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.

Kristen Rosati, Coppersmith Brockelman, PLC
Robert G. Homchick, Davis Wright Tremaine, LLP
S. Craig Holden, Baker Donelson

The Topic Teams and their members include (in alphabetical order):

- Antitrust
  - Michael Fischer, Bradley
  - Alexandra Lewis, McDermott Will & Emery
  - Najla Long, Bradley
  - Katharine O'Connor, McDermott Will & Emery

- Business Law, Transactions and Governance
  - Peter Greenbaum, Wilentz, Goldman & Spitzer, PA
  - Melania Jankowski, Arent Fox LLP
  - Rachel Ludwig, Jones Day
  - Torrey McClary, Ropes & Gray LLP
  - Nathan Money
  - Anne M. Murphy, Arent Fox LLP
  - Kimberly Ruark, Baker & Hostetler LLP
  - Victoria Stephenson, Baker & Hostetler, LLP

- EMTALA
  - Louise Joy, Joy & Young, LLP
  - Emily Mizell, Conner & Winters, LLP

- Fraud and Abuse
  - Justin K. Brown, Bradley
  - Meredith Eng, Polsinelli
  - Charise Frazier, Hall Render
  - Gavin Keene, Davis Wright Tremaine

- Travis Lloyd, Bradley
- Kim Looney, K&L Gates
- Hannah Maroney, K&L Gates
- Neal Shah, Polsinelli
- Paul Shaw, Verrill Law
- Alicia Siani, Verrill Law
- Stephanie Willis, Kaiser Permanente

False Claims Act & Government Enforcement
- Scott Cameron, King & Spaulding
- Bre Hitchen, Jones Day
- Kerrie Howze, King & Spaulding
- Gavin Keene, Davis Wright Tremaine
- Laura Laemmle-Weidenfeld, Jones Day
- Lyndsay Medlin, Bradley
- Michael Paulhus, King & Spaulding
- Brian Roark, Bass Berry
- Brad Robertson, Bradley

- Health Care Liability and Litigation
  - Jamie Ballinger, Baker Donelson
  - Allison Cooley, Baker Donelson
  - Christy Tosh Crider, Baker Donelson
  - Nora Koffman, Baker Donelson
  - Jerrick Murrell, Baker Donelson
  - Kristine Nelson, Baker Donelson
  - Emily Roberts, Baker Donelson

- Health Care Reform
  - Eric Zimmerman, McDermott Will & Emery LLP

- Health Information and Technology
  - Scott Bennett, Coppersmith Brockelman PLC
  - Alisa Chestler, Baker Donelson
  - Erin Dunlap, Coppersmith Brockelman PLC
  - Gerard Nussbaum, Zarach Associates
  - Melissa (Mel) Soliz, Coppersmith Brockelman PLC

- Labor and Employment
  - Jennifer L. Curry, Baker Donelson
  - Ajente Kamalanathan, Ogletree Deakins
  - Gillian Murphy, Davis Wright Tremaine

- Life Sciences and Clinical Research

  Life Sciences
  - Theresa Carnegie, Mintz Levin
  - Christopher Dang, Quarles & Brady
  - Ben Daniels, Amazon Pharmacy
  - Hunter DeKoninck, Quarles & Brady
  - Lindsay Holmes, Amazon.com, Inc.
  - Stephnie John, Mintz Levin
  - Bridgett A. Keller, Mintz Levin
  - Roger Morris, Quarles & Brady
  - Pat Ouellette, Mintz Levin
  - Susan Trujillo, Quarles & Brady

  Clinical Research
  - Allison Beattie, Bass, Berry & Sims PLC
  - Cara Dermody, Ropes & Gray LLP
  - Kate Gallin Heffernan, Epstein, Becker, Green, P.C.
  - Marylana Saadeh Helou, Epstein, Becker, Green, P.C.
  - Clint Hermes, Bass, Berry & Sims PLC
  - Whitney Mosey, Bass, Berry & Sims PLC
  - David Peloquin, Ropes & Gray LLP
  - Angelique Salib, Bass, Berry & Sims PLC
  - Rachel Weisblatt, Epstein, Becker, Green, P.C.

- Medical Staff, Credentialing, and Peer Review
  - Alexis Angell, Polsinelli
  - Avery Schumacher, Epstein Becker Green
  - Hilary Velandia, Conner Winters

- Payors, Plan & Managed Care
  - Robin Fisk, Metro Plus
  - Sarah Swank, Nixon Peabody

- Regulation, Accreditation, and Payment
  - Darby Allen, Davis Wright Tremaine
  - Ahsin Azim, King & Spaulding
  - Tim Blanchard, Blanchard Manning
  - Caitlin Forsyth, Davis Wright Tremaine
  - Leslie Demaree Goldsmith, Baker Donelson
  - Daniel J. Hettich, King & Spaulding
  - Jordan Keville, Davis Wright Tremaine
  - Michael LaBattaglia, King & Spaulding
  - Jeffrey Moore, Phelps Dunbar LLP
  - Colin McCarthy, McGuire Woods

- Tax
  - Michael N. Fine, Wyatt, Tarrant & Combs, LLP
  - Linda S. Moroney, Manatt, Phelps & Phillips

TABLE OF CONTENTS

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

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

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

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

Author: Michael N. Fine, Wyatt, Tarrant & Combs
(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.