (6)-(9) to 42 CFR 1001.952(h), defining certain terms. The final rule was published with an effective date of January 29, 2021, except for the amendments to 42 CFR 1001.952(h)(5), which were to be effective on January 1, 2022. However, following a lawsuit challenging the final rule filed in the U.S. District Court for the District of Columbia on January 12, 2021, the Court issued an order postponing until January 1, 2023 the effective date of all provisions of the final rule that were originally scheduled to take effect on January 1, 2022. As a result, consistent with that order, HHS notified the public via the Federal Register that the effective date of the amendments to paragraph 42 CFR 1001.952 (h)(5) in the final rule is now January 1, 2023.

4. Most Favored Nation Drug Pricing Model

The Trump Administration issued the most-favored nation ("MFN") pricing model for Medicare Part B and Medicare Part D through an Executive Order in September 2020 that would have created a mandatory, seven-year payment model for the 50 highest-priced drugs and biologics covered by Medicare Part B. HHS then released a November 2020 MFN Model interim final rule, with the model performance period beginning on January 1, 2021. The MFN model was not implemented on January 1, 2021 following four lawsuits and a nationwide preliminary injunction. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction in *California Life Sciences Ass'n v. CMS*, No. 3:20-cv-08603. The court preliminarily enjoined HHS from implementing the MFN Model and the November 2020 interim final rule. As a result, in August 2021 HHS, among other proposals, proposed to rescind the November 2020 MFN Model interim final rule and invited proposal comments, which were posted in the Federal Register on December 29, 2021.

5. Transparency in Coverage

The Trump Administration released the Transparency in Coverage Final Rule in October 2020. The Final Rule requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets to

disclose on a public website information regarding in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs. Importantly, the Final Rule requires all three figures to be published in machine-readable file formats.

The Department of Labor and HHS announced in an FAQ on August 20, 2021 that they would defer enforcement of the Final Rule requirement that plans and issuers publish machine-readable files relating to prescription drug pricing pending further rulemaking. Additionally, the rules go into effect January 1, 2022, but the Departments will defer enforcement of final rules' requirement to publish the remaining machine-readable files that are not pending further rulemaking until July 1, 2022.

The FAQ announcements followed the PCMA lawsuit against HHS and several other federal agencies filed on August 12, 2021 in the United States District Court for the District of Columbia. The lawsuit sought to invalidate the historical net price disclosure requirement promulgated under the Final Rule. Among other arguments, PCMA stated that while the requirements were adopted with the stated purpose of helping consumers make informed decisions about which health plans to purchase and how much they should expect to spend out of pocket under those plans, they actually offer no meaningful transparency to consumers because machine-readable files are designed to be automatically read and processed by computers, not human beings. As of November 2021, this lawsuit was still pending.

N. State Drug Pricing Initiatives

Authors: Theresa Carnegie, Hassan Shaikh, Bridgette A. Keller, and Pat Ouellette, Mintz Levin

States continued to be active with drug pricing legislation in 2021. Some key legislative trends that emerged throughout the year are highlighted below.

- **Drug Importation**. A handful of states have partnered with Canada to create wholesale importation programs to reduce prescription drug costs. Though there continues to be industry pushback, including a lawsuit against HHS by Pharmaceutical Research and Manufacturers of America ("PhRMA"), some states are waiting for HHS approval on their programs while others are looking at other countries as well for importation programs.

- **Drug Manufacturer Transparency**. Continuing the momentum from 2020, more states enacted laws or introduced bills designed to increase transparency around manufacturers' role in drug pricing in 2021. This type of legislation generally involves requiring drug manufacturers to report (whether to state regulators, insurers, pharmacies, or other drug supply chain stakeholders) various pricing-related information, such as price increases above a predetermined threshold during a given time period or a drug's wholesale acquisition cost.

- **Containing Price Increases**. Many more states have introduced bills with price control measures, including the imposition of fines on manufacturers for "unsupported" price increases beyond a certain rate or threshold. These bills included other manufacturer obligations such as disclosure and reporting requirements based on specified price increases.

- **PBM Regulation**. 2021 saw a continuation of the 2020 trend in which states concentrated on PBMs as part of their overall efforts to reduce prescription drug costs. From state licensure to reporting or aggregate rebate and manufacturer remuneration disclosure, states have used a variety of tactics to regulate PBMs. Other state strategies included introduction of network composition and adequacy requirements, minimum reimbursement amounts for pharmacies, limiting the amounts PBMs can charge to pharmacies for adjudicating claims, expansion of the definition of PBM to include entities that perform PBM activities, and prohibition on PBMs from using spread pricing.

O. 340B Developments

Authors: Theresa Carnegie, Stephnie John, and Pat Ouellette, Mintz Levin

- **Biden Administration and Manufacturer Litigation.** On May 17, 2021, the Biden Administration affirmatively stated its position that drug manufacturers are violating the 340B statute by denying covered entities access to 340B discounts for drugs dispensed through 340B contract pharmacies. On the same day, acting HRSA Administrator Diana Espinosa sent individual letters to six pharmaceutical manufacturers, including AstraZeneca, Lilly USA, Novartis, Novo Nordisk, Sanofi, and United Therapeutics. The correspondence informed the manufacturers that the statutory requirement to provide 340B covered entities with access to 340B priced drug products cannot be restricted because of how the covered entity chooses to distribute the covered outpatient drugs. HRSA concluded "nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing" to covered entities. As such, HRSA instructed the manufacturers to immediately begin offering 340B discounted covered outpatient drugs to covered entities regardless of whether the covered entity dispenses the drugs through an in-house pharmacy or a contract pharmacy. Furthermore, the manufacturers must credit and refund covered entities for any overcharges that resulted from the manufacturer's restrictions, dating back to when the restrictions were implemented over the summer of 2020. The correspondence from HRSA set a deadline of June 1, 2021, for each of the six manufacturers to provide HRSA with an update on their efforts to lift restrictions on covered entity access to 340B drug discounts, and warned manufacturers that they could face assessment of Civil Monetary Penalties ("CMPs") if they continued to restrict access to 340B pricing discounts.

AstraZeneca, Lilly USA, Novartis, and Sanofi have all filed emergency motions pertaining to HRSA's decision in ongoing litigation regarding the December Advisory Opinion and ADR Final Rule. On May 27, 2021, U.S. District Judge Leonard Stark held a hearing on the AstraZeneca case, but did not issue a ruling. However, Judge Stark appeared open to the possibility of another interpretation of the 340B statute regarding contract pharmacies. On the same day, U.S. District Judge Sarah Evans Barker allowed Lilly to amend its lawsuit over the December Advisory Opinion and ADR Final Rule to include claims related to the May 17 enforcement letter. While Judge Barker declined to grant Lilly's request for a temporary restraining order, she extended the June 1 deadline to June 10 to allow Lilly more time to prepare their plan for restoring discounts. If HRSA ultimately issues any CMPs against any manufacturer, the 340B Program will likely see additional lawsuits as manufacturers may appeal and challenge HRSA's authority to: (i) issue the guidance related to contract pharmacies and (ii) to impose penalties related to such guidance.

Though Two federal courts have ruled that drug companies are violating the law and do not have the right to unilaterally impose these types of restrictions on 340B discounts, a third federal court, the D.C. District Court, found HRSA's interpretation of the 340B statute was incorrect and invalidated HRSA's violation letters to two of the companies. The Biden Administration announced in December 2021 that it is appealing the D.C. District Court's ruling, a decision supported in a December 20, 2021 letter by more than 800 safety-net hospitals.

Amgen joined AstraZeneca, Boehringer Ingelheim, Eli Lilly, Merck, Novartis, Novo Nordisk, Sanofi, UCB and United Therapeutics in following through on 2020 plans to restrict 340B discounts, effective January 3, 2022. AbbVie also announced beginning February 1, 2022 it will no longer offer safety net hospitals 340B drug-pricing program discounts on drugs dispensed at contract pharmacies if the hospitals do not give AbbVie patient claims data for the contract pharmacies.

- **American Hospital Association ("AHA") v. Becerra**. In 2018, the HHS reduced the reimbursement rates for 340B hospitals because those hospitals can obtain the covered drugs far more cheaply than other hospitals and, according to HHS, it should not reimburse hospitals more than they paid to acquire the drugs. Prior to arriving to the U.S. Supreme Court, the district court ruled that HHS had gone beyond its statutory authority by reducing drug reimbursement rates for 340B hospitals.

  However, on July 31, 2020, the U.S Court of Appeals for the D.C. Circuit reversed and ruled that the HHS acted lawfully when it reduced Medicare Part B reimbursement to hospitals for 340B drugs by nearly 30%. The court stated that HHS had made its decision based on a reasonable interpretation of the Medicare statute. The Supreme Court heard oral arguments on November 30, 2021 and will likely release its decision in 2022.

P. Opioid Litigation Update

Authors: Roger Morris, Susan Trujillo, Christopher Dang and Hunter DeKoninck, Quarles & Brady

In December of 2017, the opioid multi-district litigation ("Opioid MDL") was formed in the Federal District Court for the Northern District of Ohio presided by Judge Dan Polster. Starting with an initial cluster of about 60 cases, the Opioid MDL has swelled to well over 3,000. These cases were brought by a variety of plaintiffs (*e.g.* states, counties, local municipalities) and filed in state and federal courts throughout the country. The cases were subsequently transferred to Judge Polster's court for the global coordination of pre-trial proceedings (*e.g.* dispositive motions, discovery, etc.) and, upon the conclusion of those proceedings, cases are transferred back to the original court for trial.

Generally, plaintiffs in these cases assert civil conspiracy, RICO and public nuisance claims against "defendant families," such as: drug manufacturers, drug distributors, PBMs and retail pharmacies. Plaintiffs' general allegations are that: manufacturers grossly misrepresented the risks of long-term use of opioid-based drugs; distributors failed to properly monitor for suspicious orders of those prescription drugs; and, retailers failed to fulfill their corresponding responsibilities and engage in safe and secure dispensing practices.

To address common legal and factual issues among the cases, Judge Polster either: (1) assigned cases to a specific litigation track in order to move it through to trial; or (2) stayed cases for future selection to a track. To date, Judge Polster has created the following litigation tracks, each of which have progressed at their independent pace:

- **Track 1**. Established in April 2018, this track contained three cases brought by Summit County, Ohio, Cuyahoga County, Ohio and the City of Cleveland. (*In re: Nat'l Prescription Opiate Litig.*, MDL 2804, Case No. 1:17-MD-2804, Dkt. No. 232.)

    - *Current Status*: In October 2019, shortly before trial was set to begin, the manufacturer defendants and distributor defendants settled and, therefore, this track has been discontinued with no trial.

- **Track 1-B**. This track was established in November 2019 for cases brought by Cuyahoga County, Ohio and Summit County, Ohio against pharmacy defendants that were severed from Track 1. (*Id.* at Dkt. No. 2940).

    - *Current Status*: The Track 1-B bellwether cases were originally set for trial in November 2020, but the trial date was stayed due to COVID-19 and has not yet been rescheduled.

- **Track 2**. Established in late 2019, track two involves cases filed by Cabell County, West Virginia and the City of Huntington, West Virginia. (*Id.* at 1218). The focus of this track is on certain distributor defendants and pharmacy defendants.

- *Current Status*: Judge Polster transferred the Track 2 distributor bellwether case back to its original court where trial began on May 3, 2021. The bench trial was tried before U.S. District Court Judge David Faber of the Southern District of West Virginia against distributors McKesson Corp., Cardinal Health Inc. and AmerisourceBergen Drug Corp. At trial, Judge Faber prohibited plaintiffs from presenting various pieces of evidence that Judge Polster had previously deemed admissible, including a 324-page congressional report with findings critical of the distributors, prior public statements made by distributors' executives and a variety of internal emails among distributor employees. Trial has concluded and the parties await a ruling from Judge Faber.

- **Track 3.** Established in April 2020, track three includes cases filed by Lake County, Ohio and Trumbull County, Ohio. (*Id.* at Dkt. No. 3262 & 3282). The focus of this track is on public nuisance claims against pharmacy defendants for their distribution and dispensing practices.

  - *Current Status*: The Track 3 trial began in October 2021 with a verdict reached on November 23, 2021. The jury found that CVS, Walgreens and Walmart "engaged in intentional and/or illegal conduct which was a substantial factor in producing the public nuisance," with the "public nuisance" defined as the "oversupply of legal prescription opioids and diversion of those opioids into the illicit market outside of appropriate medical channels." (*Id.* at Dkt. No. 4176). On December 21, 2021, the pharmacy defendants responded to the verdict by filing a joint motion for a new trial, arguing the court committed numerous legal errors including the court's dismissal of jurors for not being vaccinated for COVID-19, the court's refusal grant a mistrial after a juror was found to have been conducting independent research outside of court and the court's adoption of unfair jury instructions. On the same day, the defendants also sought interlocutory review by the Sixth Circuit of whether the public nuisance claim should be barred under Ohio's Product Liability Act.

- **"New Litigation" Track**. On April 7, 2021, Judge Polster identified five new tracks for cases filed against pharmacy defendants CVS, Walgreens, Walmart and Rite Aid. (*Id.* at Dkt. No. 3688).

- **Track 7**. The Montgomery County, Ohio case designated as Track 7. Dispositive motions for this track are not due until September 2022, but no trial date has been set. (*Id*. at Dkt. No. 3769).

- **Track 8**. The Cobb County, Georgia case was designated as Track 8. Dispositive motions for this track are not due until November 2022, but no trial date has been set. (*Id*. at Dkt. No. 3820.)

- **Track 9.** The Tarrant County case was designated as Track 9. Dispositive motions for this track are not due until December 2022, but no trial date has been set. (*Id*. at Dkt. No. 3817.)

- **Track 10**. The Durham County, North Carolina case was designated as Track 10. Dispositive motions for this track are not due until March 2023, but no trial date has been set. (Id. at Dkt. No. 3819.)

- **Track 11**. The Santa Fe County, New Mexico case was designated as Track 11. Dispositive motions for this track are not due until April 2023, but no trial date has been set. (Id. at Dkt. No. 3820.)

While the litigation tracks continue for most defendants, significant developments have occurred in settlement discussions for distributor defendants and one manufacturer defendant. On August 12, 2021, Judge Polster approved an agreement between the Plaintiffs' Executive Committee, many State Attorneys General, and four defendants, which resolves all opioid-related litigation brought against McKesson, Cardinal Health, AmerisourceBergen and Johnson & Johnson (including its subsidiary, Janssen Pharmaceutical). (*Id.* at Dkt. No. 3828.) Included among the terms of the settlement arrangement are: (1) the distributors' payment of no more than $21 billion over eighteen years and Johnson & Johnson's payment of no more than $5 billion over nine years; (2) states' and local governments' commitment to use settlement funds for the abatement of opioid addiction; and (3) injunctive relief that requires certain changes to the distributors' business practices and monitoring of customers' orders.

See Distributor Settlement Agreement available at: https://nationalopioidsettlement.com/wp-content/uploads/2021/12/Final-Distributor-Settlement-Agreement-12.23.21_Exhibit-Updates.pdf; Janssen Settlement Agreement available at: https://nationalopioidsettlement.com/wp-content/uploads/2021/12/Janssen-agreement-20211222.pdf

Q. Opioid-Related Cases Outside of the Opioid MDL

While most opioid-related cases have been consolidated into the Opioid MDL, several remained in state courts and, in some instances, have proceeded to trial, which have produced significant outcomes in recent months—creating momentous victories for both plaintiffs and defendants. Those cases, and their respective noteworthy outcomes, include:

- **California**: The City of Oakland, Santa Clara County, Los Angeles County and Orange County brought a lawsuit against pharmaceutical manufacturers Johnson & Johnson, Endo Pharmaceuticals, Teva Pharmaceuticals and Allergan PLC. *See People of the State of California v. Purdue Pharma, et al.*, Case No. 30-2014-00725287. On November 1, 2021, following a bench trial, the court ruled in favor of the manufacturers, finding they were not liable for fueling the opioid epidemic in the state. This decision serves as the first major victory for drug manufacturers in a state trial court.

- **New York**: A jury trial was recently held for a case brought by New York, Nassau County and Suffolk County. *See In re Opioid Litig*., Index No. 400016/2018, Suffolk County Supreme Court. Shortly before trial was to begin in July 2021, Johnson & Johnson settled with the state for $230 million. In the following months, most other defendants settled the case. However, Teva Pharmaceuticals refused to settle the case and claims against the manufacturer proceeded through trial. On December 30, 2021, the jury rendered a verdict against the company, finding it liable. A separate trial will now be held to determine the amount of damages owed by Teva.

- **Oklahoma**: A 2019 bench trial resulted in a verdict against Johnson & Johnson under a public nuisance claim, ordering it to pay $572 million, which was later reduced to $465 million. On November 9, 2021, the Oklahoma Supreme Court reversed the district court's verdict, explaining its refusal to allow veiled product liability claims to be converted into public nuisance claims. *State ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719, 2021 OK 54 (Okla. Nov. 9, 2021). This reversed the first major judgment against a drug manufacturer in the opioid crisis, which creates significant concern for all other cases proceeding in other state courts under public nuisance theories.

- **Washington**: A bench trial began on November 15, 2022 for a case brought by the state of Washington against McKesson Corp., Cardinal Health Inc. and AmerisourceBergen Drug Corp. The trial is expected to conclude in February.

In addition to the above-listed cases proceeding outside of the Opioid MDL, there are other pieces of ongoing opioid-related litigation with outcomes that may set important precedent or impact settlement discussions and settlement terms in the Opioid MDL.

First, nation-wide claims against OxyCotin manufacturer Purdue Pharma continue to have an uncertain future as the company continues to be unable settle disputes through bankruptcy. On September 17, 2021, a federal bankruptcy court approved Purdue Pharma's bankruptcy reorganization plan as part of a larger negotiated settlement with thousands of state and local governments. *In re Purdue Pharma L.P*., 633 B.R. 53 (Bankr. S.D. N.Y. Sept. 17, 2021). However, on December 16, 2021, Colleen McMahon of the U.S. District Court for the Southern District of New York rejected the plan, finding that the government plaintiffs could not release company owners from liability in civil cases involving opioid-related claims. *In re Purdue Pharma L.P*., No. 21CV7532(CM), 2021 WL 5979108 (S.D.N.Y. Dec. 16, 2021). Following the Judge McMahon's rejection, on January 3, 2022, U.S. Bankruptcy Judge Robert Drain the parties to mediation to reach new settlement terms.

Second, there has been recent movement in Walmart's October 2020 declaratory action file in Texas federal court against the Department of Justice and the Drug Enforcement Administration, which sought declaratory relief regarding pharmacies' obligations under the Controlled Substances Act. *See Walmart Inc. v. U.S. Dept. of Justice, et al*, Case No. 4:20-cv-00817-SDJ, Dkt. No. 1 (E.D. Tex. Oct. 22, 2020). In February 2021, Walmart's lawsuit was dismissed by the District Court on the grounds that Walmart failed to identify

action by the Department of Justice that adversely affected the company. *Id.* at Dkt. No. 79 (Feb. 4, 2021). On May 10, 2021, Walmart appealed the district court's ruling, requesting the Fifth Circuit to revive the declaratory judgment action. *See Walmart Inc. v. U.S. Dept. of Justice, et al.*, No. 21-40157 (5th Cir. May 10, 2021). On December 22, 2021, the Fifth Circuit affirmed the district court's dismissal of Walmart's lawsuit on the grounds that the action was barred by sovereign immunity and that there was no ripe case or controversy for the court. *Walmart Inc. v. U.S. Dept. of Justice, et al.*, No. 21-40157, 2021 WL 6063557 (5th Cir. December 22, 2021).

X. MEDICAL STAFF, CREDENTIALING, AND PEER REVIEW

Authors: Alexis Angell, Polsinelli, Avery Schumacher, Epstein, Becker, Green, and Hilary Velandia, Conner & Winters

(Updated January 2022)

Case Summaries follow the table.

TOPIC	CASE NAME AND CITATION
HCQIA IMMUNITY GRANTED	1. *Delashaw v. Seattle Times Co.*, Case No. C-18-0537JLR (W.D. Wash. Jan. 7, 2021) (Defendant enjoyed HCQIA immunity on a limited basis) https://casetext.com/case/delashaw-v-seattle-times-co-10
HCQIA IMMUNITY DENIED	2. *Kaki V. Tenet Healthcare Corporation*, No. 20-10004, 2021 WL 323249 (E.D. Mich. Feb. 01, 2021) *(See also* under "Scope of Judicial Review") 3. *Sujan v. Corona Regional Medical Center, et. al.,* No. EO71217, Cal. Court of Appeals, 4th Appellate Dist., 2nd Div. (March 8, 2021)
DATA BANK REPORTS	4. *Leadbitter v. Keystone Anesthesia Consultants, Ltd.*, 256 A.3d 1164 (Pa. 2021)
DUE PROCESS CLAIMS	5. *Melamed v. Cedars-Sinai Med. Ctr.*, B292794 (Cal. Ct. App. Mar. 22, 2021) http://www.gmsr.com/wp-content/uploads/2021/03/Melamed-v-Cedars-Sinai.pdf 6. *Natarajan v. Dignity Health*, 492 P.3d 294, 296 (Cal. 2021) 7. *Rieder V. Segal*, No. 19-0767, 2021 WL 1936057 (Iowa May 14, 2021)
BREACH OF	8. *Univ. of Miss. Med. Ctr. v. Sullivan, et al*, No. 3:19-cv-

TOPIC	CASE NAME AND CITATION
CONTRACT CLAIMS	00459-CWR-LGI (S.D. Miss. Oct. 8, 2021)
NPDB / RETALIATION / DEFAMATION / DISCRIMINATION	9. *Padmanabhan v. City of Cambridge*, No. 20-P-47 (Mass. App. Ct. Mar. 22, 2021) http://masscases.com/cases/app/99/99massappct332.html *10. Dr. Tareq Kass-Hout v. Community Care Network, Inc. et al., 2:20-CV-441-JPK (N.D. Ind. Aug. 20, 2021)* 11. *El-Khalil v. Usen*, Case No. 18-12759 (E.D. Mich., Jan. 14, 2021) https://casetext.com/case/el-khalil-v-usen 12. *Castro v. Yale Univ.*, Case No. 3:20cv330 (JBA) (D. Conn., Feb. 9, 2021) (Court denied Hospital's motion to dismiss Title IX claims) 13. *Sarkaria v. Summit Anesthesia Associates P.A.*, Case No. A-1675-19T3 (Superior Court of New Jersey, Appellate Division, Jan. 22, 2021), unpublished, non-binding opinion (Appellate court affirmed trial court's entry of summary judgment that removal from the OB call schedule due to concerns about clinical practice did not constitute an adverse employment action under the New Jersey Law Against Discrimination) 14. *Rebecca J. Denman, M.D. v. St. Vincent Medical Group, Inc., St. Vincent Carmel Hospital, Inc.*, 20A-PL-1236 (Aug. 18, 2021)
PEER REVIEW / PSQIA PRIVILEGE	*15. Hance v. Cleveland Clinic Foundation*, No. 110129, 2021-Ohio-1493 Ohio App. Ct. 8th Dist. (April 29, 2021) (Assertion of peer review protection rejected for failure to meet burden of proof.) 16. *Sujan v. Corona Regional Medical Center, et. al*., No. EO71217, Cal. Court of Appeals, 4th Appellate Dist., 2nd Div. (March 8, 2021) 17. *Palmer v. Christiana Care Health Services, Inc*., Case No. N19C-01-294CEV (Superior Court of Delaware February 22, 2021) *18. Takieh v. Banner Health,* Case No. CV-19-05878-PHX-MTL (D. Ariz. January 27, 2021)

TOPIC	CASE NAME AND CITATION
SCOPE OF JUDICIAL AUTHORITY	19. *Kaki V. Tenet Healthcare Corporation*, No. 20-10004, 2021 WL 323249 (E.D. Mich. Feb. 01, 2021) *(See also* under "HCQIA Immunity Denied") 20. *Tex. Health Huguley, Inc. v. Jones*, 02-21-00364-CV (Tex. App. Nov. 18, 2021)
NEGLIGENT CREDENTIALING	*21. Rieder V. Segal*, No. 19-0767, 2021 WL 1936057 (Iowa May 14, 2021)
ANTI-TRUST	None identified in this category.
BASIS FOR DISCIPLINARY ACTIONS	None identified in this category.

A. Case Summaries

***DELASHAW V. SEATTLE TIMES CO.*, CASE NO. C-18-0537JLR (W.D. WASH. JAN. 7, 2021)**

- Holding:
  - Summary judgment granted in part and denied in part as to a medical staff physician who sent allegedly defamatory letter critical of a professional colleague to a wide network of individuals within and outside of hospital leadership.
  - Defendant enjoyed HCQIA immunity for his complaint letter only to the extent that (i) its recipients were members of a hospital "professional review body," (ii) statements in the letter were not made with knowledge of falsity, and (iii) only as to damages, not equitable relief.

- Analysis:
  - Defendant Dr. Cobbs' communication relating to the professional conduct of his colleague, Dr. Delashaw, was a communication to a "professional review body" within the meaning of HCQIA only to the extent that it was sent to (ii) the officers and directors of the Swedish Medical Center, and (ii) the members of the MEC.
  - Copies of the letter sent by Dr. Cobb to (i) members of the Executive Council of the Swedish Medical Group, and (ii) other individuals, was not protected by HCQIA because these individuals were not members of a "professional review body."
  - Dr. Cobbs was not entitled to Summary Judgment based on HCQIA immunity for two statements in his letter as to which there was a material issues as to whether those statements were false and made with knowledge of their falsity.
  - Dr. Cobbs was not entitled to Summary Judgment as to Dr. Delashaw's claims for equitable relief.

- Facts:
  - Plaintiff, Dr. Delashaw was a neurosurgeon employed by the Swedish Medical Center since 2013, and promoted to Chair of Neurosurgery and Spine at the Swedish Neuroscience Institute (SNI) in 2015.
  - In November, 2016, Dr. Cobbs, a colleague, distributed a letter critical of Dr. Delashaw to a wide number of individuals, both within and outside of the Swedish leadership. He raised concerns regarding Dr. Delashaw's disruptive conduct, including intimidation and harassment of other staff and interference with other physicians' practices.
  - In December, 2016, Delashaw was notified that he was being moved out of his Chair position because of numerous complaints about his leadership.
  - Dr. Delashaw sued Dr. Cobbs (and others), alleging extreme reputation harm and loss of employment opportunities as a result of the letter. He brought claims of defamation, civil conspiracy, and tortious interference.

***KAKI V. TENET HEALTHCARE CORPORATION,* NO. 20-10004, 2021 WL 323249 (E.D. MICH. FEB. 01, 2021), APPEAL FILED BY *AMIR KAKI V. TENET HEALTHCARE CORPORATION, ET AL*, 6TH CIR., FEBRUARY 18, 2021**

- Holding**:**
  - The Court confirms the arbitration award in favor of plaintiff cardiologists, awarding compensatory damages in excess of ten million dollars, attorneys' fees, and reinstatement of the plaintiff cardiologists' clinical privileges for one year, holding that judicial review of the arbitrator's decision would be contrary to the Federal Arbitration Act (FAA). The arbitrator did not exceed her enumerated power under the FAA in deciding that the Health Care Quality Improvement Act (HCQIA) did not shield defendants from money damages.

- Analysis**:**
  - The defendants argued that the award should be vacated because (1) the arbitrator's decision not to grant HCQIA immunity is in manifest disregard of the law, and (2) the arbitrator exceeded her authority under the FAA.
  - The FAA provides that a court may vacate an arbitration award in four circumstances (1) where the award was procured by corruption, fraud, or undue means; (2) where there was evident partiality or corruption in the arbitrators; (2) where the arbitrators were guilty of misconduct by which the rights of any party has been prejudiced; or (5) where the arbitrators exceeded their powers. 9 U.S.C. § 10(a).
  - The Court declines to apply the common law "manifest disregard" standard to vacate the decision, as it is antiquated, contrary to the FAA, and its validity is at best an open question in the Sixth Circuit.
  - The arbitrator did not exceed her authority under the FAA because arbitration clause in the agreement between the parties specifically provided that the arbitrator could grant any remedy or relieve that was just and equitable, including specific performance or other equitable or legal remedy, and because the remedy was equitable and mandated by the False Claims Act.

- Facts**:**
  - Two cardiologists were fired from leadership positions at Detroit Medical Center (DMC) and their clinical privileges were not renewed. The adverse actions were upheld by the DMC Board despite favorable medical staff recommendations. Following their termination, the DMC informed 5,000 employees via email that the cardiologists had been fired for violating the hospital's standards of conduct.
  - The cardiologists filed suit against the DMC's parent, Tenet Healthcare Corporation, and related affiliates, alleging retaliation under the False Claims Act for reporting improper billing practices, tortious interference with business expectancies, breach of contract, and false light, among other claims. Tenet moved the trial court to compel arbitration pursuant to the arbitration provisions in the cardiologists' agreements with Tenet, which the trial court granted.
  - The arbitrator decided in favor of the cardiologists on four of their claims, finding that the defendants acted with malice and were not immune from money damages under the Health Care Quality Improvement Act (HCQIA). The plaintiff cardiologists moved the Court to confirm the award, while the Defendants sought to seal and vacate the award.

SUJAN V. CORONA REGIONAL MEDICAL CENTER, ET. AL., **No. EO71217, Cal. Court of Appeals, 4th Appellate Dist., 2nd Div. (March 8, 2021)**

- Holding:
  - Physician-plaintiff's claims of conversion of personal property, intentional interference with a prospective economic interest with his patients, intentional interference with contractual relations with his patients and that the physician and hospital defendants conspired and aided and abetted each other in committing the alleged torts were not protected "free speech on matters of public interest" activity under California's Anti-SLAPP statute because his legal complaints were based on the actions taken against him including a summary suspension.
  - The plaintiff's claims of defamation and intentional infliction of emotional distress (IIED) survived a motion to dismiss under the Anti-SLAPP statute even though based on the protected activity of peer review proceedings because he had submitted prima facie evidence to support his claims that the defendants "encouraged nursing and other staff members to file false and defamatory MIDAS reports against him. In addition, these actions, as alleged, "would support the conclusion of a trier of fact that the defendants' conduct was outrageous and, at a minimum, was done with conscious disregard of causing [the plaintiff] extreme emotional distress.
  - The defendants' argument that the lawsuit should be dismissed for the physician's failure to exhaust his administrative remedies in the form of his hearing and appeals right when he was summarily suspended failed because these proceedings would not have addressed his defamation and his IIED claims.
  - The defendants' argument that the physician's right to sue was contractually barred based on an agreement he signed in order to reinstate his clinical privileges was denied because his willingness not to "retaliate" against individuals involved in making and abetting the filing of the MIDAS reports did not include a prohibition

against filing a lawsuit.

- Their defense that the absolute immunity provisions of the California litigation privilege which protects statements made in anticipation of litigation, or in this instance hospital peer review, did not apply because the evidence to date supported a "reasonable inference that the MIDAS reports were not filed with the good faith intention to resolve a genuine dispute with [the plaintiff], but were filed with the express intention of ruining his professional reputation and running him out of the hospital."
- The defendants' claim of immunity under HCQIA also was rejected because the protections do not apply if the submission of information which formed the basis of the professional review action "is false and the person providing it knew that such information was false" citing to 42 U.S.C. Section 11111(a)(2). The plaintiff's evidence "defeat[ed] that immunity by submitting evidence defendants encouraged and/or pressured hospital and nursing staff to submit MIDAS reports the staff members know to be false".
- In addition, the trial court had concluded that the defendants' claim of absolute immunity protection under California law which is intended to protect acts taken by a committee of a hospital's professional staff as well as individuals communicating information to a peer review committee in evaluating a practitioner did not apply because their alleged conduct did not occur "in the course and scope of their roles as members of the peer review committee". The Court of Appeals accepted this result because there was evidence of malice which is not protected.
- Finally, the Court held that the defendants' argument that the California peer review privilege statute, which would have prohibited the introduction of the MIDAS reports into evidence so as to defeat the plaintiff's defamation and IIED claims failed because they had not raised this argument before the trial court which therefore was waived for purposes of the appeal.

❖ Analysis:

- The Court stated that the Anti-SLAPP statute was passed in California as a means of protecting the " constitutional rights of freedom of speech" and "continued participation in matters of public significance, and that this participation should not be chilled through the abuse of the judicial process", citing to the Code of Civil Procedure, Section 425.16, subd. (a).
- In determining whether the action in question is a SLAPP, courts apply a two pronged test. First, was the challenged action, as applied here, based on written or oral statements relating to proceedings with are authorized by law. Peer review proceedings would qualify under the statute. Second, if the prong is satisfied, the cause of action can be stricken "unless the court determines that the plaintiff has established that there is a probability that the plaintiff will prevail on the claim".
- Both the trial court and the Court of Appeals focused on the fact that the plaintiff's complaint referenced in the first holding above were based on alleged actions taken against him and not solely on the peer review process of preparing and submitting the MIDAS reports even though each of the claims includes by reference the submission of the allegedly false reports. It determined that the actions alleged, such as conversion of property and the other torts, would not be considered protected speech

under the first prong of the Anti-SLAPP statute as opposed to the defamation and IIED claims which were directly related to the peer review process and therefore qualified as protected activity. The underlying decision which formed the basis of his claims was the action to summarily suspend him which is not protected under the statute.

- Although the defamation and IIED claims are based on protected peer review activity, the plaintiff submitted prima facie evidence that would establish a probability he would prevail on both claims thereby satisfying the second prong of the Anti-SLAPP statute. This evidence included declarations by a colleague that she was aware of the efforts of other physicians who targeted her and the plaintiff by encouraging nurses to submit meritless MIDAS reports. In addition, a hospital director, in conducting an audit of the 86 reports determined that most were "petty or simply unworthy of consideration" ad many were fabricated. Furthermore, she concluded the plaintiff was unfairly targeted "for reasons unrelated to his professional practice".
- The failure to exhaust internal administrative remedies, in this case the plaintiff's decision to waive his hearing and appeals rights under the Bylaws, and instead enter into an agreement to abide by certain standards in order to be reinstated, is a common defense raised by hospitals if the physician instead runs to court seeking a temporary restraining order or similar judicial remedy. While this argument might apply regarding the decision to impose a summary suspension, the Court determined that the hearing process would not have addressed or satisfy his defamation and IIED claims. Therefore, this argument did not apply to those claims.
- On the contractual waiver claim, the Court looked close to the language contained therein. It noted that the physician had waived his right to a hearing and agreed not to retaliate against those who participated in the peer review process and his suspension. The Court observed, however, that the agreement was silent on the issue of whether the agreement not to retaliate meant that he would be prohibited from filing a lawsuit and nothing in the defendants' brief provided support for an argument that the term "retaliation" was broad enough to mean the filing of a suit.
- As to the claim of absolute immunity under the California litigation privilege, this argument failed as described in the Court's holding set forth above.
- Regarding the Court's analysis of the defendants' arguments that they were entitled to a qualified immunity under the HCQIA and also under California law see also the analysis set forth in the holdings above.

❖ Facts:

- The plaintiff, Dr. Sunil Sujan, was a board-certified internist on the medical staff at Corona Regional Medical Center from August, 2010 to July, 2016. In response to his competition with other physicians, he claimed that he was the subject of a targeted campaign to defame him by using the peer review process to encourage the filing of false MIDAS reports accusing him of being "unresponsive, dilatory, and ill-tempered" as a means of having him censured or suspended. MIDAS reports are used to identify when physicians allegedly are in violation of the hospital's and relevant policies which are then reviewed to determine whether the formal peer review process should be initiated which ultimately could include a review by the Medical Executive Committee and the possible imposition of disciplinary action.

- There were 86 MIDAS reports filed against him. The reports were audited by the Director of Risk Management to determine whether they met the criteria for peer review but in doing so, Sujan claimed that the Director uncovered a scheme to target him, that there was no basis for most of the claims and further, that the Director was told that "some of the nurses…were being directed to submit MIDAS reports against [Sujan] based on false and/or misleading allegations".
- In June 2016, one of his patient's died of heart failure under Sujan's care. Without conducting any investigation, or interviews or whether he was somehow negligent or responsible for the patient's death, the Chief of Staff convened the MEC who immediately summarily suspended his medical staff membership and clinical privileges. The patient in question was a heavy drug user and had a serious heart condition. A review by his insurance carrier later determined that he was not at fault for the patient's death. During the time of his suspension, Sujan alleged that the defendants took his patients and reassigned them to a competing group.
- July 7, 2016, the MEC voted to sustain the suspension unless he signed an agreement which established various conditions in order to be reinstated. Although he disagreed with the stated concerns set forth in the agreement and believed they were largely based on the false MIDAS reports, he signed anyway in order to get back on the medical staff and avoid a report to the Data Bank. The agreement also required that he waive his hearing rights and that he not retaliate against anyone involved in the peer review process including the filing of the MIDAS reports. The agreement was signed on July 13, 2016. Soon thereafter, he resigned from the medical staff.
- During the Summer of 2017 he was offered the position of a full-time hospitalist at another hospital. Initially, Corona refused to respond the other hospital's request for verification but agreed to do so if Sujan signed an absolute waiver of liability form from all claims relating to the verification information. The verification, however, included a detailed summary of what he alleged were the false and defamatory statements which were used to support his summary suspension. Sujan refused to sign. He subsequently filed suit as discussed above seeking compensatory damages.

***LEADBITTER V. KEYSTONE ANESTHESIA CONSULTANTS, LTD.*, 256 A.3D 1164 (PA. 2021)**

- Holding**:**
  - The Pennsylvania Supreme Court reversed the decision of the state appellate court, and held that medical peer review documents may be protected under the Pennsylvania Peer Review Protection Act (PRPA) even if they are not generated by a committee whose main focus is peer review (i.e., a "peer review committee"), if the documents are generated from committee performing a peer-review function (i.e., the credentialing committee). It also held that HCQIA protects National Practitioner Data Bank (NPDB) query responses from production, regardless of contrary state law. This holding limits Pennsylvania Supreme Court case law precedent (*Reginelli v. Boggs*) and is contrary to the decision of the lower court.

- Analysis**:**
  - A credentials committee is a "review committee" under PRPA to the extent that it is

reviewing the quality and efficiency of care provided by a health care practitioner.
- Hospital licensing regulations do not require hospitals to specify which committees undertake peer review, and hospitals can have multiple committees that do so.
- The statutory text and purpose of HCQIA clearly establish that NPDB query responses are privileged, and federal law supersedes contrary state law. HCQIA and its regulations treat as privileged the information the NPDB provides to hospitals in response to requests concerning a specific practitioner; this privilege exists regardless of any aspect of state law to the contrary.

❖ Facts**:**
- Pennsylvania state appellate court upheld an order compelling a hospital to produce the un-redacted contents of a physician's credentialing file. The appellate court also compelled the hospital to produce NPDB query responses in the hospital's possession.
- At the lower appellate court level, appellant hospital unsuccessfully asserted that the Pennsylvania peer review statute and HCQIA protected the peer review documents from production.
- While the lower appellate court agreed that the professional evaluations used by the hospital's credentialing committee evaluated the quality and efficiency of services performed by the physician, and thus met the definition of peer review documents under the PRPA, the state peer review statute, it cited the 2018 Pennsylvania Supreme Court decision in *Reginelli* as binding precedent against protecting the credentialing documents in question. *Reginelli v. Boggs,* 181 A.3d 293 (Pa. 2018).
- In *Reginelli*, the Pennsylvania Supreme Court held that the state peer review privilege only applies to peer review documents of a review *committee*, and not to peer review documents of a review *organization*. In interpreting the state peer review statute, the *Reginelli* court defined a "review committee" as "any committee engaging in peer review" and a "review organization" as "any hospital Board, committee, or individual reviewing the professional qualifications or activities of its medical staff or applicant for admission thereto." The lower appellate court applied the holding in *Reginelli* to the credentialing file, and held that because a credentialing committee is a review *organization* its documents are not protected. The Pennsylvania Supreme Court clarified and limited its holding in *Reginelli*, explaining *Reginelli* does not stand for the premise that a committee must engage *exclusively* in peer review to qualify as a review committee.

***MELAMED V. CEDARS-SINAI MED. CTR.*, B292794 (Cal. Ct. App. Mar. 22, 2021)**

❖ Holding:
- The appellant surgeon failed to exhaust administrative remedies as to the only issue he raised on appeal (i.e., whether the medical staff's decision to uphold the summary suspension after 14 days was supported by sufficient evidence), accordingly the appeal is dismissed.

❖ Analysis:
- The issue on appeal is whether the appellant surgeon exhausted administrative

remedies with respect to the limited grounds for appeal.

- Facts:
  - The appellant orthopedic surgeon was summarily suspended for clinical quality of care issues in July of 2011. After a fair hearing on the summary suspension (and other issues not relevant to the appeal), the Hearing Committee concluded (among other things) that the summary suspension was reasonable and warranted at the time it was imposed, but that the portion of the suspension still in effect should be lifted. The surgeon appealed the summary suspension to a trial court, which denied the petition. On appeal, the appellant surgeon did not challenge the summary suspension at the time it was imposed, but instead challenges the sufficiency of the evidence supporting the medical staff's decision to uphold the summary suspension for more than 14 days.

***NATARAJAN V. DIGNITY HEALTH*, 492 P.3D 294, 296 (CAL. 2021)**

- Holding**:**
  - The Supreme Court of California held that a hospital fair hearing officer is not presumptively biased in favor of the hospital by virtue of the fact that the hearing officer could be hired again for future engagements at the same hospital or system; whether such a financial interest creates an "intolerable risk of bias requiring disqualification" depends on the circumstances.

- Analysis**:**
  - In some cases, depending on the circumstances, the hearing officer's financial interest in currying favor with the hiring entity could create an intolerable risk of bias, requiring disqualification, but those circumstances were not present in the instant case. The Court specifically cited to a provision in the hearing officer's contract that prevented the hearing officer from serving again for the same entity for a period of 3-years, as eliminating any substantial financial likelihood of bias.
  - While hospitals are free to use hearing officers that they have used before and could use again without implicating financial bias, courts will examine the selection process for hearing officers and the existence of safeguards (such as contractual provisions) to determine whether the financial interest creates an intolerable risk of bias.

- Facts**:**
  - The hospital MEC adopted the recommendation of its *ad hoc* committee to terminate a hospitalist physician's privileges, following an investigation into continued and pervasive recordkeeping deficiencies. The hospitalist physician requested a hearing to appeal the revocation.
  - During the hearing, the physician invoked his statutory right to challenge the impartiality of the hearing officer. California law prohibits fair hearing panels and fair hearing officers from gaining a direct financial benefit from the outcome of the hearing. The hearing officer exercised his authority to deny the challenge. The hearing panel upheld the MEC's recommendation for revocation. The hospitalist physician filed an administrative appeal with the hospital's governing board, citing the hearing officer's purported financial conflict. The Board affirmed the panel's

decision.

- The hospitalist physician filed suit, and the superior court denied the petition, holding that the physician had not established that the hearing officer stood to gain a direct financial benefit from the outcome of the proceeding. The court of appeal affirmed the denial of the petition, holding that potential reappointment within the same hospital or system does not qualify as a direct financial benefit.
- The Supreme Court of California disagreed with the lower courts' reasoning, but affirmed the judgement.

***RIEDER V. SEGAL*, No. 19-0767, 2021 WL 1936057 (Iowa May 14, 2021)**

- Holding**:**
  - Prior malpractice lawsuits may be admissible in negligent credentialing cases in Iowa.
  - Iowa hospitals may not be afforded summary judgment when there is an expert witness stating the hospital engaged in negligent credentialing.

- Analysis**:**
  - Assuming, without deciding, that Iowa recognizes the tort of negligent credentialing, the Iowa Supreme Court held that while evidence surrounding prior malpractice lawsuits may not be admissible in malpractice cases, it may be admissible in negligent credentialing cases. Moreover, an expert witness's opinion on the issue of negligent credentialing created a disputed issue of material fact, thus rendering summary judgment in favor of the hospital inappropriate.

- Facts**:**
  - The defendant physician performed surgery on the plaintiff patient at the defendant hospital. On the same day the patient was discharged from the hospital, the Iowa Board of Medicine filed a statement of charges against the physician. In addition, the physician had previously given the hospital notice of the Iowa Board of Medicine's investigation into the physician's professional practices. Despite its knowledge of this, as well as numerous malpractice lawsuits against the physician and the physician's previous need to go to the Center for Personalized Education for Physicians, the hospital did not initiate an investigation into the physician. Ultimately, the physician discontinued his surgical practice due to his diagnosis of Parkinsonism. After the surgeries had bad outcomes, the patient filed suit against the hospital for negligent credentialing.

UNIV. OF MISS. MED. CTR. V. SULLIVAN, ET AL, No. 3:19-cv-00459-CWR-LGI (S.D. Miss. Oct. 8, 2021)

- Relevant Holding:
  - Plaintiff's Motion for Default Judgment against all Defendants was granted due to Defendants' repeated perjury, evidence destruction, and concealment of evidence which amounted to bad faith and willful abuse of the judicial process.

- Facts/Analysis:
  - Defendant Dr. Spencer Sullivan was head of Plaintiff University of Mississippi Medical Center's (UMMC) Hemophilia Treatment Center. The terms of Dr. Sullivan's employment agreement prohibited him from (i) taking or using patient information for his own benefit, and (ii) soliciting patients for his own independent practice. Less than two years after he was hired, Dr. Sullivan and his lawyer began preparations for Dr. Sullivan to open his own hemophilia clinic and pharmacy. Other UMMC employees including Defendants Linnea McMillan and Kathryn Sue Stevens, assisted Dr. Sullivan by preparing a spreadsheet with patient information such as birthdate, diagnosis, prescription information, insurance, and telephone numbers (the "List").
  - UMMC first brought a state lawsuit alleging Dr. Sullivan removed patient information in violation of his employment agreement. Throughout the state case, Dr. Sullivan, McMillan, and Stevens consistently denied taking or using the List or other patient information. After a newspaper published an article on the alleged theft, McMillan's ex-husband notified UMMC he had (and what was later confirmed to be) the List which he had obtained from his ex-wife's car.
  - UUMC subsequently filed a federal lawsuit alleging claims under the Computer Fraud and Abuse Act and Federal Trade Secrets Act. Initially, the Defendants continued to deny taking, possessing, or using the List. However, Defendant, Rachel Harris, hired independent counsel and produced over a thousand pages of previously unproduced text messages which contradicted Defendants' prior testimony. Additionally, in a response to a request for admission, Harris admitted that the Defendants all possessed and used the List at Dr. Sullivan's new clinic and that she previously lied. Dr. Sullivan eventually admitted to retaining a hard drive containing files and emails from UMMC (which contradicted his prior deposition testimony and discovery responses) and arranged for their production. The court found that the Defendants' repeated perjury, destruction of relevant evidence such as the List and patient files, and concealment of evidence through false statements amounted to bad faith and willful abuse of the judicial process. Accordingly, the court granted Plaintiff's Motion to Dismiss.

***PADMANABHAN V. CITY OF CAMBRIDGE*, No. 20-P-47 (Mass. App. Ct. Mar. 22, 2021)**

- Holding:
  - While a majority of the appellant neurologist's claims were properly dismissed on statute of limitations grounds, three claims alleging retaliation, defamation, and fraud based on the incorrect NPDB report survive, as the actual report took place within the 3-year time period.

- Analysis:
  - The issue related to this case is whether the Appellant neurologist's claims were barred by the 3-year statute of limitations. A fair hearing was held, and the recommendation was in part favorable to the appellant (the summary suspension was warranted, but immediate termination was not). The MEC nevertheless determined to keep the suspension in place pending further investigation. Further investigation

ensued by an independent third party, whose findings were similar to the findings of the fair hearing committee.
- A month after the independent report was submitted, the MEC had not issued a final determination. At which time, the appellant neurologist filed a complaint of discrimination against the hospital. Shortly thereafter, in October of 2011, the hospital filed a report to the National Practitioner Data Bank (NPDB). The NPDB report did not mention the allegation of "prescribing to a known addict" but instead stated that the appellant neurologist had voluntarily resigned (which was not true). The investigation continued for an additional 2.5 years (about 3.5 years from the initial summary suspension) until May 28, 2014, at which time the MEC commenced formal disciplinary proceedings against the appellant neurologist.
- The appellant filed suit raising Federal claims for retaliation, abuse of power, defamation, and deprivation of due process, alongside State law claims for defamation, abuse of process, intentional infliction of emotional distress, fraud, and a request for declaratory judgment. The lower court dismissed the complaint on statute of limitations grounds

❖ Facts:
- Appellant, an employed neurologist presenting *pro se*, had a history of complaints against the radiology department at the hospital where he worked. Around that time, in November of 2010, the appellant neurologist was summarily suspended for "prescribing to a known addict" after one of his patients died of an overdose. The MEC recommended immediate termination of privileges, citing that incident.

***Dr. Tareq Kass-Hout v. Community Care Network, Inc. et al.*, 2:20-CV-441-JPK (N.D. Ind. Aug. 20, 2021)**

❖ Relevant Holding:
- Defendants' Motion to Dismiss was granted in part on the grounds that Plaintiff physician adequately alleged he was Defendant hospital's employee and not an independent contractor, such that he may be entitled to relief under Title VII.

❖ Facts/Analysis**:**
- Plaintiff was a physician employed by Rush University Medical Center. Pursuant to a contract between Rush and Defendant hospital, Plaintiff was credentialed at Defendant hospital and worked there full time. Plaintiff was replaced by another physician and his contract was terminated. Plaintiff alleged claims for discrimination under Title VII and defamation.
- Defendant moved to dismiss Plaintiff's discrimination claims on the ground that Plaintiff was an independent contractor, and as such, was not entitled to seek relief under Title VII. The court applied a five factor test, finding that three factors weighed in favor of Plaintiff being considered Defendant's employee (i.e., Defendants' control and supervision over Plaintiff; Defendants' responsibility for the costs of operation, such as equipment, supplies, feels, licenses, workplace, and maintenance of operations; the length of the job commitment). Specifically, the Plaintiff alleged that hospital administration dictated how services were to be

provided, refused to provide him with specific equipment, forbade him from referring to providers outside the hospital, and required him to consult with certain physicians. In addition, Plaintiff alleged that the hospital had control over equipment, supplies, and operations, required Plaintiff to apply for medical staff membership, and was solely responsible for billing and collecting. Finally, the contract for Plaintiff's services auto renewed indefinitely, and when it was terminated he was replaced by someone else indicating that the position was ongoing.

***EL-KHALIL V. USEN*, Case No. 18-12759 (E.D. Mich., Jan. 14, 2021)**

- Holding**:**
  - Medical Center was entitled to summary judgement on physician plaintiff's claims that, in violation of the anti-retaliation provisions of the federal False Claims Act, 31 USC § 3729 *et seq*., he was denied reappointment in retaliation for his having reported several colleagues on the medical staff to federal authorities for alleged billing fraud.

- Analysis:
  - Under an FCA retaliation claim, the plaintiff must establish a *prima facie* case of retaliation, following which the defendant must establish a legitimate, non-retaliatory reason for the adverse action, and if it does, the plaintiff must then prove that the reasons given by the defendant are pretextual. In this case, Dr. Khalil was unable to make out a *prima facie* case, for two reasons.
  - First, there was no final "adverse action" alleged in his Complaint, because when plaintiff filed suit his application for reappointment was still pending and no final action had been taken by the Board – neither the Departmental recommendation nor the MEC recommendation rose to the level of an "adverse action" because neither was final.
  - Second, the plaintiff produced no evidence of any causal nexus between the denial of reappointment and his having reported several of his colleagues to the federal government for suspected billing fraud.
  - The court also dismissed the pendant state law claims without prejudice to refile them in state court.

- Facts:
  - Plaintiff Dr. El-Khalil, a podiatrist, had staff privileges at Detroit Medical Center (DMC) starting in 2008 and was reappointed every two years until his last term, a one year (probationary) term that expired on December 2, 2017.
  - In late 2016, Dr. El-Khalil met with federal authorities to report what he believed to be billing fraud by several other podiatrists on the DMC medical staff, including the Chair of Podiatry, Dr. Usen.
  - Because of delays in processing his reappointment application, Dr. El Khalil's privileges lapsed on December 2, 2017, but the review of his application continued beyond that date.
  - At Dr. El-Khalil's request, Dr. Usen was not directly involved in the reappointment approval process, but may have indirectly provided input; ultimately, the Department

of Podiatry recommended against approval of Dr. El-Kahlil's reappointment.
- The Credentials Committee and MEC both voted to deny reappointment, based largely on the denial recommendation by the Department.
- Dr. El-Khalil requested a fair hearing, and the hearing panel voted to reverse, leading the MEC then to vote in favor of reappointment. However, the Governing Body then voted to deny reappointment and that denial was upheld on appeal by the Board.
- After the MEC vote, but before any Governing Body action, Dr. El-Khalil sued DMC, alleging retaliation under the FCA.

***CASTRO V. YALE UNIV.*, CASE NO. 3:20CV330 (JBA) (D. CONN., FEB. 9, 2021)**

- Holding:
  - Court denied hospital's motion to dismiss Title IX claims, finding that since the hospital was a teaching hospital receiving federal funds for its residency program, plaintiffs had satisfactorily plead Title IX claims against hospital; Court also denied hospital's and university's motions to dismiss Title IX claims, finding that employees of educational programs may bring suit against federally-funded employers for sex-based discrimination even if they can seek remedy by suit under Title VII.

- Analysis:
  - Yale New Haven Hospital (the hospital) filed a motion to dismiss, arguing, among other things, that (1) Title IX does not apply to the hospital, an entity not principally engaged in the business of education; (2) the plaintiffs' relationships to an educational program or activity are too attenuated to entitle them to Title IX coverage; and (3) Title IX does not provide a private remedy for employment discrimination based on sex.
  - The court listed a series of factors that federal appellate courts have used to determine the "educational nature" of a program or activity: "the structure of the program, including the involvement of instructors and inclusion of examinations or formal evaluations; whether tuition is required; the benefits conferred through the program, such as degrees, diplomas, or other certifications; the 'primary purpose' of the program; and whether regulators accrediting the institution 'hold it out as educational in nature.'"
  - Applying the above factors, the court found the following allegations supported the conclusion that Yale New Haven Hospital, an academic medical center, was subject to Title IX: (1) the university and hospital have a contractual agreement formally integrating the hospital and the university, designed for the sharing of both staff and resources; (2) instructors at the hospital were employed by both the university and the hospital; (3) the hospital received federal funding because of its status as a teaching hospital; (4) participation in the residency program prepares residents and fellows to sit for examinations necessary for board certification; and (5) the hospital's website states that it is the primary teaching hospital of the university.
  - The court rejected the hospital's Title IX arguments and determined Title IX applies to academic medical centers when certain criteria are met.

- Facts:
  - Six female physicians alleged their male superior at Yale New Haven Hospital sexually harassed them, and that both the hospital and university ignored their complaints. One physician reported her superior touched her in a sexual manner, grabbed her face and kissed her over her objections. Another physician reported she subjected to discriminatory comments from her supervisor about her pregnancy and that she would not be assigned patients due to maternity leave, which was seven months away. After she gave birth, the male superior allegedly made unwanted comments about her appearance and attempted to spoon-feed her, grope and massage her on multiple occasions. Another physician reported she was grabbed and fondled by the supervisor at her residency graduation and provided video evidence. Plaintiff physicians filed claims against University, hospital and individual physician; relevant claims included sex discrimination and retaliation in violation of Title VII and Title IX.

***SARKARIA V. SUMMIT ANESTHESIA ASSOCIATES P.A.*, CASE NO. A-1675-19T3 (SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION, JAN. 22, 2021), UNPUBLISHED, NON-BINDING OPINION**

- Holding:
  - Appellate court affirmed trial court's entry of summary judgment and determination that the removal from the OB call schedule due to concerns about clinical practice did not constitute an adverse employment action under the New Jersey Law Against Discrimination.

- Analysis:
  - The Law Against Discrimination prohibits discrimination against an employee based in the employee's age. If a plaintiff establishes a prima facie case, that creates an inference of discrimination, which shifts the burden to the defendant to "articulate a legitimate, nondiscriminatory reasons for the employer's action." Plaintiff had argued that the group's October 2015 action of temporarily removing her from the OB call schedule was an adverse employment action. However, in the summary judgment ruling, the trial court determined such action was not an adverse employment action. The trial court allowed the age discrimination claim to go forward, finding a genuine issue of material fact as to whether the termination of her employment violated the New Jersey Law Against Discrimination.
  - The appellate court determined the trial judge did not err in determining the October 2015 temporary removal from the call schedule was an adverse employment action and that the physician could not establish she suffered an adverse employment action as a matter of law. The record showed the physician was removed from call schedule for a period of time after well-grounded complaints were filed by physicians and nurses not affiliated with the group. The physician also admitted she continued to work her regular night shifts and her pay and benefits did not change. After an investigation, she was permitted to return to the call schedule after completing a simulation training. At that point, the physician was medically unable to perform the simulation, as she herself stated.

- The appellate court determined the physician did not establish prima facie Law Against Discrimination case as she did not present any evidence that her age played a role in the group's actions.

❖ Facts:
- An anesthesiologist filed claims against her employer, a physician group, for breach of contract and age discrimination under the New Jersey Law Against Discrimination. Plaintiff was a 69-year-old anesthesiologist who had been employed by the anesthesia group since 1977. When the anesthesia group was bought by a large national company that acquires medical practices, co-workers began asking her when she would retire, slow down, or take less call. The physician and the group had a contract agreeing that should the physician have a disability for more than 120 consecutive days, the group could terminate the employment contract.
- In October 2015, the physician was temporarily removed from the call schedule after she was reported to be acting strangely after a case. The physician continued to work her regular night shifts and her pay and benefits did not change. The group opened an investigation and advised her on October 28 that she would not be terminated and could return to the OB call schedule after completing an OB training simulation. The physician reported she was "not in any shape or form" to participate in the simulation and did not complete the simulation.
- On November 7, the group terminated the physician's employment contract pursuant to the long-term disability provision of the employment contract. The physician brought claims of breach of contract and age discrimination under the New Jersey Law Against Discrimination.
- The trial court granted summary judgment to the group finding no breach of contract. The trial court allowed the age discrimination claim to go forward, finding a genuine issue of material fact as to whether the termination of her employment violated the New Jersey Law Against Discrimination.
- At trial, the judge granted a directed verdict in favor of the group after the physician's case in chief. Physician appealed.

***REBECCA J. DENMAN, M.D. V. ST. VINCENT MEDICAL GROUP, INC., ST. VINCENT CARMEL HOSPITAL, INC.,* 20A-PL-1236 (AUG. 18, 2021)**

❖ Holding**:**
- The Indiana Court of Appeals upheld a physician's $4.75 million jury verdict against a hospital for defamation and tortious interference with an employment relationship. The Court held that whether the hospital acted without justification, an element of tortious interference with an employment relationship, was appropriately a question for the jury. Likewise, the Court held that whether the nurse who reported the physician's suspected impairment was motivated by ill will, destroying the common interest privilege defense to defamation, was appropriately a question for the jury.

❖ Analysis**:**
- By failing to follow its own written physician impairment policy, which required immediate reporting, a prompt assessment, and blood testing, the physician was

denied notice, and the ability to defend herself.

- To prevail on a claim of defamation, a plaintiff must prove four elements: (1) a communication with defamatory imputation, (2) malice, (3) publication, and (4) damages. In Indiana, a qualified privilege is a defense to defamation, and a "common interest" privilege applies to intracompany communications regarding the fitness of an employee. However, that privilege is destroyed upon a showing of abuse. The Court found that the physician presented enough evidence to withstand a directed verdict as to whether the qualified privilege was abused (i.e., it was appropriately a question for the jury), where there was evidence that the nurse was motivated by ill will in reporting the physician.

❖ Facts**:**

- In December of 2017 a charge nurse reported an OB/GYN physician to the hospital for allegedly responding to hospital call smelling of alcohol. The hospital's written physician impairment policy required immediate reporting, to be followed by a prompt assessment, blood testing, and immediate relief from duty, none of which occurred. The charge nurse reported the physician approximately twelve hours after the interaction, at which time it was too late for the physician to submit to an evaluation or testing to clear her name. No one else smelled alcohol on the physician, and no one, including the charge nurse, witnessed concerning or unusual behavior.
- The hospital referred the physician to the Indiana State Medical Association's Physician Assistance Program, which led to a third-party evaluation, six weeks of in-patient treatment, and participation in an intensive five-year alcohol monitoring program.
- The physician sued the hospital and charge nurse claiming defamation, tortious interference with an employment relationship, fraud, and negligent misrepresentation and the jury returned the $4.75 million verdict for the physician in January of 2020.

***HANCE V. CLEVELAND CLINIC FOUNDATION*, NO. 110129, 2021-OHIO-1493 OHIO APP. CT. 8TH DIST. (APRIL 29, 2021)**

❖ Holding:

- Clinic failed to meet its burden of establishing that documents created by its Utilization Review Committee were privileged under the Ohio peer review statute (R.C. 2305.252) or under the Ohio Uniform Trade Secrets Act (R.C. 1333.61-1333.69) (UTSA) in which the Committee discussed efforts needed to improve the volume of neurosurgical cases.

❖ Analysis:

- In determining whether the documents were privileged under the peer review statute, the Court of Appeals, in citing to the statute and prior judicial precedence noted that the purpose of the law was "to protect the integrity of the peer-review process" in order to "improve the quality of health care" but it "is not a generalized cloak of secrecy over the entire peer-review process". In addition, the proponent must establish that a committee meets the statutory definition of a "peer review committee" and that each of the documents in dispute is a "record within the scope of a peer

review committee". Generalized assertions that the privilege applies is insufficient. Evidence must be produced in order to satisfy its burden of proof.

- The Clinic argued that the requested documents were created by a "utilization committee", which is a committee listed under the statute, that involves the "quality of patient care" and that it used the requested information to "increase patient access and improve patient care."
- In analyzing the trial court's decision to reject the Clinic's assertion that the documents were privileged under the peer review statute, the Court made the following findings:
- The only evidence to support the Clinic's arguments was a single affidavit which failed to establish that the "utilization review committee" or any other committee met the definition of a "peer review Committee". In fact, the affidavit does not even identify any specific committee.
- The affidavit does not assert that the physician affiant, his team or the Center for Spine Health which allegedly benefitted by the materials was a "peer review committee"
- The headings of the meeting minutes did not make any reference that it was a peer review committee or a utilization review committee and only recorded what was covered during the Center's meetings.
- For similar reasons, the Court found that the trial court did not abuse its discretion in ruling that the documents also were not privileged under the UTSA finding that the Clinic provided no substantive evidence that the requested documents contained trade secrets. And although it noted that under the UTSA will protect the secrecy of information alleged to be a trade secret by granting a request for a protective order, the Clinic never moved for such an order.

❖ Facts:

- This is a medical malpractice case in which the plaintiff sued the Clinic alleging that an employed neurosurgeon misdiagnosed the cause of her back pain and the resulting surgery left her permanently paralyzed from the waist down along with continuous and persistent pain. An amended complaint further claimed that she was never informed that the surgery could "substantially and permanently worsen her condition".
- Based on statements made during a deposition of one of the Clinic's neurosurgeons, the plaintiff filed a motion to compel the disclosure of documents which "referred to or described any intent or desire to motivate the neurology staff to improve patient access, increase time slots, recapture market share, counter loss of patient volume to competitors, or otherwise increase revenues and/or number of patients" including copies of any minutes in which these subjects were discussed.
- After reviewing the documents in camera, the trial court rejected the Clinic's argument that they were privileged under the Ohio peer review statute or the UTSA and ordered that they be produced. The Clinic appealed.

***SUJAN V. CORONA REGIONAL MEDICAL CENTER*, ET. AL., NO. EO71217, CAL. COURT OF APPEALS, 4TH APPELLATE DIST., 2ND DIV. (MARCH 8, 2021)**

See Case No. 3 above for summary

***PALMER V. CHRISTIANA CARE HEALTH SERVICES, INC.*, CASE NO. N19C-01-294CEV (SUPERIOR COURT OF DELAWARE FEBRUARY 22, 2021)**

- Holding:
  - The Court held requested peer review information maintained by the morbidity and mortality committee and credentials committee documents produced exclusively for use by the credentials committee were subject to the privilege, but other types of credentialing committee documents were not subject to the privilege.

- Analysis:
  - Whether documents should be withheld from production under the state statutory peer review privilege necessitates an analysis of the type of litigation where they are being sought, the type of committee whose documents are being queried and the type of information being sought.
  - Information of morbidity and mortality committee or similar quality assurance committee may be appropriate for peer review privilege because of the sensitivity of the information discussed.
  - However, the Court determined that credentialing committees are very different from a M&M committee and are less likely to implicate the peer review privilege so only records that are part of the committee's work, can be protected under the peer review privilege.
  - The Court distinguished between those peer review records which were part of the consideration of the outcome of the surgery from those regarding credentialing of the doctor; the latter were permitted for discovery, but the former were not.
  - Further, any documents produced by the credentialing committee that were shared with a different person, group or entity concerning the credentialing of the doctor or were not exclusively for the use of the credentialing committee were not subject to discovery.

- Facts:
  - The surviving spouse of a patient sued the hospital under allegations of respondeat superior, agency, supervision, and failure to control the doctor.
  - The plaintiff's request for peer review information was generic and did not differentiate the type of peer review committee, or whether the requested documents related to the surgery itself or the credentialing of the doctor.
  - The order came because of a motion to compel.

***TAKIEH V. BANNER HEALTH*, CASE NO. CV-19-05878-PHX-MTL (D. ARIZ. JANUARY 27, 2021)**

- Holding:
  - A prior peer review action and state court decision upholding the hospital's decision allowed the application of issue preclusion in a subsequent action brought under §1981 for racial bias.

- Analysis:
  - The Court held that under §1981, the plaintiff must show that his race was the but-for cause of the hospital revoking his PSA. The Court found that on the face of the complaint there were several independent non-discriminatory reasons for revoking the PSAs, so the §1981 claim was implausible.
  - The Court found that that the plaintiff was barred from relitigating the issues resolved in the peer review matter as part of his §1981 case because of issue preclusion when there was a judicial review of the peer review process and the hospital's peer review process was like an administrative agency.
  - The Court held that the plaintiff is precluded from relitigating only the factual issues that have been decided by the Court, not that the decision of the Court barred his § 1981 claim by res judicata. Because an Arizona state court found that the hospital's reasons for revoking the doctor's PSA were supported by substantial evidence of patient care issues, alteration of medical records and destructive behavior, the doctor was precluded from raising these issues in his § 1981 action.
  - The Court dismissed the claims with prejudice and the doctor did not have the right to amend his complaint; the court held amending the complaint would be futile considering that reasons other than racial motivation were the basis for the peer review decision.

- Facts:
  - After a fair hearing and appeal a hospital terminated a doctor's medical staff membership, clinical privileges, and physician service agreement (the "PSA"). This action was upheld in state court determining that the doctor was not deprived of due process in the hospital peer review hearing. This decision was on appeal when the doctor filed a new lawsuit asserting claims for relief under 42 U.S.C. § 1981.
  - The doctor's §1981 complaint included allegations that the PSA was revoked because he testified against the hospital in a wrongful death case and certain peer review doctors were motivated by professional jealousy and competition, and that another doctor initiated the MEC's peer review process because the plaintiff reported him to the hospital's chief clinical officer.

***KAKI V. TENET HEALTHCARE CORPORATION,* NO. 20-10004, 2021 WL 323249 (E.D. MICH. FEB. 01, 2021), APPEAL FILED BY *AMIR KAKI V. TENET HEALTHCARE CORPORATION, ET AL*, 6TH CIR., FEBRUARY 18, 2021**

See Case No. 3 above for summary

***TEX. HEALTH HUGULEY, INC. V. JONES*, 02-21-00364-CV (Tex. App. Nov. 18, 2021)**

- Holding**:**
  - The trial court's temporary injunction order requiring the hospital to grant a physician temporary hospital privileges to administer Ivermectin was reversed. The judiciary lacks the legal authority to intervene and compel a particular outcome in the hospital's legal exercise of its discretion to make credentialing decisions.

- Analysis**:**
  - "Just as we cannot legislate from the bench, we cannot practice medicine from the bench." The courts are generally not empowered to decide whether a particular medication should be administered, or whether a particular doctor should be granted ICU privileges.

- Facts**:**
  - Plaintiff's husband was in a medically induced coma in the hospital's intensive care unit (ICU) due to COVID-19. The Plaintiff requested that the hospital administer Ivermectin, a drug normally used to treat parasitic worms in livestock, which is not approved or authorized by the Food and Drug Administration (FDA) for treatment of COVID-19. The hospital and the patient's attending physician refused. The Plaintiff subsequently obtained a prescription and order for administration of Ivermectin through a telehealth visit with a physician unaffiliated with the hospital (i.e., a physician without privileges at the hospital where patient was being treated). The hospital refused to accept the order, and declined to administer Ivermectin.
  - The Plaintiff filed suit to force the hospital and its staff to administer Ivermectin to the Plaintiff's husband. Instead of ordering the hospital and its physicians to administer the treatment, the trial court issued a temporary injunction ordering the hospital to grant the telehealth physician temporary hospital privileges for the sole purpose of administering Ivermectin to the patient in the hospital's ICU. The appellate court reversed the order of the trial court, citing inappropriateness of judicial intervention.

***RIEDER V. SEGAL*, No. 19-0767, 2021 WL 1936057 (Iowa May 14, 2021)**

See Case No. 7 above for summary

XI. REGULATION, ACCREDITATION AND PAYMENT
(Updated January 2022)

A. Medicare/Medicaid Reimbursement: Professionals

1. 2022 Physician Fee Schedule: Critical Care Services
Author: Caitlin Forsyth, Davis Wright Tremaine LLP

Historically, CMS's policy for billing critical care services (and split/shared evaluation and management services) was reflected in several provisions in the Medicare Claims

Processing Manual. However, CMS withdrew these sections effective May 9, 2021 in response to a petition under the Department of Health and Human Services' Good Guidance regulation at 45 CFR 1.5. Following withdrawal of the Manual provisions, CMS announced it would address split/shared and critical care services through rulemaking.

In the calendar year (CY) 2022 Physician Fee Schedule (PFS) final rule, in accordance with its announcement that it would codify its policies on critical care services in rulemaking, CMS adopted the CPT Codebook prefatory language regarding critical care services as the definition of critical care services for Medicare purposes and the current CPT listing of bundled services. The CPT Codebook prefatory language regarding critical care services provides as follows:

> … critical care is the direct delivery by a physician(s) or other qualified healthcare professional (QHP) of medical care for a critically ill/injured patient in which there is acute impairment of one or more vital organ systems, such that there is a probability of imminent or life-threatening deterioration of the patient's condition. It involves high complexity decision-making to treat single or multiple vital organ system failure and/ or to prevent further life-threatening deterioration of the patient's condition.

86 Fed. Reg. 64996, 65159 – 65160 (Nov. 19, 2021).

As to the time duration for the correct reporting of critical care services, CMS adopted the rule that the physician or NPP will report CPT code 99291 for the first 30–74 minutes of critical care services provided to a patient on a given date, and that CPT code 99291 will be used only once per date. Thereafter, the physician or NPP will report CPT code 99292 for additional 30-minute time increments provided to the same patient. When critical care crosses midnight, a continuous service does not reset and create a first hour. However, any disruption in the service does create a new initial service. CMS gives the following example:

> [I]f intravenous hydration (96360, 96361) is given from 11 p.m. to 2 a.m., 96360 would be reported once and 96361 twice. For continuous services that last beyond midnight (that is, over a range of dates), report the total units of time provided continuously.

86 Fed. Reg. at 65161.

2. 2022 Physician Fee Schedule: Split/Shared Evaluation and Management Services

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

In the calendar year (CY) 2022 Physician Fee Schedule (PFS) final rule, CMS established the following with respect to its policies on split/shared evaluation and management

(E/M) services:

- A definition of split/shared E/M visits as E/M visits provided in the facility setting by both a physician and non-physician practitioner (NPP) in the same group. The visit is billed by the physician or NPP who provides the substantive portion of the visit. A "facility setting" is an institutional setting in which payment for services and supplies furnished incident to a physician or NPP's professional services is prohibited under 42 C.F.R. § 410.26(b)(1).

- For 2022, the "substantive portion" of the E/M visit will be defined as history, physical exam, medical decision-making, or more than half of the total time (except for critical care, which can only be more than half of the total time.

- For 2023, the substantive portion of the visit will be defined as more than half of the total time spent.

- To identify split/shared services, a modifier must be used on the claim

- The medical record must identify the two individuals who performed the visit. The individual providing the substantive portion must sign and date the medical record.

3. 2022 Physician Fee Schedule: Teaching Physician Services

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

Under current CMS policy, "if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service. For residency training sites that are located outside a metropolitan statistical area, PFS payment may also be made if a teaching physician is present through audio/video real-time communications technology (that is, ''virtual presence'')." 86 Fed. Reg. at 65165. In the CY 2022 PFS final rule, CMS adopted the policy that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included.

4. 2022 Physician Fee Schedule: Telehealth Services

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

In the CY 2022 PFS final rule, CMS announced that certain services added to the Medicare telehealth services list during the COVID-19 public health emergency (PHE) will remain on the list through December 31, 2023, which will give CMS additional time to evaluate whether the services should be permanently added to the Medicare telehealth services list.

CMS also implemented Section 123 of the Consolidated Appropriations Act of 2021 (CAA), which removes geographic restrictions and adds the home of the beneficiary as a permissible originating site for telehealth services furnished for the purposes of diagnosis, evaluation or treatment of a mental health disorder. For these services, there must be an

in-person (non-telehealth) service with the physician or practitioner within six months prior to the initial telehealth service and at least once every 12 months following the initiation of the telehealth services.

CMS also amended the current definition of interactive telecommunications system for telehealth to include audio-only communications technology, but only when such technology is used for telehealth services for mental health disorders furnished to established patients in their homes.

5. 2022 Physician Fee Schedule: Therapy Services

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

Under current CMS policy, CMS makes payment at 85 percent of the Part B payment amount for physical therapy and occupational therapy services furnished in whole or in part by physical therapist assistants (PTAs) and occupational therapist assistants (OTAs). CMS defines services furnished in whole or in part by PTAs or OTAs as those for which the time spent by the PTA or OTA exceeds a *de minimis* threshold.

In the CY 2022 PFS final rule, CMS revised the policy for the *de minimis* standard to allow a 15-minute timed service to be billed without the modifiers that signal to CMS to pay at 85 percent of the applicable fee schedule if the PTA/OTA participates in providing care to a patient, but the PT/OT meets the Medicare billing requirements for the timed service on their own, without the minutes furnished by the PTA/OTA. This means that the PT/OT must independently provide 8 or more minutes of services.

6. 2022 Physician Fee Schedule: Physician Assistant Services

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

Section 403 of the Consolidated Appropriations Act of 2021 (CAA) authorizes CMS to make direct payment to physician assistants (PAs) for professional services that they furnish under Part B. Previously, CMS could only make payment to the employer or independent contractor of a PA. In the CY 2022 PFS final rule, CMS implemented this authorization and effective January 1, 2022, PAs may bill Medicare directly for their professional services, reassign payment for their professional services, and incorporate with other PAs in a group practice to bill Medicare for PA services.

B. Breaking News: Medicare Re-Defines "Reasonable And Necessary"

Author: Timothy P. Blanchard, Blanchard Manning

More than 40 years after the inception of the Medicare program, CMS took the opportunity to "implement[] regulatory standards to be used in making reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Part A and Part B." The "reasonable and necessary" test is one of the most important coverage and payment policy concepts in the Medicare program. This new regulation was included within rulemaking establishing a new Medicare Coverage of Innovative Technology (MCIT) pathway to Medicare

coverage for "new cures and technologies to improve health outcomes," but it applies to all coverage determinations. 86 Fed. Reg. 2987, 3009 (Jan. 14, 2021), amending 42 C.F.R. § 405.201(b)(definitions).

The final rule, which was originally to go into effect March 15, 2021, has been delayed twice by the Biden Administration, initially through May 15, 2021, 86 Fed. Reg. 14542 (March 17, 2021), and now until December 15, 2021, in a final rule explaining that "[f]uture rulemaking will provide an opportunity for us to fully consider the significant objections to the rule, and will provide another opportunity for the public to present contrary facts and arguments." 86 Fed. Reg. 26849, 26853 (May 18, 2021). The further delay will give CMS "an opportunity to address all of the issues raised by stakeholders, especially Medicare patient protections, evidence criteria and lack of coordination between coverage, coding and payment" before the rule goes into effect. *Id.*

The preamble to the now-delayed final rule explained that this rule is intended, in part, in response to recent rulings. 86 Fed. Reg at 2994. In Azar v. Allina Health Services, 139 S. Ct. 1804 (2019) the Supreme Court made clear that 42 U.S.C. § 1395hh(a)(2) requires that: "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation." Although the rule adopts longstanding subregulatory standards from the Medicare Program Integrity Manual, it also adds an alternative test for the Medicare "appropriateness" standard, based solely on commercial insurance coverage for the item or service (which would allow Medicare coverage on this basis even if the item or service exceeds the patient's medical need), and establishes the new MCIT (explicitly reversing longstanding published coverage policy interpretations that FDA determinations are not controlling for Medicare coverage purposes because "practical concerns" regarding "delayed access" to an unidentified "unique set of innovative devices").

It appears, however, that the main driver of this rulemaking was an Executive Order on Protecting and Improving Medicare for Our Nation's Seniors, No. 13890 (Oct. 3, 2019), 84 Fed. Reg. 53573 (Oct. 8, 2019), that directed encouragement of innovation by "streamlining of approval, coverage and coding process." Unfortunately, CMS appears to have been rushed to issue this rule, which was adopted only 73 days after the comment period closed and fails to adequately address important public comments on the proposed rule, resulting in errors in the preamble that render part of the regulatory text unintelligible. *See* 86 Fed. Reg. at 3009. While reportedly driven by Executive Order 13890, the preamble also failed to explain how the regulatory changes are consistent with the Executive Order, which also directs protecting and improving the Medicare program "by enhancing it fiscal sustainability" and "Eliminating Waste . . . to Protect Beneficiaries and Taxpayers."

C. Medicare/Medicaid Reimbursement: Facilities

Authors: Daniel J. Hettich and Ahsin Azim, King & Spalding

1. Medicare Bad Debt Changes

- Under current CMS policy, providers are permitted to claim reimbursement from Medicare for the bad debt of Medicare beneficiaries. For patients who are dually-eligible for Medicare and Medicaid, hospitals must first attempt to collect any unpaid balance from Medicaid before claiming reimbursement for the balance from Medicare. This is commonly referred to as the "must-bill" policy.

- Many states do not permit certain classes of providers to enroll in Medicaid. This has prevented many hospitals from complying with Medicare's must-bill policy because they cannot attempt collection from Medicaid before claiming the balance from Medicare.

- In the FY 2022 Inpatient Prospective Payment System ("IPPS") final rule, CMS finalized its proposal to require state Medicaid programs to accept enrollment of all Medicare-enrolled providers and suppliers for the limited purpose of determining Medicare cost-sharing obligations.

- CMS is requiring Medicaid programs to accept enrollment of all Medicare-enrolled providers and suppliers so that all classes of Medicare providers will be able to comply with the must-bill requirement.

2. Imputed Rural Floor

- In the FY 2022 IPPS final rule, CMS reestablished the imputed rural floor, *i.e.*, a minimum wage index for hospitals located in states that do not have rural areas.

- CMS first established the imputed rural floor in 2005. The additional payments made to hospitals under this policy were offset by a budget neutrality adjustment.

- CMS discontinued this policy in 2019 out of concern that the budget neutrality adjustment was putting hospitals in states with rural areas at a disadvantage.

- Section 9831 of the American Rescue Plan Act of 2021 ("ARPA") (enacted on March 11, 2021) instructed CMS to revive the imputed rural floor policy beginning in FY 2022.

- In accordance with that instruction, CMS reestablished the imputed rural floor policy in the final rule for FY 2022.

- Section 9831 of ARPA further specifies that the imputed rural floor should not be applied in a budget-neutral manner. Accordingly, CMS did not adopt a nation-wide budget neutrality adjustment for the imputed rural floor.

3. Rural Reclassification

- In the FY 2022 IPPS final rule, CMS finalized changes to the cancellation rules for rural reclassification under 42 C.F.R. § 412.103.

- In the FY 2022 IPPS proposed rule, CMS proposed requiring requests to cancel rural reclassification must be submitted to the CMS regional office not earlier than one calendar year after the reclassification effective date. CMS further proposed to repeal the current rule that a cancellation request must be submitted 120 days prior to the end of the federal fiscal year.

- In the final rule, CMS finalized its proposal that rural reclassifications must be in effect for at least one year before cancellation can be requested. However, in response to comments received, CMS elected not to finalize its proposal to repeal the current rule that cancellation requests must be submitted 120 days prior to the end of the federal fiscal year.

4. DGME Fellow Penalty

- Under current CMS policy, if a hospital is training residents in excess of its unweighted FTE cap for direct graduate medical education ("DGME"), and some of those residents are "fellows" (residents who are beyond their initial residency period), then the hospital's total DGME payment is reduced for each additional fellow it trains. 42 C.F.R. § 413.79(c)(2)(iii).

- Hospitals challenged CMS's policy in the U.S. District Court for the District of Columbia, alleging: (1) CMS's regulation at 42 C.F.R. § 413.79(c)(2)(iii) violates the statute by creating an impermissible third way of calculating weights for graduate medical education reimbursement and (2) the regulation should not be afforded deference because it is arbitrary and capricious under the Administrative Procedure Act. *Milton S. Hershey Med. Ctr. v. Becerra*, No. 19-CV-3411, 2021 WL 1966572 (D.D.C. May 17, 2021).
- On May 17, 2021, the District Court held that CMS's regulation is contrary to the statue because it conflicts with the statutorily mandated weights for fellows. The District Court instructed CMS to recalculate the plaintiffs' DGME payments accordingly. The government dismissed its initial appeal to the U.S. Court of Appeals for the D.C. Circuit rendering the district court decision final.

5. Exhausted/MSP Days

- On May 5, 2020, the Ninth Circuit vacated CMS's policy, adopted in 2005 rulemaking, of treating days that were not entitled to Part A payment as nonetheless being "entitled to benefits under Part A" for purposes of DSH. *See Empire Health Found. for Valley Hosp. Med. Ctr. v. Azar*, 958 F.3d 873 (9th Cir. 2020).

- Two prior circuits, DC and Sixth, had previously upheld CMS's policy. The Ninth Circuit, however, ruled that CMS's 2005 policy violated the plain meaning of the statute because CMS was effectively treating anyone "eligible" for Part A as being "entitled" to Part A but those words have different meanings under the statute.

- The Ninth Circuit, therefore, vacated CMS's 2005 regulation and ordered CMS to reinstate the prior version under which only "covered" Part A days are included in the Medicare fraction.

- In November of 2021, CMS posted the 2019 Medicare SSI fractions for hospitals nationwide. *See* CMS Manual System, Pub 100-09 Medicare Contractor Beneficiary and Provider Communications, Transmittal 11127 (Nov. 16, 2021). Consistent with the Ninth Circuit's mandate, CMS calculated those fractions for the over 500 hospitals within the Ninth Circuit's jurisdiction using the pre-2005 regulation in which only days that were covered, *i.e.*, paid, under Part A were included. Over eighty percent of Ninth Circuit hospitals saw their Medicare fractions increase based on the restoration of CMS's pre-2005 regulation.

- The Supreme Court heard oral arguments in November 2021, and a decision is expected by the Summer of 2022.

6. Section 1115 Days

- On November 13, 2020, the United States Court of Appeals for the District of Columbia Circuit affirmed a grant of summary judgment to the Florida Hospital Association and ten Florida hospitals in their challenge to the calculation of their Medicare DSH payments, directing CMS to include in the hospitals' Medicaid fraction inpatient days attributable to uninsured and underinsured patients covered by the Florida Low-Income Pool. *See Bethesda Health, Inc. v. Azar*, No. 19-5260 (D.C. Cir. 2020).

- CMS did not allow Florida hospitals to include LIP days in their Medicaid fractions. The court said Section 1115 days can be counted so long as patients received inpatient services regardless of whether the project gave a patient right to these services or allowed the patient to enroll in an insurance plan that provided the services.

- In reaching this conclusion, Judge Collyer relied in part on the Fifth Circuit's decision in *Forrest General Hospital v. Azar*, 926 F.3d 221 (5th Cir. 2019), which had reached a similar ruling with respect to a 1115 waiver approved for Mississippi. Importantly, both courts distinguished the D.C. Circuit's earlier decision in *Adena Regional Medical Center v. Leavitt*, 527 F.3d 176 (D.C. Cir. 2008), and similar cases in which patients had received inpatient hospital services funded not by 1115 waiver authority but by state-law mandates or Medicaid DSH grants.

- CMS proposed in the 2022 IPPS proposed rule to limit the universe of Section 1115 days that can be included in the Medicaid fraction. Specifically, CMS proposed that Section 1115 days may only be counted in the Medicaid fraction if the patient directly received inpatient hospital insurance coverage on such days.

- CMS decided not to finalize its proposed treatment of Section 1115 waiver days in the 2022 IPPS final rule. CMS said that it is continuing to review the comments received and will address them in a separate document.

7. Consolidated Appropriations Act, 2021

- Eliminated $4 billion in Medicaid DSH cuts that were scheduled to go into effect in FY 2021, 2022, and 2023; essentially just a delay of the cuts as they will be implemented in FY 2026 and 2027.

- Increased Medicare-funded residency cap for teaching hospitals by 1,000 slots, effective FY 2023. The increase will be phased in with 200 new slots per year until the slots are filled.

- Revamped method for calculating hospital-specific Medicaid DSH limit to remove all costs for Medicaid-eligible patients with primary third-party coverage from the calculation of the hospital's uncompensated care. Provision is effective Oct. 1, 2021.

- The Act created Rural Emergency Hospitals ("REHs"), a new category of provider that will be eligible to enroll in the Medicare program effective January 1, 2023. REHs can only provide emergency department and observation care and certain outpatient services. The statute authorizes CMS to allow REHs to provide skilled nursing facility services in distinct part units. REHs will be paid at a rate of 105% of the outpatient prospective payment ("OPPS") rate for covered outpatient services, including the application of any copayment amount, and will receive a monthly subsidy.

    - In the CY 2022 OPPS proposed rule, CMS solicited comments regarding the health and safety requirements that should apply to REHs, and conditions of participation that should apply to them.

    - CMS received numerous comments on this topic, but it did not address them in the final rule.

    - In the press release that accompanied the issuance of the final rule, CMS said that it "looks forward to taking each of those comments into consideration during the rulemaking process for the development of the REH requirements."

    - Since January 1, 2023 is the statutory implementation deadline for REHs, CMS is expected to implement them in the CY 2023 rulemaking.

8. Graduate Medical Education Changes

- In the FY 2022 IPPS proposed rule, CMS proposed to implement the statutory changes to the GME payment rules that were enacted in the Consolidated Appropriations Act, 2021 ("CAA").

    - Section 126 of the CAA instructs CMS to distribute 1,000 new residency full-time equivalent ("FTE") cap positions to qualifying hospitals over a five-year period spanning 2023 to 2027.

    - Section 131 of the CAA provides an opportunity for qualifying hospitals to establish new FTE caps and/or per-resident amounts.

    - Section 127 of the CAA repeals the "separate accreditation" requirement for rural training track ("RTT") programs.

- In the FY 2022 IPPS final rule, CMS stated that it intends to address the public comments in a separate document due to the number and nature of the comments it received. The final rule does not indicate when providers can expect CMS to finalize its implementation of these statutory changes.

- The FY 2022 IPPS proposed rule also contained proposed changes to the guidelines for submitting data to the Intern and Resident Information System ("IRIS").

    - First, CMS proposed requiring hospitals to submit IRIS data in the new XML IRIS format that CMS has adopted starting with cost reporting periods beginning on or after October 1, 2021.

    - Second, CMS proposed that Medicare cost reports would be rejected unless both the cost report and the IRIS data contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents.

- In the FY 2022 IPPS final rule, CMS finalized (with modifications) its proposed changes to the IRIS submission guidelines. Hospitals will still be required to report IRIS data on the cost report for reporting periods beginning on or after October 1, 2021. But cost reports will not be rejected if the IRIS data does not match the cost report until cost reports for reporting periods beginning on or after October 1, 2022. CMS said it will implement tolerance thresholds for variances between IRIS and cost report data to account for potential rounding variances. Finally, CMS stated that it is in the process of validating vendor IRIS software to ensure that it meets IRIS XML specifications and will release a list of all approved IRIS software vendors.

9. Disclosure of Median Negotiated Medicare Advantage Rates on Cost Reports

- In the 2021 IPPS rule, CMS finalized a requirement for hospitals to include their median negotiated Medicare Advantage rates for every MS-DRG beginning with cost reporting periods ending on or after January 1, 2021.

- CMS's objective was to "reduce the Medicare program's reliance on the hospital chargemaster and to support the development of a market-based approach to payment under the Medicare FFS system" beginning in FY 2024. 85 Fed. Reg. 58437.

- In the FY 2022 IPPS final rule, CMS finalized its proposal to repeal the requirement that hospitals report their median payer-specific negotiated charges for Medicare Advantage organizations in the Medicare cost report.

- CMS explained that this data would not be particularly helpful in bringing true market-based payment rates into the rate setting process because Medicare Advantage plans invariably use Medicare fee-for-service relative weights.

D. Medicare/Medicaid Reimbursement: Provider-Based

Author: Darby Allen, Davis Wright Tremaine, LLP

1. Provider-Based Reimbursement Updates

The 2015 Balanced Budget Act created the "site neutral" payment policy for the Medicare program. The law limits eligibility for provider-based reimbursement to off-campus provider based locations in existence as of 11/2/15 (grandfathered sites) and to new or existing on-campus provider-based departments.

CMS expanded on the policy through rulemaking by reducing reimbursement for clinic E&M visits (G0463) performed at grandfathered sites to match the reduced reimbursement at non-grandfathered sites (40% of OPPS rate). 83 Fed. Reg. 58818 (Nov. 21, 2018). The rate reductions were phased in over two years in 2019 and 2020.

AHA and hospitals challenged the 2019 cuts in court (*Am. Hosp. Ass'n v. Azar*, No. 1:18-cv-02841 (D.D.C. Dec. 4, 2018)).

D.C. District Court ruled CMS does not have authority to reduce rates for grandfathered sites. 410 F. Supp.3d 142 (D.D.C. Sept.17, 2019)

CMS went forward with second round of payment cuts in the 2020 OPPS Final Rule. 84 Fed. Reg. 61365 (Nov. 12, 2019).

AHA filed suit challenging agency again (*Am. Hosp. Ass'n v. Azar*, No. 1:20-cv-00080)

On July 17, 2020, the D.C. Circuit reversed the District Court's ruling on the 2019 rule

and held that the agency's site-neutral payment policy may stand (*Am. Hosp. Ass'n v. Azar*, No. 19-5352); petition for rehearing denied Oct. 16, 2020

E. Innovation Models

1. Home Health Value-Based Purchasing (HHVBP) Model

Caitlin Forsyth, Davis Wright Tremaine LLP

CMS implemented the HHVBP Model in nine states on January 1, 2016. According to CMS, the original HHVBP Model "resulted in an average 4.6 percent improvement in HHAs' total performance scores (TPS) and an average annual savings of $141 million to Medicare without evidence of adverse risks."

In January 2021, CMS announced the HHVBP Model would be expanded nationwide. On November 2, 2021, CMS published the calendar year 2022 Home Health Prospective Payment System (HH PPS) final rule establishing the end of the original model and the start of the expanded Model. The final rule also established Home Health Agency (HHA) eligibility criteria, payment adjustment rates, definition of cohorts, applicable quality measures, and payment methodology.

The expanded HHVBP Model begins on January 1, 2022 and includes Medicare-certified HHAs in all fifty (50) states, District of Columbia, and the U.S. territories. Under the expanded HHVBP Model, HHAs will receive adjustments to their Medicare fee-for-service payments based on their performance against a set of quality measures, relative to their peers' performance.

https://innovation.cms.gov/innovation-models/expanded-home-health-value-based-purchasing-model

2. Oncology Care Model

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

Under the Oncology Care Model, physician practices have entered into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. CMS is partnering with commercial payers in the model.

As of July 2021, there are 126 practices participating in the Oncology Care Model. Participating practices may bill Medicare a $160 monthly enhanced oncology service (MEOS) fee for each fee-for-service (FFS) Medicare beneficiary with a chemotherapy episode that is attributed to the practice. The money is intended to support enhanced oncology services. Participating practices can also receive retrospective performance-based payments if they are able to meet cost and qualify goals.

The six-year Oncology Care Model began with six-month episodes starting on July 1, 2016 and will operate for 11 consecutive performance periods. The last episodes will end

on June 30, 2022.

https://innovation.cms.gov/innovation-models/oncology-care

3. Radiation Oncology Alternative Payment Model

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

The Radiation Oncology Alternative Payment Model is a mandatory model that tests whether changing the way radiotherapy services are currently paid - via fee-for-service payments – to prospective, site neutral, modality agnostic, episode-based payments incentivizes physicians to delivery high-value radiotherapy care.

A participant in the model can be a physician group practice, a freestanding radiation therapy center, or a hospital outpatient department. CMS will pay model participants a prospective, bundled payment based on the patient's cancer diagnosis. The payment will cover the radiotherapy services furnished in a 90-day period for the 16 cancer types described in the final rule. The payment will be based on a common, adjusted national base payment, and will not vary depending on the setting where the radiotherapy is furnished (i.e., the payment will be site-neutral).

The model includes four quality measures starting performance year 2. The four quality measures are: plan of care for pain, treatment summary communication, screening for depression and follow-up plan, and advance care plan.

Beneficiaries are still responsible for cost-sharing, but because CMS is applying a discount, beneficiary cost-sharing may be, on average, lower relative to what is typically paid under traditional Medicare FFS.

The model will operate in randomly selected Core-Based Statistical Areas (CBSAs). A ZIP Code look up tool on the RO Model website provides all zip codes linked to the selected CBSAs. Radiotherapy providers and suppliers that furnish radiotherapy services in any of the zip codes are required to participate in the model.

The model has a five-year model performance period that, while originally slated to begin July 1, 2021, has been pushed back to January 1, 2023.

https://innovation.cms.gov/innovation-models/radiation-oncology-model

4. ESRD Treatment Choices Model

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

On September 18, 2020, CMS finalized its rule outlining the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, which aims to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD, while reducing Medicare expenditures and preserving or enhancing the quality of care furnished to ESRD beneficiaries.

Participation in the model is mandatory for ESRD facilities and managing clinicians in geographic areas that have been randomly selected by CMS. CMS aims to account for approximately 30 percent of the ESRD facilities and managing clinicians in the United States.

There are two payment adjustments in the model:

- The home and dialysis payment adjustment is a positive adjustment on all home dialysis and home dialysis-related claims, to incentivize investment in home dialysis infrastructure.

- The performance payment adjustment is an upward or downward payment adjustment based on the facility's or clinician's rate of home dialysis, and rate of transplant waitlisting and living donor transplant.

The model went into effect January 1, 2021. In July 2021, CMS proposed changes to the ETC Model to address health and socioeconomic disparities, which are a major contributor to chronic kidney disease. These proposed changes were part of the ESRD Prospective Payment System (PPS) Notice of Proposed Rulemaking.

On October 29, 2021, CMS issued a final rule under the ESRD PPS that finalized modifications to the ETC Model policies to encourage certain health care providers to decrease disparities in rates of home dialysis and kidney transplants among ESRD patients with lower socioeconomic status. The changes include incentives for participating ESRD facilities and managing clinicians to address health equity among their patients, including enabling access to alternatives to in-center dialysis, specifically home dialysis and transplantation, for ESRD patients of lower socioeconomic status.

https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model

https://www.cms.gov/newsroom/fact-sheets/cy-2022-end-stage-renal-disease-prospective-payment-system-final-rule-cms-1749-f

5. Comprehensive Care for Joint Replacement (CJR) Model

Author: Caitlin Forsyth, Davis Wright Tremaine LLP

The CJR model is a mandatory pilot program that pays hospitals in certain Metropolitan Statistical Areas ("MSAs") retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. The CJR model holds participant hospitals financially accountable for the quality and cost of a CJR episode of care from admission to 90 days post-discharge, with the goal of incentivizing increased coordination of care among hospitals, physicians, and post-acute care providers.

The first CJR model performance period began April 1, 2016. In May 2021, CMS issued a final rule extending the length of the CJR model through December 31, 2024 by adding

an additional 3 performance years. Performance year 6 began on October 1, 2021 and will end on December 31, 2022. Performance year 7 will begin on January 1, 2023 and performance year 8 will begin on January 1, 2024. The final rule also revised the episode of care definition, the target price calculation, the reconciliation process, the beneficiary notice requirements and the appeals process.

As of October 1, 2021, 330 hospitals are participating in the model.

https://www.federalregister.gov/documents/2021/05/03/2021-09097/medicare-program-comprehensive-care-for-joint-replacement-model-three-year-extension-and-changes-to

https://innovation.cms.gov/innovation-models/cjr

6. Emergency Triage, Treat, and Transport (ET3)

Author: Michael LaBattaglia, King & Spalding

The ET3 Model is a voluntary, five-year payment model that will provide greater flexibility to ambulance care teams to address emergency health care needs of Medicare Fee-for-Service (FFS) beneficiaries following a 911 call.

7. Primary Care First Model

Author: Michael LaBattaglia, King & Spalding

Voluntary five-year payment options that reward value and quality by offering an innovative payment structure to support delivery of advanced primary care.

In response to input from primary care clinician stakeholders, Primary Care First is based on the underlying principles of the existing CPC+ model design: prioritizing the doctor-patient relationship; enhancing care for patients with complex chronic needs and high need, seriously ill patients; reducing administrative burden; and focusing financial rewards on improved health outcomes.

CMS will use a focused set of clinical quality and patient experience measures to assess quality of care delivered at the practice.

The program was originally slated to start in January 2020, but was delayed until January 2021. Primary Care First includes two cohorts of participating practices: Cohort 1 began in January 2021 and Cohort 2 will start in January 2022.

8. Geographic Direct Contracting Model

Author: Michael LaBattaglia, King & Spalding

On December 3, 2020, CMS announced a new payment and care delivery model testing whether a geographic-based approach to care delivery and value-based care can improve health and reduce costs for Medicare beneficiaries across an entire geographic region.

The model will enable Direct Contracting Entities (DCEs) to build integrated relationships with healthcare providers and community organizations in a region to better coordinate care and address the clinical and social needs of Medicare beneficiaries.

DCEs will assume financial risk in return for enhanced flexibilities, making it possible for these entities to offer Medicare beneficiaries an increased focus on care coordination through care delivery innovation.

The model will be tested over a six-year period in four to ten regions and will include two three-year Model Agreement periods. Though initially slated to begin on January 1, 2022, the model is currently under review and will no longer begin on January 1, 2022. CMS will share additional information when available.

9. CHART Model

Author: Michael LaBattaglia, King & Spalding

In the summer of 2020, in light of rural hospital closures, CMS announced the Community Health Access and Rural Transformation (CHART) Model.

The CHART Model is a voluntary payment model designed for rural communities.

CMS aims to address disparities by providing a way for rural communities to transform their health care delivery systems by leveraging innovative financial arrangements as well as operational and regulatory flexibilities.

The model contains two tracks:

- Community Transformation Track that focuses funding on transforming care systems. CMS announced the selected Lead Organizations in fall 2021.

- Accountable Care Organizations (ACO) Transformation Track that uses value-based payment models where they are paid for quality and outcomes. ACO Transformation Track Request for Application (RFA) release date will be spring 2022.

10. Most Favored Nation Model (Rescinded)

Author: Michael LaBattaglia, King & Spalding

On November 20, 2020, CMS announced a mandatory, nationwide model that tests whether more closely aligning payment for Medicare Part B drugs with international prices and removing incentives to use higher-cost drugs can control growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.

Instead of paying solely based on manufacturers' average sales price (ASP), Medicare will pay based on a blending formula that includes the lowest adjusted international price, (the "MFN Price").

The model is scheduled to operate for seven years, from January 1, 2021, to December 31, 2027.

On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction in Biotechnology Innovation Organization v. Azar, No. 3:20-cv-08603, which preliminarily enjoins HHS from implementing the Most Favored Nation Rule.[1] Given this preliminary injunction, the MFN Model was not implemented on January 1, 2021, as scheduled.

CMS published a final rule on December 27, 2021, that rescinds the November 27, 2020, MFN Model interim final rule with comment period and removes the associated regulatory text, effective February 28, 2022.

See CMS-5528-F at: https://www.federalregister.gov/documents/2021/12/29/2021-28225/most-favored-nation-mfn-model.

F. Price Transparency Issues

Author: Jeff Davis, Bass Berry & Sims

1. Hospital Price Transparency Regulations

CMS updated several provisions under the hospital price transparency rules (86 Fed. Reg. 63458 (Nov. 16, 2021)), effective January 1, 2022, as part of the 2022 Outpatient Prospective Payment System (OPPS) Final Rule.

The hospital price transparency rules first went into effect January 1, 2021 (84 Fed. Reg. 65524 (Nov. 27, 2019)). They implement the statutory provision that requires each hospital to "establish…and make public (in accordance with the guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital." 42 U.S.C. § 300gg-18(e). The rules apply to all Medicare and non-Medicare hospitals, except those that are federally owned, and includes all entities and locations operated under the same state license, as well as services provided through their employed physicians and non-physician practitioners. The rules impose two requirements on hospitals: (1) establish, update, and make public a list of all standard charges for all items and services; and (2) make public and update a consumer-friendly list of standard charges for a limited set of "shoppable services."

Under the transparency rules, hospitals must report the following five types of standard charges for each item or service provided by the hospital, whether in the inpatient or outpatient department setting: gross charge, payer-specific negotiated charge, de-identified minimum negotiated charge, de-identified maximum negotiated charge and discounted cash price. The information must be in a single digital file, in a machine-readable format, posted in a publicly available internet location, displayed prominently and clearly identify the hospital location associated with the charge information.

Hospitals also must make public standard charges for "shoppable services," including as

many of the seventy (70) shoppable services specified by CMS that are provided by the hospital and as many additional shoppable services selected by the hospital, for a combined total of at least three hundred (300) shoppable services. CMS defines a "shoppable service" as a service that can be scheduled by a health care consumer in advance. Hospitals may use a format of their choosing to make the shoppable service information public online, so long as it is easily accessible through a publicly available internet location, is displayed prominently, and identifies the hospital location with which the information is associated. CMS will deem a hospital to meet the requirement if the hospital maintains an internet-based price estimator tool that meets certain criteria.

- *Updates to Requirement to Publish a Machine-Readable File of Standard Charges*

Based on CMS's concern over the inability of the public to access the machine-readable files posted by hospitals, CMS proposed additional guidance on methods through which hospitals must make standard charges available as part of the 2022 OPPS Proposed Rule (86 Fed. Reg. 42018 (Aug. 4, 2021)). CMS finalized these proposals in the 2022 OPPS Final Rule, effective January 1, 2022. Specifically, CMS finalized an amendment to the regulations to indicate that making the standard charge information publicly available without barriers includes, but is not limited to, "ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website." The change is intended to prohibit practices such as the failure to include a link for downloading the machine-readable file, use of "blocking codes" or CAPTCHA, and requiring agreement to terms and conditions or the submission of other information to access the pricing data.

- *Clarification of the Price Estimator Tool Option*

Additionally, CMS asserted as part of the Proposed Rule that the price estimator tools being used by some hospitals to meet the "shoppable services" posting requirements, fail to meet those requirements. CMS reiterated that, for hospitals that choose to comply with the requirement to post standard charges for shoppable services through use of a price estimator tool, the tool must produce a price estimate that is "tailored" to an individual user and the estimate must specify the amount the hospital anticipates the individual would pay for a shoppable service, absent unusual or unforeseen circumstances. CMS reiterated the clarification in the 2022 Final Rule, indicating that the agency does not view the clarification as a change to the existing price estimator tool requirements that CMS previously finalized.

- *Update to Applicability of Hospital Price Transparency Rules to State Forensic Hospitals*

In the 2022 Final Rule, CMS finalized its proposal to exempt state forensic hospitals from the price transparency rules.

- *Updates to Enforcement of Hospital Price Transparency Rules*

Under the hospital price transparency rules implemented effective January 1, 2021, CMS was authorized to take a number of actions related to non-compliance, including: provide a written warning notice; request a corrective action plan for material violations; and, if a hospital fails to respond to a request for a corrective action plan or fails to comply with the terms of a corrective action plan, impose civil monetary penalties of up to Three Hundred Dollars ($300.00) per day and publicize the penalty on the CMS website.

Based on CMS's concern over a high rate of hospital noncompliance and particular concern over noncompliance of large hospitals, the agency proposed to update the enforcement process as part of the 2022 OPPS Proposed Rule. Specifically, CMS proposed to increase penalties for noncompliance and proposed additional guidance on methods through which hospitals must make standard charges available. CMS finalized these proposals in the 2022 OPPS Final Rule, effective January 1, 2022.

Under the updated enforcement penalties, beginning January 1, 2022, the CMP amount will be scaled and vary based on hospital size, as measured by the number of beds, as follows:

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for Full CY of Noncompliance
30 or less	$300 per hospital	$109,500 per hospital
31 up to 550	$310 to $5,500 per hospital (number of beds times $10)	$113,150 to $2,007,500 per hospital
>550	$5,500 per hospital	$2,007,500 per hospital

See Table 76, 86 Fed. Reg. 63458, 63945 (Nov. 16, 2021).

CMS will determine the number of beds for a Medicare-enrolled hospital using the most recently available, finalized Medicare hospital cost report. If such information cannot be determined using Medicare hospital cost report data, CMS will request that the hospital provide documentation of its number of beds, in a form and manner and by the deadlines prescribed by CMS in a written notice provided to the hospital. If the hospital does not provide CMS with such documentation, CMS will impose a CMP on the hospital at the highest, maximum daily dollar amount ($5,500 per day).

- *Enforcement Actions To-Date Related to the Hospital Price Transparency Rules*

In April 2021, CMS began sending warning letters to hospitals that were not in compliance with the hospital price transparency regulations, which went into effect on January 1, 2021. CMS previously notified hospitals through a MedLearn Connects article dated December 18, 2020, that CMS would audit a sample of hospitals for compliance starting in January 2021, in addition to investigating complaints that are submitted to CMS related to hospitals that are allegedly failing to comply with the hospital price transparency regulations. CMS warned providers that they may face civil monetary

penalties for non-compliance with the price transparency regulations.

According to a media report, CMS reported that the agency had issued approximately 335 warnings for violations as of early December 2021. CMS requested that 98 hospitals submit corrective action plans. As of late December 2021, CMS had not imposed any CMPs against hospitals.

2. Transparency in Coverage Final Rules

On November 12, 2020, the Department of Health and Human Services, Department of Labor and Department of Treasury (the "Departments") published the Transparency in Coverage Final Rules ("TiC Final Rules") (85 Fed. Reg. 72158 (Nov. 12, 2020)). According to CMS, "The requirements in the transparency in coverage final rule will reduce the secrecy behind healthcare pricing with the goal of bringing greater competition to the private healthcare industry." The TiC Final Rules generally apply to traditional health plan coverage and does not apply to account-based group health plans or short-term limited-duration insurance.

The TiC Final Rules requires two types of disclosures: (1) disclosures to the public, and (2) disclosures to plan participants.

- *Disclosures to the Public:*

  According to CMS, most non-grandfathered group health plans or health insurance issuers offering non-grandfathered health insurance coverage in the individual and group markets will be required to make available to the public, including stakeholders such as consumers, researchers, employers, and third-party developers, three (3) separate machine-readable files that include detailed pricing information. These three (3) files must include the following:

Negotiated rates for all covered items and services between the plan or issuer and in-network providers;

The historical payments to, and billed charges from, OON providers; and

The in-network negotiated rates and historical net prices for all covered prescription drugs by plan or issuer at the pharmacy location level.

The TiC Final Rules required these files to be made public for plan years that begin on or after January 1, 2022.

- *Disclosures to plan participants:*

Most non-grandfathered group health plans and health insurance issuers offering non-grandfathered health insurance coverage in the individual and group markets will be required to make available to participants, beneficiaries and enrollees personalized out-

of-pocket cost information, and the underlying negotiated rates, for all covered healthcare items and services, including prescription drugs, through an internet-based self-service tool and in paper form upon request. According to CMS, an initial list of five hundred (500) shoppable services as determined by the Departments will be required to be available via the internet-based self-service tool for plan years that begin on or after January 1, 2023. The remainder of all items and services will be required for these self-service tools for plan years that begin on or after January 1, 2024.

According to the TiC Final Rules, a group health plan may satisfy the disclosure requirements by entering into a written agreement with its Third Party Administrator ("TPA") pursuant to which the TPA will provide the information required by the Rule. However, if the TPA fails to provide the required information, the group health plan remains responsible for non-compliance.

In March 2021, CMS issued new guidance on Github for developers and consumers of the machine-readable files required under the TiC Final Rules after it was determined that many hospitals, required to comply with the pricing transparency regulations, were using embedded code to block information from showing up on search engines. CMS states in its Github posting that, "All machine-readable files must conform to a non-proprietary, open standards format that is platform independent and made available to the public without restrictions that would impede the re-use of that information."

- *Delay of Enforcement of Certain Transparency in Coverage Final Rule Requirements*

On August 20, 2021, the Departments issued FAQs regarding implementation of certain provisions of the Consolidated Appropriations Act, 2021 (the CAA) and their intersection with the TiC Final Rules. The Departments indicated that they intend to enforce the machine-readable file provisions in the TiC Final Rules, subject to two exceptions. First, the Departments will defer enforcement of the requirement that plans and issuers publish machine-readable files regarding prescription drug pricing, pending further rulemaking (see below for discussion of additional rulemaking to address reporting of prescription drug pricing as required by the CAA).

Second, the Departments will defer enforcement of the requirement for plans and issuers to publish the other machine-readable files, including in-network rates and out-of-network allowed amounts and billed charges, until July 1, 2022. The Departments will begin enforcement of these requirements on July 1, 2022. In the case of 2022 plan years and policy years beginning prior to July 1, 2022, the Departments instructed plans and issuers to post the machine-readable files in the month in which the plan year (or policy year) begins.

3. No Surprises Act

- *The Legislation*

On December 27, 2020, the Consolidated Appropriations Act, 2021 ("CAA") was signed into law, which contains the "No Surprises Act" ("NSA") to ban "surprise medical bills," which Congress considers to be bills that a patient receives when an out-of-network ("OON") medical provider unexpectedly renders care to the patient. This Federal ban puts an end to making consumers responsible for the difference between the provider's charge and their insurer's allowed amount, a practice commonly known as "balance billing." The ban on surprise medical billing takes effect January 1, 2022. Key elements of the No Surprises Act include the following:

Providers are prohibited from balance billing patients and health plans are required to hold patients harmless from balance billing for all (1) OON air ambulance and emergency services and (2) for OON services provided at in-network facilities. A patient's out-of-pocket costs for these services, including deductibles, copayments and coinsurance, is limited to what they would have been had the services been provided in-network.

Under the "notice and consent" exception, the ban against balance billing does not apply if the facility or provider notifies the patient of the balance billing protections and obtains the patient's consent to waive the protections. The exception does not apply to pre-stabilization emergency services, certain ancillary services, or if the items or services result from unforeseen, urgent medical needs

The patient is taken out of any payment dispute process related to medical bills covered by the No Surprises Act. The law requires that insurers and providers first negotiate the payment rate during a thirty (30) day period. If an agreement cannot be reached, the provider and health plan may initiate a binding arbitration process called "Independent Dispute Resolution" to determine how much payment the insurer will provide for the service.

Health care providers would be required to share "good faith estimates" of the total expected charges for scheduled items or services with a health plan (if the patient is insured) or the patient (if the patient is uninsured).

Health plans would be required to send patients an "Advanced Explanation of Benefits" prior to scheduled care or upon request by patients looking for more information prior to scheduling.

Health plans would be required to ensure their in-network providers are up-to-date by updating their provider directory on a regular basis. This requirement includes a verification process that patients could access on-line or within one (1) business day of inquiry.

The No Surprises Act includes specific timely billing requirements for providers to bill patients and their health plans. Patients receiving bills after ninety (90) days would not be obligated to pay the bill, and if a patient paid such an untimely bill, the provider would be required to refund the payment with interest.

The new law applies to all types of health insurance plans patients receive from an employer as well as marketplace plans, including plans covered by the Affordable Care Act.

Ground ambulance services are not currently covered by the surprise medical billing ban, but a special advisory committee will look at ground ambulance services to determine if they should be covered in the future.

4. The Regulations

- *Requirements Related to Surprise Billing; Part I*

On July 13, 2021, the Departments of Health and Human Services, Labor, and Treasury (the "Departments"), along with the Office of Personnel Management, released an interim final rule with comment period ("IFC") implementing portions of the federal ban on surprise medical bills, entitled "Requirements Related to Surprise Billing; Part I" ("Part 1 IFC") (86 Fed. Reg. 36872 (July 13, 2021)).

The Part 1 IFC outlines the ban on balance billing with respect to emergency services furnished at OON emergency facilities, including post-stabilization services, as well as non-emergency services furnished by OON providers during visits at in-network facilities. The ban does not apply to non-emergency services and post-stabilization services if notice is furnished to a patient outlining the protections against balance billing and the patient consents to waive the protections and be balance billed. The notice and consent exception does not apply in the case of certain ancillary services, where balance billing is common, or if the items or services result from unforeseen, urgent medical needs.

The Part 1 IFC codifies a prohibition on patient cost-sharing that exceeds in-network levels. That cost-sharing amounts must generally be calculated based on the "recognized amount" for such services, which is:

An amount determined by an all-payer model agreement in place in a given state, if applicable;

If no all payer model agreement, an amount determined under state law; or

If no applicable state law, the lesser of either the billed charge or the qualifying payment amount ("QPA"), which is generally the plan's or issuer's median contract rate.

The Part 1 IFC addresses how the QPA should be determined. That amount will be used

to set cost-sharing amounts for patients treated OON and will be used as a factor in the independent dispute resolution ("IDR") process to determine payment amount to OON providers.

The Part 1 IFC details certain consumer notification requirements applicable to providers and facilities, as well as the complaint process that must be followed where violation by payers is asserted. Facilities and providers must make publicly available, post on a public website, and provide to any commercially insured patient, information regarding patient protections against balance billing. Similarly, group health plans and health insurance issuers must make publicly available, post on a public website, and include on each explanation of benefits, information regarding patient protections against balance billing.

- *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement*

On September 16, 2021, the Departments published a notice of proposed rulemaking ("NPRM"), entitled "Reporting Requirements Regarding Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement" (86 Fed. Reg. 51730 (Sept. 16, 2021)). The NPRM includes proposals to implement provisions in the NSA that require air ambulance service providers to submit data to HHS and require plans and issuers to report information about air ambulance claims data. The NPRM also includes proposals to implement NSA provisions related to payer disclosure of direct and indirect agent and broker compensation. The NPRM also addresses enforcement of certain NSA provisions.

- *Requirements Related to Surprise Billing; Part II*

On October 7, 2021, the Departments published an IFC entitled, "Requirements Related to Surprise Billing; Part II" ("Part 2 IFC") (86 Fed. Reg. 55980 (Oct. 7, 2021)). The Part 2 IFC outlined the IDR process to be used by payers and OON providers to determine OON payment rates. Under the IDR process, each party will submit to an IDR entity an offer for a payment amount, along with supporting documentation. The IDR entity will select one of the offers to be the payment amount. In deciding which offer to accept, the IDR entity will presume that the qualifying payment amount QPA is the appropriate OON rate. The IDR entity must select the offer closest to the QPA unless the IDR entity determines that "credible information submitted by either party clearly demonstrates that the QPA is materially different" than the appropriate OON rate.
The IDR entity may not consider usual and customary charges, billed charges, or public payer reimbursement rates.

The NSA also directs the IDR entity to consider several provider-specific factors when determining payment amounts, including the following:

- Provider training and quality of outcomes

- Market share of parties

- Patient acuity or complexity of services
- Teaching status, case mix, and scope of services (for facilities)
- Demonstrations of previous good faith efforts to negotiate in-network rates
- Prior contract history between the two parties over the previous four years

Several lawsuits have been filed challenging the provision in the Part 2 IFC requiring IDR entities to presume the offer closest to the QPA is the appropriate OON payment amount (*See Am. Med. Asoc. Et. Al. v. HHS (D.D.C.)* and *Tx. Med. Assoc. Et. Al. v. HHS (E.D. Tex.)*).

At issue is whether the NSA requires an IDR entity to give weight to both the QPA and certain provider-specific factors when determining the OON payment amount. The lawsuits request an order vacating this provision and an injunction barring enforcement but do not challenge other aspects of the IFC.

The Part 2 IFC also implements the requirement for facilities and providers to furnish a good faith estimate ("GFE") of expected charges to uninsured and self-pay individuals. Facilities and providers must determine if a patient is "uninsured" or "self-pay" and must notify uninsured/self-pay individuals of their right to request a GFE of expected charges. Facilities/providers must provide a GFE of expected charges, both for the primary service that is the reason for the visit and any services that are reasonably expected to be provided in conjunction with the primary service. The GFE must be provided either upon scheduling of a service or upon request.

Different requirements apply to a "convening" facility or provider versus a "co-facility" or "co-provider." A convening facility/provider is the entity that receives the initial request/would be responsible for scheduling the primary service. A co-facility/co-provider is any other facility or provider that furnishes services that are customarily provided in conjunction with the primary service. The convening facility/provider must request a GFE of charges from a co-provider/co-facility to be included in the estimates furnished by the convening facility/provider to the patient. HHS will exercise its enforcement discretion through 2022 when a GFE does not include expected charges from co-providers or co-facilities.

The Part 2 IFC implements a patient-provider dispute resolution ("PPDR") process, under which an uninsured/self-pay patient can file a claim with a select dispute resolution ("SDR") entity to challenge a charge if it is "substantially in excess" of the GFE of expected charges (i.e., at least $400 more than the GFE). Patients must initiate the process within 120 calendar days of receiving a bill. Similar to the IDR process, the SDR entity will presume that the expected charges are the appropriate amount, unless the facility/provider shares credible information demonstrating that the difference in costs is based on unforeseen circumstances that could not have been reasonably anticipated.

- *Prescription Drug and Health Care Spending Interim Final Rule with Request for Comments*

On November 23, 2021, the Departments published an interim final rule with request for comments (IFC) on Prescription Drug and Health Care Spending (86 Fed. Reg. 66662 (Nov. 23, 2021)). The IFC implements Section 204 of Title II of Division BB of the CAA, which requires health plans and health insurance issuers in the group and individual markets to submit to the Departments certain information about prescription drug and health care spending. The information to be submitted includes the following:

General information regarding the plan or coverage;

Enrollment and premium information, including average monthly premiums paid by employees versus employers;

Total health care spending, broken down by type of cost (hospital care; primary care; specialty care; prescription drugs; and other medical costs, including wellness services), including prescription drug spending by enrollees versus employers and issuers;

The 50 most frequently dispensed brand prescription drugs;

The 50 costliest prescription drugs by total annual spending;

The 50 prescription drugs with the greatest increase in plan or coverage expenditures from the previous year;

Prescription drug rebates, fees, and other remuneration paid by drug manufacturers to the plan or issuer in each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates; and

The impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs.

Although the CAA requires plans and issuers to begin submitting the information by December 27, 2021, and in ensuing years to submit the information by June 1 of each year, the Departments are exercising temporary enforcement discretion. The Departments will not take enforcement actions against a plan or issuer that submits the required information for 2020 and 2021 by December 27, 2022.

5. Future Rulemaking

On August 20, 2021, the Departments issued FAQs regarding implementation of the following provisions of the CAA:

- The CAA requires plans and issuers to make available a price comparison tool with respect to plan years or policy years beginning on or after January 1, 2022. In the

FAQs, the Departments specify plans to issue additional rulemaking to consider whether compliance with similar provisions under the TiC Final Rules would satisfy the CAA price comparison tool requirement. In the meantime, the Departments are delaying enforcement of the CAA price comparison tool requirement before plan years or policy years beginning on or after January 1, 2023, to align with the enforcement under the TiC Final Rules.

- The CAA requires plans and issuers to include out-of-pocket maximum limits and contact information for consumers on plan or insurance identification ("ID") cards. The CAA provisions apply with respect to plan or policy years beginning on or after January 1, 2022. According to the FAQs, the Departments intend to issue regulations to implement this requirement, and pending future rulemaking, "plans and issuers are expected to implement the ID card requirements using a good faith, reasonable interpretation of the law."

- The CAA requires facilities and providers to furnish a GFE of expected charges for insured patients to the patient's plan or coverage. The provision applies with respect to plan or policy years beginning on or after January 1, 2022. According to the FAQs, HHS plans to issue regulations to implement this provision and until there is rulemaking to fully implement the provision, HHS will defer enforcement of the requirement.

- The CAA requires plans and issuers to send to covered patients an Advanced Explanation of Benefits notification that certain information, such as the contracted rate, if the provider or facility is OON, the GFE received from the provider/facility, a GFE of the amount the plan or issuer would be responsible for paying, and certain disclaimers. The requirement applies to plan or policy years beginning on or after January 1, 2022. In the FAQs, the Departments indicate plans to issue further rulemaking to implement the provision and, until then, the Departments will defer enforcement.

- The CAA prohibits plans and issuers from implementing gag clauses on price and quality data, effective December 27, 2020. In the FAQs, the Departments specify that further rulemaking is not required to implement this provision, as it is self-implementing, although the Departments plan to issue implementation guidance regarding the submission of attestations of compliance beginning in 2022.

- The CAA requires plans and issuers to update and verify the accuracy of provider directory information and create processes for responding to patient requests about provider network participation status. The provision include a protection for patients, ensuring that if they are incorrectly informed that a provider or facility is in-network, the plan or issuer cannot charge a cost-sharing amount that is greater than the in-network cost-sharing. The provisions apply to plan or policy years beginning on or after January 1, 2022. In the FAQs, the Departments specify that they will issue rules to implement the provisions and, until then, "plans and issuers are expected to implement these provisions using a good faith, reasonable interpretation of the

statute."

- The CAA ensures continuity of care for patients covered by a group health plan or group or individual health insurance coverage offered by an issuer, requiring that individuals whose coverage is terminated, resulting in OON status, receive notification of such changes and continue to pay in-network cost-sharing amounts to allow for a transition of care. The requirements apply to plan or policy years beginning on or after January 1, 2022. In the FAQs, the Departments indicate plans to issue rulemaking to implement these provisions and, until then, "plans, issuers, providers, and facilities are expected to implement the requirements using a good faith, reasonable interpretation of the statute."

XII. TAX-EXEMPT ORGANIZATIONS

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(Updated January 2022)

A. IRS Update

The Internal Revenue Service released its Fiscal Year 2021 Accomplishments Letter (https://www.irs.gov/pub/irs-pdf/p5329.pdf) in January 2022.

As part of its ongoing compliance strategy examinations, the IRS will continue to concentrate on hospital organizations with unrelated business income where expenses materially exceeded gross income reported on Form 990-T (Exempt Organization Business Income Tax Return). The IRS continues ongoing compliance checks, which include, among other areas, questions about section 501(r)(4)[110] noncompliance by tax-exempt hospitals concerning their financial assistance policies, and failures to file certain forms, like Form 990-T (Exempt Organization Business Income Tax Return) and Form 940 (Employer's Annual Federal Unemployment Tax Return).

On a three-year rolling basis, the IRS reviews each tax-exempt hospital's section 501(r) compliance. In IRS fiscal year 2021, 1,019 such hospital reviews were completed. 71 hospitals were referred for examination. The most common issues identified included a hospital's lack of assessing community health needs under section 501(r)(3) and adopting financial assistance policies under section 501(r)(4).

Even amid hiring headwinds, the IRS's tax-exempt division continues to grow its staff. It has hired approximately 30 employees during late fall 2021, according to Robert Malone, director of the Tax Exempt & Government Entities Division ("TE/GE").[111] TE/GE has added 17 agents to work on determinations, and 11 agents to focus on examinations. The IRS is aware of its need to increase its workforce and to address is plummeting customer service.

[110] All "section" references herein refer to provisions of the Internal Revenue Code, as amended.
[111] *See* David Hood, "IRS Tax-Exempt Unit Hires Nearly 30 Employees in a Month," Daily Tax Report (Dec. 9, 2021) available online at: https://www.bloomberglaw.com/product/tax/bloombergtaxnews/daily-tax-report/X57JDQHO000000?bna_news_filter=daily-tax-report#jcite.

Perhaps in light of its customer service or paper processing delays, TE/GE is determined to roll out a secure messaging tool for communication with taxpayers. The tool will be voluntary and offer a protected mailbox to help facilitate the electronic exchange of up to one gigabyte of data between the IRS, taxpayers, and their representatives.[112]

B. LLC Exemption

The IRS continues to actively consider the circumstances in which LLCs might be recognized as section 501(c)(3) organizations. The IRS addressed challenges associated with treating LLCs as exempt organizations nearly 20 years ago, in its 2000 and 2001 Exempt Organizations Continuing Professional Education Texts, which generally acknowledged an incompatibility with the requirements for federal income tax exemption and most states' LLC statutes. Nonetheless, an LLC seeking exempt status would need to first make an election under the so-called "check the box" regulations (see Treas. Reg. §301.7701) to be classified as an association (and thus taxed as a corporation) for federal income tax purposes, and then could undertake an effort to persuade the IRS that, based on its organizational documents and applicable state laws, it meets the "organizational test" for exemption under section 501(c)(3). Alternatively, an LLC having an exempt organization as its sole member would be "disregarded" under the partnership rules and treated as a division of its sole member, effectively resulting in the LLC sharing in its member's exempt status. See Ann. 99-102, 1999-43 I.R.B. 545.

A decade later, the IRS acknowledged that contributions made to a disregarded LLC treated as a division of its sole section 501(c)(3) member could be treated as deductible charitable contributions under section 170(c)(2). See Notice 2012-52 (July 31, 2012). Now, with the considerable proliferation in the use of LLCs by healthcare systems (including as a means of effectuating collaborative arrangements falling short of full-scale mergers and acquisitions), the nonprofit healthcare community may view the inclusion of the topic of tax-exempt LLCs in the new Priority Guidance Plan as a positive development.

In October 2021, the IRS published Notice 2021-56 to clarify the standards that an LLC must satisfy to receive a favorable determination letter.[113] Notice 2021-56 requires that each member of the LLC must be either: (a) an organization described in section 501(c)(3) and exempt from tax under section 501(a); or (b) a governmental unit described in section 170(c)(1) (or a wholly owned instrumentality of such a governmental unit). In addition, the LLC's governing documents must include a contingency plan for members that lose their status. For example, if a section 501(c)(3) member losses its tax-exempt status because it failed to file 990s for three consecutive years, then that member's rights could be suspending while it applies for reinstatement of its tax-exempt status.

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[112] *See* Allyson Versprille, "IRS Exempt Orgs Division to Launch Secure Messaging in 2022," Daily Tax Report (Nov. 17, 2021) available online at: https://www.bloomberglaw.com/product/tax/bloombergtaxnews/daily-tax-report/BNA%200000017d2e5cd4e8afff3fdffb680001?bna_news_filter=daily-tax-report.

[113] *See* IRS Notice 2021-56, available online at https://www.irs.gov/pub/irs-drop/n-21-56.pdf.

Both the LLC's Articles of Organization and its Operating Agreement must express charitable purposes and include dissolution provisions that comply with section 501(c)(3). The reason for these rules is to ensure that applicant LLCs satisfy the basic requirements of section 501(c)(3). Their assets must be dedicated to an exempt purpose and must not inure to the benefit of private parties. These standards will apply for all LLC tax exemption applications filed after October 2021.

C. IRS E-Filing Developments

As we noted previously, the IRS is increasingly moving toward expanded electronic filing. Thanks to a gentle nudge from Congress via The Taxpayer First Act (H.R. 3151), this includes Forms 1023, 1023-EZ, 990 and 990-EZ, which tax-exempt organizations now file electronically. Forms 990-T with due dates on or after April 15, 2021 all must be filed electronically (though returns or amended returns for prior years may still be submitted in paper form).

IRS Form 1024-A, which is used by social welfare organizations, including most tax-exempt health maintenance organizations, has migrated online. And, beginning January 3, 2022, applications for recognition of exemption on Form 1024 must be submitted electronically online at Pay.gov.

In shifting Forms 1024 online, certain kinds of tax-exempt organizations may no longer request exemption through letter applications. This applies to credit unions under section 501(c)(14), employee pension benefit plans under section 501(c)(18), black lung trusts under section 501(c)(21), and state-sponsored high-risk health insurance pools under section 501(c)(26), and qualified nonprofit health insurance issuers under section 501(c)(29). The required user fee for Form 1024 remains $600 for 2022.

Tax professionals and their clients can now electronically sign third-party authorization Form 2848 (Powers of Attorney), and Form 8821 (Tax Information Authorization). For more information, visit https://www.irs.gov/tax-professionals/submit-forms-2848-and-8821-online.

Next to come will be IRS Form 4720 (Return of Certain Excise Taxes Under Chapters 41 and 42) which is used to disclose certain excise tax penalties. For now, according to IRS Notice 2021-1, organizations *other than* private foundations are encouraged to, but not required to, file the Form 4720 electronically.[114]

D. State and Local Taxing Authorities Increasing Community Benefit Oversight

According to an April 2021 study published in *Health Affairs*, tax-exempt nonprofit hospitals provided fewer services free of charge to financially disadvantaged patients than their government and for-profit hospital counterparts. Aside from Senator Grassley, Congress has been relatively quiet about hospital community benefit oversight since 2010's Affordable Care Act. So quiet that states have continued to step into the fold,

[114] Notice 2021-01, 2021-2 I.R.B. 315, available online at https://www.irs.gov/irb/2021-02_IRB#NOT-2021-01.

including Oregon and Pennsylvania.

Oregon recently established minimum community benefit spending thresholds for hospitals following the 2019 adoption of House Bill 3076, which introduced significant changes to Oregon's hospital community benefits policy. The Oregon Health Authority ("OHA") amended its administrative regulations governing community benefit reporting effective December 21, 2020.[115]

The author believes Oregon's standard is the nation's most rigorous regulatory framework yet. OHA is required to calculate the spending floor every two years. So, for some Oregon hospitals, the first spending floor cycle began January 1, 2021 and will end on December 31, 2022. All hospitals are expected to exceed the minimum, which is a known dollar amount given to hospitals at the start of the fiscal year. Hospitals or health systems, once they receive their floor amount, have 30 days to notify health officials if they wish to challenge the spending floor. While hospitals can choose from a menu of ten categorical options for their spending, hospitals are encouraged to support unreimbursed cost of care, which includes unreimbursed Medicaid, charity care and subsidized health services, as opposed to direct spending, which includes research, health professions education, grants, and community building activities.

Oregon's minimum spending floor is unique in that a hospital's target is linked to its operating margin. For example, if a hospital is in robust financial health, then its spending floor will be adjusted upward, even if it is already making strong community benefit investments. Further, if a hospital is struggling financially, then its spending floor will be adjusted downward. It will be interesting to see how COVID's impact on net patient revenue affects community benefit forecasts in years to follow.

Oregon's developments could blossom into a national trend. According to the Hilltop Institute at the University of Maryland, 31 states have community benefit public reporting requirements. And some states, like Illinois and Texas, already have minimum community benefit requirements. In 2012, for example, Illinois adopted a statute requiring nonprofit hospitals desirous of property tax exemption to provide charity care and other specified services or activities at levels at least equivalent to the amounts the hospitals otherwise would have been required to pay in property taxes.[116] This statute was adopted following the Illinois Supreme Court's decision in *Provena Covenant Medical Center v. Dept. of Revenue*, 925 N.E. 2d 1131 (Ill. 2010).

In addition, a Pennsylvania trial court in exurban Philadelphia denied a "non-charitable" nonprofit hospital system's property tax exemption appeal, in part, due to its lack of financial assistance. Judge Jeffrey Sommer of the Chester County Court of Common Pleas ruled that three local, nonprofit hospitals affiliated with Tower Health were not tax-exempt "charities" under the 1997 Institutions of Purely Public Charity Act.[117] Tower

[115] Available online at https://www.oregon.gov/oha/HPA/ANALYTICS/HospitalReporting/409-023-rule-CLEAN-12.3.20.pdf
[116] *See* 35 ILCS 200/15- 86(c).
[117] 10 Pa. Stat. §371-385.

Health operated the hospitals as single-member LLCs after acquiring them from Community Health Systems in a 2017 transaction. Tower Health financed their acquisition with a $590,500,000 tax-exempt bond issuance.

In rejecting Tower Health's appeal, Judge Sommer questioned Tower Health's decision to extract millions of dollars in management fees from the hospitals, pay local and parent executives significant amounts of compensation while short-changing its financial assistance obligations.[118] Without donating or rendering "gratuitously a substantial portion of services," these hospitals would not satisfy the Pennsylvania Supreme Court's test for property tax exemption.[119] Tower Health argued that uncompensated care, including unreimbursed Medicare expenses, should be considered. That evidence was rejected and, without including "undercompensated" care, each hospital's approximate uncompensated care was 0.00076% of services rendered.[120]

The Tower Health decision comes as municipalities and school districts consider sending property tax bills to nonprofit healthcare organizations.[121] In fact, Judge Sommer used his opinion to encourage Pennsylvania lawmakers to revisit tax exemption standards noting the "outdated, competing, and often contradictory [tax exemption authorities] no longer offer appropriate direction as each one fails to reflect the current state of medical care and the delivery of such care in the 21st century."[122] Only time will tell whether more local jurisdictions will jump into the fray before Congress next takes action.

E. Is Mayo Clinic an "Educational" Organization?

A recent Eighth Circuit opinion involving Mayo Clinic, a Minnesota nonprofit corporation and tax-exempt organization under section 501(c)(3), remands to a Minnesota district court the determination of whether Mayo Clinic is an "educational organization" entitled to tax-exempt treatment of investment income earned from several partnerships holding debt-financed real property.[123]

Tax-exempt charitable organizations under section 501(c)(3) can exclude from their unrelated business taxable income ("UBTI") certain income from passive sources, like rent, dividends, royalties, etc. If such passive income is earned using debt-financing, however, then the amount of passive income excluded from UBTI gets reduced proportionately. Exceptions to the exception exist such that passive income from debt-financed property can be excluded from UBTI in certain circumstances. One such exception exists for a "qualified organization" under section 514(c)(9)(C). Included among the eligible qualified organizations is "an organization described in section

[118] *In re: Appeal of Brandywine, Jennersville, and Phoenixville Hospitals, et al.*, Chester County Court of Common Pleas (October 14, 2021).
[119] *See Hospital Utilization Project v. Commonwealth*, 487 A.2d 1306 (Pa. 1985).
[120] *In re: Appeal of Brandywine, Jennersville, and Phoenixville Hospitals* at page 29.
[121] Tower Health has since made a decision to shutter two of the three facilities permanently, Jennersville Hospital and Brandywine Hospital, after a failed transaction with Canyon Atlantic Partners. *See* https://towerhealth.org/jennersville-hospital-and-brandywine-hospital-closure-announcement.
[122] *In re: Appeal of Brandywine, Jennersville, and Phoenixville Hospitals* at page 2.
[123] *Mayo Clinic v. U.S.*, 2021 BL 177645 (8th Cir. May 13, 2021).

170(b)(1)(A)(ii)," which is an educational organization that normally maintains a regular faculty and curriculum and normally has a regularly enrolled body of pupils or students in attendance at the place where educational activities are regularly carried on.

The IRS agreed that Mayo Clinic was an "educational organization" under section 170(b)(1)(A)(ii) because Mayo Clinic, which oversees healthcare system subsidiaries, operates the Mayo Clinic College of Medicine and Science. However, it denied Mayo Clinic's debt-financed income exception concluding that Mayo Clinic was not an "educational organization" as further defined in 26 C.F.R. § 1.170A-9(c)(1). Under this Treasury Regulation, an organization is "educational" if its "primary function is the presentation of formal instruction" and its noneducational activities "are merely incidental to the educational activities." Mayo Clinic, which paid the tax due and sought a refund, argued to the district court that these further elaborations on what it means to be an "educational organization" were unreasonable where Congress unambiguously chose not to include such requirements in section 170(b)(1)(A)(ii).

A federal district court in Minnesota agreed, finding that Congress did not include "primary function" or "merely incidental" requirements in the statute.[124] Specifically, the district court concluded that the Treasury regulation was invalid "because it adds requirements…Congress intended not to include in the statute."[125] This invalidation would have entitled Mayo Clinic to summary judgment on its refund claim ($11,501,621 plus interest) for unrelated business income tax paid across tax years 2003, 2005-2007, and 2010-2012.

The Eight Circuit, however, reversed the district court's invalidation of Treasury Regulation § 1.170A-9 to the extent it is not inconsistent with section 170(b)(1)(A)(ii). In short, now the district court will be tasked with determining whether Mayo Clinic's overall purpose and operations establish that it is "organized and operated exclusively" for educational rather than for other purposes. While Mayo Clinic's involvement has raised this case's profile, given the infrequency with which qualified organizations within the meaning of section 514(c)(9)(C) have debt-financed UBTI, the case (though a curiosity) may be of limited application to other tax-exempt healthcare organizations.

For its part, the IRS did not agree with part of the Eight Circuit's decision either. In November 2021, the IRS released an Action on Decision (AOD) 2021-4[126] announcing its nonacquiescence to that portion of the Eighth Circuit's decision that invalidated a requirement under Treas. Reg. §1.170A-9(c)(1) which requires that the primary function of an educational organization described in section 170(b)(1)(A)(ii) must be the presentation of formal instruction.

[124] *Mayo Clinic v. U.S.*, 412 F. Supp. 3d 1038 (D. Minn. 2019)).
[125] *Id.* at 1042.
[126] Internal Revenue Bulletin 2021-47 (Nov. 22, 2021), available at https://www.irs.gov/pub/irs-irbs/irb21-47.pdf.

F. Interpreting "Disqualified Person" Status Under Section 4958

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A recent U.S. Tax Court decision confirms that "disqualified person" status for purposes of the intermediate sanctions regime in section 4958 can exist even where an individual does not hold any official role or title in relation to a tax-exempt organization. *Fumo v. Commissioner*, T.C. Memo 2021-61 (May 17, 2021), involved a former Pennsylvania state senator, Vincent Fumo, who participated in the establishment of a local tax-exempt organization and was active in fundraising on its behalf. In 2009, Fumo was convicted of mail and wire fraud, with one of his victims being the charitable organization.

At his criminal trial, Fumo admitted that he was a "disqualified person" in relation to the charitable organization, insofar as he had substantial influence over the organization as contemplated by section 4958. Fumo testified that, though he didn't have a title or job at the charitable organization, he viewed it as "my non-profit . . . my entity, my baby . . . I created it. I helped it. I guided it. I gave it strategy. I gave it my time and effort. I raised money for it. If it weren't for me, it wouldn't exist."

In 2013, the IRS assessed Fumo with the 25% penalty tax applicable to disqualified persons under section 4958(a)(1). At trial, the Tax Court granted partial summary judgment, finding no genuine dispute of material fact as to Fumo's status as a disqualified person.