ANNUAL FRAUD AND ABUSE UPDATE

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FCA, STARK LAW, AND AKS: RECENT CASES AND SETTLEMENTS

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- Third Circuit vacates its previous decision, but still upholds under a different interpretation of the Stark Law that *qui tam* relators plead facts sufficient to demonstrate a possible Stark violation
  - The court's original September 2019 decision relied on a controversial construction of the Stark Law's "volume or value" test to hold that the relators demonstrated the surgeons' compensation both varied with **and** took into account the volume or value of their DHS referrals to defendant's hospitals, creating an impermissible indirect compensation arrangement
  - The Third Circuit's revised December 2019 decision left unresolved the meaning of "varies," but held that the surgeons' "suspiciously high compensation" suggested that compensation "took into account" referrals. The court emphasized:
    - The relators' "great detail" regarding specific physicians with high compensation and specific ways the surgeons padded their bills
    - The existence of a prior FCA settlement regarding similar practices
- Decision means relators need more than an allegation that hospital-based physicians were paid a productivity bonus for their personally performed services to plead a Stark violation

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[redacted]

- Allegedly violated FCA by improperly paying physicians in violation of Stark and AKS laws and submitting the claims to Medicare and TennCare
- Hospital's financial arrangements with its physician practice, Tennessee Heart, were allegedly improper
  - Hospital paid the Tennessee Heart physicians inflated salaries and bonuses to attract cardiologists to a small town
  - Hospital lost millions of dollars on the practice because of the payments, but the revenue generated by procedures in the Hospital more than made up the losses
- Whistleblower who originally brought case will receive $779,000

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[redacted]

- Allegedly violated FCA by improperly compensating referring physicians in violation of Stark and AKS laws and submitting the claims to Medicare
- Hospital reverses its financial troubles by hiring more physicians, mostly as employees, whose compensation arrangements were:
  - Based on the volume or value of the physicians' referrals of DHS or
  - Above fair market value (some physicians paid at more than 90% of MGMA)
- Whistleblower who originally brought case will collect $10 million

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[redacted]

- Allegedly violated FCA by providing improper remuneration to referring physicians in violation of Stark Law and AKS and submitting the claims to Medicare, Medicaid, and TRICARE
- Tenet affiliates allegedly provided improper remuneration to certain physicians for patient referrals through:
  - Free or below-FMV office space, employees, and supplies
  - Compensation in excess of FMV for certain physicians
  - Equity buyback provisions and payments for certain physicians that exceeded FMV and
  - Preferential investment opportunities
- Whistleblower case, but relator's share is as yet undetermined

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[redacted]

- **First Settlement:** Sutter Health allegedly violated Stark law by billing Medicare for services referred by Sac Cardio
  - Sutter Health paid Sac Cardio under a series of compensation arrangements that exceeded FMV for the services provided
- **Second Settlement:** Sutter Health self-disclosed additional Stark violations for billing Medicare for:
  - Referrals from physicians who it paid compensation that exceeded FMV
  - Leasing office space at below-market rates to referring physicians
  - Reimbursing physician recruitment expenses in amounts that exceeded the actual expense
- **Third Settlement:** Sac Cardio allegedly submitted duplicative bills to Medicare for physician assistant services
- Whistleblower who originally brought certain allegations against Sutter Health and Sac Cardio will receive $5.89 million

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[redacted]

- Hospital "presented claims for designated health services furnished . . . that resulted from prohibited referrals"
- OIG imposes a civil monetary penalty upon hospital for providing excessive compensation for 16 providers under:
  - Emergency Department call coverage arrangements
  - Advanced Practice Providers (APP) arrangements
- Violations discovered during a merger between the community hospital and Southeast Alaska Regional Health Consortium
- Hospital used OIG's Self-Disclosure Protocol to report the violations

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[redacted]

- Allegedly violated FCA by receiving referrals from physicians that violated the Stark Law and submitting the claims to Medicare
- Community Health Network, an integrated health system in Indiana, allegedly entered into improper employment relationships with a number of physicians by:
  - Compensating the physicians at well above FMV
  - Conditioning paying physician bonuses on achieving a minimum target of referral revenues to the hospital
- Whistleblower originally brought the case

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[redacted]

- Allegedly violated FCA by submitting millions in claims to Medicare for procedures only partly performed or supervised by attending surgeons in operating room "assembly line" case
- Irregular practices by the Lenox Hill's Chair of Urology, Dr. David Samadi, allegedly included:
  - Scheduling two separate surgeries—one endoscopic and one robotic—at the same time in adjacent operating rooms without informing patients so that:
    - The endoscopic surgeries were performed at least in part by unsupervised medical residents
    - The robotic surgery patients were left unattended so that Samadi could supervise the endoscopic surgeries

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[redacted]

- Irregular practices by Lenox Hill allegedly included:
  - Billing for operating room services for Samadi's patients undergoing minor diagnostic services
  - Compensating Samadi at more than $2 million more than FMV and factored in the value of his referrals to the hospital
- Whistleblowers who originally brought cases will receive $2.58 million

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[redacted]

- Former Surgeon at Orlando Health Network sues for $800K for unlawful retaliation, Stark and AKS violations
- Surgeon claims that Orlando Health's "mandatory self-referral" practices violate Stark and "patients' freedom of choice"
- Alleges Orlando Health's encouragement to conduct surgeries only at system hospitals and refer patients to only system imaging center eventually turned into a mandate
  - Surgeon claims he was threatened, then fired, because he did not refer to Orlando Health entities
- Originally filed qui tam; DOJ declined; surgeon dropped suit
- Filed new suit August 28, 2020

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[redacted]

- Allegedly violated FCA by submitting claims to Medicare, Medicaid and other federal health care programs for procedures performed by one of its top neurosurgeons who was violating the AKS and for medically unnecessary spinal surgeries
- Sanford Health allegedly ignored repeated warnings that neurosurgeon Dr. William Asfora:
  - Received kickbacks from his use of implantable devices distributed by his physician-owned distributorship
  - Performed medically unnecessary procedures involving the devices in which he had a substantial financial interest
- Sanford Health paid $625,000 in 2014 to settle similar kickback claims involving Dr. Asfora
- Whistleblowers who originally brought case will receive $3.4 million

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[redacted]

- Two employed neurosurgeons at Sanford Hospital brought a qui tam case against Dr. Asfora
- The complaint alleged that by ordering and using devices manufactured and sold by MDLLC and Sicage (entites owned by Dr. Asfora) in his surgeries, Asfora profited from the sales in violation of the False Claims Act.
- Relators contend that Asfora violated the AKS and the surgeries were medically unnecessary.
- The federal government intervened in the whistleblower action.
- Court refused dismissal of case on Sept. 16, 2020

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[redacted]

- AKS law and submitting the claims to Medicare, Medicaid, and TRICARE
- Dr. Choi solicited and received improper payments and other benefits through two spinal equipment distributorships that he created
  - The distributorships provided spinal implant equipment to hospitals for use in surgeries that Dr. Choi performed
  - Dr. Choi arranged for third parties to serve as registered owners of the distributorships while he secretly maintained control of both businesses and the money they made
- OIG issued a Fraud Alert in 2013 warning of physician-owned distributorship schemes

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[redacted]

- FCA whistleblower cases alleging it paid over $8 million in sham consulting payments as kickbacks to spine surgeons to induce use of its surgical devices
  - Company allegedly created an IME to give the false impression that the surgeons were consulting through an independent third-party entity
  - Paid surgeons per medical device used, not for consulting hours
- DOJ settled claims against five physicians for $1.56 million for seeking and obtaining kickbacks through this arrangement
- Neurosurgeon and distributor plead guilty to AKS – one year supervised release and forfeiture of any profits

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[redacted]

- DOJ settles for $5.99 million allegations that company recruited surgeons to serve as paid consultants and supported the surgeons' products to market in exchange for the surgeons' use of LIFE SPINE products. LIFE SPINE allegedly paid surgeons:
  - To provide training and/or educations services
  - Royalties on future sales to provide new product input
  - Large acquisition fees and royalties for their patents/applications

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[redacted]

- Allegedly violated FCA by inducing improper physician referrals in violation of Stark Law and AKS and submitting the claims to Medicare, Medicaid, and TRICARE and other irregular billing practices
- Boston Heart coordinated with small Texas hospitals' independent marketers to create "management service organizations" (MSOs) that made payments to referring physicians disguised as investment returns
  - Payments were actually based on and in exchange for the physicians' referrals
  - Boston Heart helped identify physician targets, referred interested physicians to MSOs, and participated in MSO sales pitches to physicians

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[redacted]

- Other irregular practices allegedly included:
  - Submitting claims for outpatient lab testing for patients who were not hospital outpatients
  - Paying processing and handling fees, waiving copays and deductibles, and providing referring physician practices with in-office dietitians
  - Provided tests that went "beyond medical necessity"
  - Pressured sales representatives to sell its "life plan" of personalized nutrition and additional tests
- Whistleblowers who originally brought cases will receive $4.36 million

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[redacted]

- Intraoperative neuromonitoring (IONM) service provider allegedly violated FCA by submitting fraudulent Medicare claims
- Medsurant allegedly billed Medicare for:
  - Units of services without regard to concurrent services that it was providing to patients insured by payors other than Medicare and
  - Services that were not provided "exclusively to one patient," as required by Medicare regulations

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[redacted]

- Allegedly violated FCA by paying kickbacks in violation of the AKS law and submitting the claims to Medicare
- ResMed allegedly generated DME supplier, sleep lab, and physician referrals by providing physicians with free equipment and services such as:
  - Free telephone call center and other patient outreach services
  - Free and below-cost positive airway pressure masks, diagnostic machines, and installation
  - Free home sleep testing devices
  - Guaranteed interest-free loans from third-party financial institutions so suppliers could purchase ResMed equipment
- ResMed entered into a CIA with OIG to implement controls around pricing and sales and monitor arrangements with referral sources
- Whistleblowers who originally brought the case will receive $6.2 million

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- More than 345 defendants in 51 judicial districts
- Charged with participating in health care fraud schemes involving more than $6 billion in alleged losses to federal health care programs
- Alleged conspirators include telemedicine, DME, pharmacies, genetic testing laboratories, medical practitioners, marketers
- Federal health care billing privileges revoked for 256 medical professionals

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- Telefraud – alleged criminal scheme through telemarketing calls, direct mail, television advertisements, and internet pop-up advertisements.
- Defendant telemedicine executives allegedly paid medical practitioners to order unnecessary DME, genetic and other diagnostic testing, and medications, either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen.
- Often, DME, test results, or medications were not provided to the beneficiaries or were worthless to the patients and their actual primary care doctors
- The proceeds of the fraudulent scheme were allegedly laundered through international shell corporations and foreign banks for the benefit of the defendants.

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- DOJ prosecutes Kentucky substance abuse treatment clinic office manager for EKRA violation for soliciting kickbacks from the CEO of a lab in exchange for referrals
  - DOJ's first publicly disclosed EKRA prosecution
  - EKRA applies only to recovery homes, labs, and clinical treatment facilities, but also applies public and private health plans

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- Digital medical advertising provider admitted to defrauding its lenders, investors, and pharmaceutical company clients by selling advertising inventory that it didn't have
- Outcome Health sold its clients advertising space on televisions and tablets in doctors' offices but overcharged clients by $6 million in 2015 and more than $25 million in 2016
  - Inflated numbers to give clients the false impression that Outcome Health's network included more of the clients' targeted doctors than it actually did
  - Invoiced clients for full ad campaigns even when Outcome Health didn't have the necessary devices to run the ads when they were scheduled to start
  - Sent clients false proof that campaigns had run as planned and in places they had not
- DOJ and Outcome Health entered into a non-prosecution agreement, but DOJ criminally charged 4 former executives and 2 former employees with over-inflating the company's revenue figures to fraudulently obtain $1 billion in debt financing

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PATIENT ASSISTANCE PROGRAMS, ADVISORY OPINIONS, AND ENROLLMENT ENFORCEMENT REGULATIONS

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- DOJ settles with PSI for $3 million - January 2020
- Foundations allegedly violated the FCA by creating pharmaceutical company-sponsored funds to cover patient copays for select drugs through so that patients don't have to fully consider the costs of their treatment
- Patient Services, Inc. (PSI)
  - Foundation provided Insys, the only donor to PSI's fund, with exclusive access to a "referral portal" to see the copay assistance status of each referred patient
  - Aegerion helped set eligibility criteria for patients to receive copay assistance for its drug
  - Created fund with Alexion to cover copays, premiums, services, and travel expenses for almost exclusively for patients using the company's drug
  - PSI entered a three-year Integrity Agreement with OIG as part of settlement

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[redacted]

- Novartis to pay DOJ and Oklahoma over $729 million to resolve two separate settlements - July 2020
- **First Settlement:** Novartis allegedly violated the FCA by using three different foundations to pay Medicare copays for patients using its drugs
  - Collaborated with the first foundation to cover multiple sclerosis drug copays so that patients who had been receiving the drug for free would have their Part D copays covered when they ordered the drug through Medicare
  - Required the second foundation to narrow its eligibility definition so that more of its copay recipients would use a Novartis cancer drug
  - Asked a third foundation to open copay assistance to patients using another Novartis cancer drug
- **Second Settlement:** Paid kickbacks in the form of speaker program fees to doctors to prescribe Novartis drugs
  - Required Novartis to entire into a CIA to (i) significantly reduce the number of paid speaker programs and the amount spent on such programs and (ii) implement measures to promote independence from patient assistance programs to which it contributes.
- Whistleblower case, but relator's share is as yet undetermined

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[redacted]

- DOJ Settles with Gilead for $97 million - September 23, 2020
- Gilead Sciences, Inc.
  - Pharmaceutical company used a 501(c)(3) foundation to pay the copays of thousands of Medicare patients taking its pulmonary arterial hypertension drug to induce the patients to take the drug despite its high cost
  - Company routinely and inappropriately obtained data from the foundation detailing how much the foundation had spent for patient copays and:
    - Used the information to decide how much to pay the foundation and
    - Confirmed that its payments were sufficient to cover the copays of only patients taking its drug
  - Company also referred Medicare patients to the foundation

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- 20-05 – Did not approve pharmaceutical company issuing a subsidy card which would pay for all patient co-payments for its Drug
  - Highly suspect under AKS because one purpose is to induce Medicare beneficiaries to purchase Requestor's federally reimbursable medications.
  - Most expensive Drug ever launched in the US
  - Subsidy card would cover all co-pays; valued at approximately $13,000/year; would remove the patient's financial impediment, leaving the Medicare program to pay for the rest.
  - Generous financial need criteria resulting in 91% of Medicare beneficiaries covered
  - Other risks include risk of patient steering to use the Drug; and potentially impact clinical decision-making

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- 19-06 – Approved a grocery store expanding a loyalty program to permit customers to use loyalty points to pay out of pocket costs for pharmacy products.
- 20-01 – Approved a provider allowing EMTs and firefighters to use a provider's training facility at below market rates because EMTs follow state-mandated protocols when steering patients to providers and the public benefits from the arrangement.
- 20-02 – Approved pharmaceutical company providing some assistance to patients for the costs associated with travel and lodging after drug infusions because monitoring is required to meet FDA requirements associated with drug and mitigate potential harm; any willing provider may participate in arrangement and drug is a one time, potentially curative treatment

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[redacted]

- 20-03 – Approved a discount medical plan organization offering a $5 referral fee to chiropractors who refer patients to the plan because the plan neither furnishes nor arranges for the furnishing of federally reimbursable services and the plan is, essentially, an intermediary.
- 20-04 – Approved nonprofit entity paying off medical debt because the arrangement is low risk under AKS and CMP because:
  - Providers do not publicize sale or donation of debt
  - Requestor notifies patient that debt has been paid
  - Debt forgiveness occurs only after Provider has rendered services

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[redacted]

Low Risk	High Risk
• Advisory Opinion 19-01 (nonprofit clinic eliminating cost-sharing) • Advisory Opinion 19-02 (providing patients with monitoring device) • Advisory Opinion 19-06 (grocery store loyalty program) • Advisory Opinion 20-02 (paying fees ancillary to patient monitoring) • Advisory Opinion 20-04 (nonprofit debt-forgiveness organization)	• Advisory Opinion 20-05 (paying cost-sharing for pharmaceutical patients)

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[redacted]

- 2020-01 – Approved an expansion of a physician owned hospital that occurred prior to March 23, 2010, including additional beds and operating rooms.
- All beds and ORs were in existence and operational prior to March 23, 2010.
- However the State erred in not issuing a license including the new beds until June 2010.

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[redacted]

- Effective November 4, 2019, final rules became effective which broadly expands CMS authority to suspend payment and revoke or deny a provider or supplier enrollment in Medicare, Medicaid or CHIP.
- Upon request, a prospective or enrolled provider and supplier must disclose any and all **affiliations** that it or any of its owners or managing employees or organizations has or, *within the past five years*, had, with a currently or formerly enrolled provider or supplier that has a **disclosable event**. CMS may request such disclosure when it has determined that the provider may have at least one such affiliation.

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[redacted]

A provider must disclose all affiliations, which include any person or organization with:

- A five percent (5%) or more direct or indirect ownership interest
- A general or limited partnership interest regardless of percentage
- An interest with operational or managerial control or directly or indirectly conducts the day-to-day operations of another organization
- An acting officer or director of an organization
- Any reassignment relationship

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[redacted]

- Currently has an "uncollected debt" to CMS that was referred to the Treasury Department
  - Regardless of the amount of debt or whether in process of repayment or appeal.
    - Uncollected debt (42 C.F.R. 424.516) only applies to Medicare/Medicaid overpayments for which CMS or the state has sent notice of the debt to the provider; CMPs; other assessments.
- Has been or is subject to a payment suspension
  - Regardless of when the payment suspension occurred or was imposed
- Has been excluded by the OIG
  - Regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed;
- Has had its Medicare enrollment denied, revoked or terminated
  - Regardless of the reason for denial, is being appealed or when imposed

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[redacted]

CMS can deny initial enrollment or revoke existing enrollment for a variety of reasons. The final rule includes the following additional bases, including if the provider/supplier:

- Has failed to report data required under §424.516(d) or (e) (changes in business or adverse actions), §410.33(g)(2) or §424.57(c)(2) (DMEPOS suppliers certification).
- Has uncollected debt is referred to the US Treasury.
  - CMS may consider factors such as the reason for failure to repay; whether attempted to repay; the amount outstanding; whether the provider has responded to CMS questions and other "evidence CMS deems relevant".
- Bills for services from a non-compliant location
  - CMS may consider the following factors: the reasons and facts behind the non-compliance; the number of other compliant locations involved; history of final adverse actions; the degree of risk posed by the non-compliance; the length of time of the non-compliance; and the amount billed from the non-compliant location.
- Has an Affiliation that poses "undue risk" of fraud, waste or abuse.

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[redacted]

- Exhibits a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, service or drugs.
- Failure to report ownership, practice location or adverse action changes in 30 days or other change in enrollment data in 90 days.
- Payments to the provider, an owner or any managing employee are currently suspended.
- A provider circumvents program rules by coming back into the program or attempting to come back in under a different name or identity.
- A provider has Affiliations that CMS determines presents undue risk of fraud, waste or abuse.

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COVID-19 ENFORCEMENT, DOJ COMPLIANCE PROGAM GUIDANCE, AND GOOD GUIDANCE RULEMAKING

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- In March 2020, DOJ confirmed, through a memo to all US Attorneys and in a press release, that DOJ will prioritize the investigation and prosecution of COVID-19-related fraud schemes [memo]
- AG Barr also directed US Attorneys to appoint a "Coronavirus Fraud Coordinator" in each district and established a national system for whistleblowers to report suspected fraud
- Reaffirmed in June 2020 speech by DOJ Civil Division Principal Deputy Assistant Attorney General Ethan Davis [written remarks]
  - Highlighted scrutiny on COVID-19-related stimulus program fraud (Paycheck Protection Program, Main Street Credit Facility, Provider Relief Fund)

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[redacted]

- DOJ guidance and press releases compiled at justice.gov/coronavirus
  - Nearly 500 press releases between 3/18/20 and 10/6/20
- Selected examples:
  - Marketer charged with soliciting and receiving kickback payments from companies involved in COVID-19 testing in exchange for steering patients, including Medicare beneficiaries, to those companies (3/30/20)
  - Medical technology company president charged in scheme to defraud investors and health care benefit programs in connection with COVID-19 testing (6/9/20)
  - NFL player charged for role in alleged PPP-related fraud (9/10/20)
  - Veterans Affairs respiratory therapist pleads guilty to stealing and selling COVID-19 respiratory supplies (10/5/20)

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[redacted]

- OIG Work Plan now includes 40 active audits, evaluations, and inspections that are underway or planned concerning COVID-19 [https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp]
  - Use of Medicare Telehealth Services During the COVID-19 Pandemic
  - Audit of CARES Act Provider Relief Funds—General and Targeted Distributions to Hospitals
  - Infection Control at Home Health Agencies, Nursing Homes, and Dialysis Centers During the COVID-19 Pandemic
  - Audit of Medicare Payment for Inpatient Discharges Billed by Hospitals for Beneficiaries Diagnosed with COVID-19
  - Trend Analysis of Medicare Laboratory Billing for Potential Fraud and Abuse with COVID-19 Add-on Testing

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[redacted]

- On June 1, 2020, DOJ Criminal Division released updated guidance on the evaluation of corporate compliance programs [https://www.justice.gov/criminal-fraud/page/file/937501/download]
- Guidance structured around three fundamental questions, which are to be asked at the time the offense occurred as well as at time of the charging decision and resolution:
  1. Is the compliance program well designed?
  2. Is the compliance program adequately resourced and empowered to function effectively?
  3. Does the compliance program actually work in practice?

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[redacted]

- Most significant revision concerns framing of the second question
  - Change from whether the compliance program is "being implemented effectively" to the more practical question of whether the program is "adequately resourced and empowered to function effectively"
- Emphasis on need for compliance to have meaningful data access
  - Directs prosecutors to ask whether compliance personnel have "sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of policies, controls, and transactions"
  - Must also consider whether there are impediments that limit access to relevant sources of data

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- Emphasis on ongoing monitoring of third parties
  - Guidance asks whether a company "engage[s] in risk management of third parties throughout the lifespan of the relationship, or primarily during the onboarding process"
- In the context of M&A, focus on post-closing integration
  - While previous guidance focused on due diligence process, revised guidance focuses on "timely and orderly integration of the acquired entity into existing compliance program structures"

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- On Aug. 2020, HHS issued proposed rule setting forth "good guidance" practices that would apply to HHS (except for FDA) [85 FR 51396]
- Applicable to "guidance documents," which are defined to include "any statement of general applicability which is intended to have future effect on the behavior of regulated parties …"
  - Includes Medicare manuals, program memoranda, bulletins, advisory documents
  - Excludes notice-and-comment rulemaking, internal HHS documents
- Unless otherwise authorized by statute, HHS may not issue any guidance document that establishes legal obligations not reflected in duly enacted statutes or regulations lawfully promulgated under them, and may not use any guidance document for purposes of requiring persons or entities outside HHS to take any action or to refrain from taking any action beyond what is already required by the terms of an applicable statute or regulation

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- Proposed rule would also create a process for issuing guidance that formalizes guardrails designed to ensure that guidance documents are appropriate issued and used
  - Each guidance document would be required to include the following statement (unless authorized by law to be binding): "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law."
  - Each guidance document must include the following information: (1) the activities to which and the persons to whom it applies; (2) the date issued by HHS; (3) a unique agency identifier; (4) a statement indicating whether it replaces or revises a previously issued guidance document; (5) a citation to the statutory provision(s) or regulation(s) that it interprets or applies; and (6) a short summary of the subject matter

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- Additional procedures for "significant" guidance documents (generally, those with likely economic impact > $100 million, but with some additional categories)
  - Submitted to OIRA for review under E.O. 12866 prior to issuance
  - Required to comply with applicable requirements for significant regulatory actions, as set forth in executive orders
  - Prior to issuing any significant guidance document, HHS must offer public notice and comment period of at least 30 days (must also publish an "easily accessible public response" to "major concerns")
- All guidance documents to be made available at hhs.gov/guidance
  - By 11/16/20, HHS must have posted all guidance documents in effect
- Any interested party may petition HHS to withdraw or modify any guidance document (and HHS's action, due within 90 business days, would be considered final agency action reviewable in court)

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