Midwest MGMA Webinar

# Emerging from COVID and Beyond…

**Jesse A. Berg, Lathrop GPM, LLP**

Jesse.berg@lathropgpm.com

**(612) 632-3374**

**Randal L. Schultz, Lahtrop GPM LLP**

Randal.Schultz@lathropgpm.com

**(913) 451-5192**

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# Today’s Agenda

- Review of federal response to COVID
- Key Fraud & Abuse Laws
- Status of 2019 Stark Law & Anti-kickback rulemaking
- Fraud and abuse in natural disasters
- Regulatory flexibility for Providers under COVID
- Potential areas of risk / enforcement actions

# Highlights of federal response to COVID

- Coronavirus Preparedness & Response Act - $8 Billion
  - Vaccine development ($3 B); preparedness and CHC funding ($1 B); waive restrictions for Medicare telehealth and other spending ($1 B); increased CDC funding ($2 B)
- Families First Coronavirus Response Act - $192 Billion
  - Waiver of Medicare/Medicaid cost-sharing; increased agency spending on COVID needs (e.g., increased Medicaid matching funds to states ($50 B), funding for COVID testing ($10 B))
- CARES Act - $2.7 Trillion
  - PPP Program ($349 B); aid to states for pandemic-related costs ($150 B); Public Health and Social Services Provider Relief Fund ($100 B); increased Medicare payments; expansion of telehealth; CHC funding ($28 B)
- PPP and Health Care Enhancement Act - $733 Billion
  - Added $321 Billion to PPP, increased funding for Emergency Injury Disaster loans and grants $60 billion; increased health provider emergency grant fund program for COVID preparedness and expenses ($75 B); additional funds for COVID testing ($25 B)

Jesse Berg (jesse.berg@lathropgpm.com, 612-632-3374); Randy Schultz (randal.schultz@lathropgpm.com, 913-451-5192)

# Key Health Regulatory Laws: Anti-kickback Statute

- Prohibits knowing and willful offer, payment, solicitation or receipt of "remuneration" to induce or reward referral of items or services reimbursable by federal health care programs
- Penalties include felony conviction, fines up to $100,000 for each violation, or imprisonment for not more than 10 years, or both
- Safe harbors exist to protect certain relationships but most are difficult to satisfy
  - Without safe harbor compliance, parties are at risk that OIG will view an arrangement as a way to disguise payments for referrals
  - If a relationship does not satisfy a safe harbor, it is not necessarily illegal: question becomes whether intent to violate law is present
  - An arrangement that does not satisfy a safe harbor, but does not evince the intent necessary to violate the Anti-Kickback statute, is permissible

# Key Regulatory Laws: Stark Law

- Unless an exception applies, Stark Law prohibits a physician from referring patients for designated health services (“DHS”) to an entity, or the entity from billing for the DHS, if the physician has a “financial relationship” with the entity
- Penalties include: denial or repayment, per claim fines of $15,000, and permissive or mandatory exclusion
  - Violations also typically form basis for False Claims Act prosecutions
- Financial relationships can be based on ownership or compensation and can be direct or indirect
  - Different exceptions exist depending on which type of financial relationship is present
- Unlike the Anti-Kickback statute, Stark only applies if certain elements, with specific definitions, like “DHS,” “entity” and “referral,” are triggered
- Stark Law is a strict liability statute

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# Key Federal Laws: Civil Monetary Penalties Statute

- Beneficiary Inducement “CMP” prohibits any person or entity from offering remuneration to a Medicare or Medicaid beneficiary if that remuneration is likely to influence the beneficiary's selection of a provider
- Penalties for violating beneficiary inducement CMP include fines of up to $15,270 per item/service provided
- Various exceptions exist; historically very narrow
- Definition of remuneration amended to include exceptions which went into effect in 2017. New exceptions include:
  - Copayment reductions for certain hospital outpatient department services;
  - Certain remuneration that poses a low risk of harm and promotes access to care;
  - Coupons, rebates, or other retailer reward programs that meet specified requirements;
  - Certain remuneration to financially needy individuals; and
  - Copayment waivers for the first fill of generic drugs.

# Key Regulatory Laws: False Claims Act

- Prohibits knowingly presenting or causing presentment of false claims for payment to United States
- Also prohibits knowing retention of an “obligation” (i.e., an “overpayment”)
  - Failure to report and return “overpayments” within 60 days of identification actionable as a “reverse” false claim
- Violations of many substantive regulatory laws (e.g., Stark Law, Anti-kickback Statute and other “conditions of payment”) often form basis for FCA claims
- Penalties include ***treble damages*** and ***per claim*** fines between $10,781—$21,563
- Difficult to overestimate how effective FCA has been for DOJ and relators as enforcement tool
  - 2017 was 8th straight year DOJ recovered more than $3 billion in health care fraud under FCA

# Effectiveness of False Claims Act

# Number of Filed FCA Cases

# Key Regulatory Laws: False Claims Act

- “Relators” can take home between 15%--25% of recovery
  - – Enticing—in 2017, relators pocketed $392 million
- The “experienced” whistleblower
- Cecelia Guardiola, RN (worked in clinical documentation and case management)
  - Successful 3-time relator
    - – Christus Spohn Health System (2012, $5 million)
    - – Renown Health (2016, $9.5 million)
    - – Banner Health (2018, $18 million)
- Quote from Ms. Guardiola’s attorney—”she’s really unemployable at this point in her career”.

# 2019 Stark Law, Anti-kickback Statute CMP Rulemaking

- Proposed regulations from October 2019 would create significant rewrite of these laws
  - – 84 Fed. Reg. 55694 (Oct. 17, 2019) (Anti-kickback and CMP)
  - – 84 Fed. Reg. 55766 (Oct. 17, 2019) (Stark Law)
- Changes to Stark Law include new exceptions for value-based arrangements, new definitions of fair market value, commercial reasonableness and what it means to take into account the volume or value of referrals
  - – CMS also offered several “clarifications” of its current interpretation of key Stark principles
- Changes to Anti-kickback Statute would create new safe harbors for value-based arrangements, new safe harbors for patient engagement, EHRs and modify existing safe harbors
- Changes to Beneficiary Inducement CMP intended to facilitate patient participation in value-based arrangements

# Fraud and Abuse in Federal Disaster Relief Funding

- Common for U.S. government to respond quickly to disasters / significant economic problems with large funding package, launched quickly and with minimal program integrity
- Hurricane Katrina led to creation of Public Health and Social Services Emergency Fund (2005)
- Creates opportunity tor unscrupulous actors to take advantage of programs
- Correlation between significant federal expenditures and increase in False Claims Act cases?
  - 2005 response to Hurricane Katrina led to FEMA trailer cases
  - 2008 Financial Crises – TARP fraud cases
  - 2010 Gulf Oil Spill – FEMA/SBA cases

# Examples of False Claims Act Cases (Natural Disasters)

- U.S. v. Xavier University of Louisiana / AECOM
  - Claims submitted to FEMA for repair / replacement of facilities damaged by Hurricane Katrina violated False Clams Act
  - Funds could only be used to repair facilities to pre-Katrina condition
  - Xavier settled for $12 million
  - AECOM alleged to have submitted false certifications about buildings' pre-hurricane conditions
- U.S. v. City of New York
  - City paid $ 5.3 million to DOJ to settle claims that city fraudulently obtained FEMA disaster relief funds (in response to Hurricane Sandy)
  - Allegation that city requested reimbursement for "damaged" vehicles. Problem was that apparently the vehicles had been damaged long before the hurricane occurred.
  - City official signing certification did not have personal knowledge of compliance.
  - City self-discovered problem, but failed to return funds until after federal investigation was launched.

# DOJ / OIG Position on Fraud in COVID Context

- DOJ statement makes enforcement position clear:
  - DOJ “is committed to pursuing all manner of fraud in federal health care programs, including violations disclosed by whistleblowers under the False Claims Act, especially during this critical time as our nation responds to the outbreak of COVID-19... We encourage anyone with information to report fraudulent acts to the appropriate authorities."
- DOJ position on criminal conduct:
  - "Every U.S. Attorney's Office is thus hereby directed to prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic."
- DOJ launched National Center for Disaster Fraud Hotline
- OIG issued Special Fraud Alert on COVID (Mar. 23, 2020)
- OIG has dedicated COVID fraud and abuse webpage.  Illustrates OIG view of likely fraud schemes
- OIG encourages people to contact DOJ Hotline above

# Potential for Fraud and Abuse in Health Care Industry

- Financial pressure on providers as result of cessation of non-emergency services
- Large number of layoffs
- Significant political interest
- Budgetary problems make “waste, fraud and abuse” an attractive target
- Wide variety of providers received additional funding under various COVID responses:
  - Hospitals
  - Nursing facilities
  - Telehealth providers
  - Clinical labs
  - Manufacturers, suppliers of personal protective equipment
  - Manufacturers of drugs, devices, biologics
  - Many others

# Potential Areas of Fraud & Abuse in COVID Response

- Numerous theories of FCA liability could be tailored to providers' COVID response
- Following theories have been successful in FCA and related cases. Readily adaptable to COVID:
  - "False" applications for funds, grants
  - Failure to meet certification / participation requirements, while retaining funds
  - "Lying" on claims (e.g., not performing services at all, failing to deliver products, etc.)
  - Violations of Stark Law and Anti-kickback Statute and going beyond what is excepted under CMS/ OIG waivers
  - Identify theft (labs, testing companies offering "free" tests in exchange for personal details
  - Price gauging
  - Poor quality / worthless products and services sold to govt. programs
  - Lack of medical necessity
  - Inaccurate coding (diagnosis, upcoding, etc.)
  - False/misleading statements

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# Provider Relief Fund Terms & Conditions: what did I sign up for?

- Recipients required to agree to following commitments as condition of receiving of Provider Relief Funds:
  - Payment will only be used to prevent, prepare for, and respond to coronavirus, and ... shall reimburse the Recipient only for healthcare related expenses or lost revenues that are attributable to coronavirus.
  - Recipient will not use the Payment to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse
  - For all care for a presumptive or actual case of COVID-19, Recipient ... will not seek to collect from the patient out-of-pocket expenses in an amount greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network Recipient.
  - None of the funds ... shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II [$197,300/year].
- HHS made clear that "full compliance … is material to the Secretary's decision to disburse these funds to you".
- Addresses potential FCA argument that compliance is not "material" to payment

# Regulatory Flexibility for Health Care Industry

- CMS issued nationwide "blanket" waivers on March 13, 2020, effective retroactively to Mar. 1. Numerous developments since issuance of initial waivers:
  - Public Health Emergency (clearinghouse)
    - https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page
  - Partner Toolkit (materials organized by provider / supplier category)
    - https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit
  - Newsroom (sign up for updates)
    - https://www.cms.gov/newsroom
  - Interim Final Rule on CARES Act (85 Fed. Reg. 19230, Apr. 6, 2020)
  - Medicaid & CHIP
    - https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/index.html
- Guidance on Stark Law, Anti-kickback Statute and Beneficiary Inducement CMP

# Flexibility Under Stark Law & Anti-kickback Statute

- CMS releases Stark Law waivers on Mar. 30, 2020, effective Mar. 1
- Waivers protect remuneration between an entity and physician and referrals from the physician to the entity so long as the remuneration and referrals are "solely related to COVID-19 purposes"
- COVID-19 Purposes include:
  - Addressing medical practice or business interruption due to the outbreak so as to maintain the availability of medical care and related services for patients and the community
  - Securing services of physicians and other practitioners to provide patient care services
  - Ensuring the ability and expanding the capacity of providers to address patient and community needs due to the outbreak
  - Shifting diagnosis and care of patients to alternative settings because of COVID
  - Diagnosing or providing medically necessary treatment of COVID for any patient / individual (regardless of whether diagnosed)

# Flexibility Under Stark Law & Anti-kickback Statute

- Waives all sanctions related to the exchange of specific types of remuneration. Examples include:
  - Payments that are above or below FMV of services provided, equipment/space leased
  - Loans between DHS entities and physicians that are on favorable terms, including below market interest rates
  - Referrals by physician owners to group practices they own that fail to meet certain elements of relevant Stark Law exceptions
  - Payments that exceed limits established under nonmonetary compensation or medical staff incidental benefits exceptions
  - Expansion of rural provider exception
  - Arrangements between entities and physicians that fail to meet the “writing” and “signature” requirements of various exceptions
- 18 separate Stark Law waivers
- Providers can also submit requests for individual waivers (via email)

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# Flexibility Under Stark Law & Anti-kickback Statute

- On Apr. 3, 2020 OIG issued policy statement: OIG will not impose AKS sanctions for remuneration covered under majority of the Stark Law Waivers
  - OIG Policy effective after Apr. 3.
- OIG positon applies to 11 of the 18 types of remuneration waived under Stark Law Waivers
- Waivers 12-17 not encompassed under OIG guidance, but likely due to technical differences between Stark Law and Anti-kickback Statute and not policy judgement
- Stark Law waivers and OIG policy terminate at end of Public Health Emergency

# Flexibility Under Stark Law & Anti-kickback Statute

- Other OIG guidance:
  - Mar. 17: policy statement making clear OIG would not impose administrative sanctions under Anti-kickback Statute or Beneficiary Inducement CMP for waiving telehealth cost sharing obligations during COVID emergency
  - Mar. 30, “Message from leadership on minimizing burdens on providers”: For any conduct during this emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action.
  - New process for FAQs on Anti-kickback Statute and Beneficiary Inducement CMP

# Flexibility Under Stark Law & Anti-kickback Statute

- FAQs intended to provide expedited guidance on relatively straightforward Anti-kickback/CMP questions
- Currently 9 FAQs published
- Example—Apr. 3: FAQ addressing providers furnishing services for free / reduced costs to assist long-term care providers with staff shortages. OIG said, low risk of fraud and abuse so long as services offered are:
  - Necessary to meet patient care needs as a result of staffing shortages directly connected to the outbreak
  - provided for free or at a reduced cost only when necessary as a result of outbreak
  - limited to the period subject to the emergency declaration; and
  - Not contingent on referrals for any items or services that may be reimbursable in whole or in part by FHCPs, either during or after declaration

# Current COVID Fraud and Abuse Enforcement Actions

- *United States v. Erik Santos* (March 26, 2020):
  - Marketing company charged with soliciting and receiving kickbacks on a per-test basis for COVID clinical lab tests, provided that each was bundled with a much more expensive panel test (which did not identify or treat COVID)
- *United States v. Ashleg Hoobler Parris* (May 14, 2020)
  - Conspiracy to commit anti-kickback violations for providing medically unnecessary COVID tests; tests were bundled with more expensive and more lucrative panel tests that could not detect COVID
  - Defendant initially had similar scheme focused on CGX (dna sequencing) testing, adapted scheme to address COVID testing when pandemic hit US
- *United States v. Jeremiah Faber* (May 25, 2020)
  - Conspiracy to defraud Medicaid (and money laundering). Involved marketing online, administering, and submitting Medicaid claims for COVID testing as part of company's "Comprehensive Whole-body testing" program, much of which was allegedly unnecessary
  - Also involved fraudulent billing for non-emergency medical transportation and billing for transports that never occurred.

# Current COVID Fraud and Abuse Enforcement Actions

- *Indictment of Keith Middlebrook* (Jun. 12, 2020)
  - Wire fraud charges for soliciting investors in company that would market pills (QC20) that would "prevent" coronavirus infections and produce injectable cure for those suffering from COVID
- *United States v. Christopher Parris* (Apr. 10, 2020)
  - Wire fraud for making misrepresentations in an attempt to secure orders from V.A. for 124 million 3M face masks that would have totaled over $750 million
- *United States v. Singh* (Apr. 24, 2020)
  - Price gauging—accumulating numerous scarce materials, including masks, respirators and thermometers, for the purpose of resale at excess prices
- *United States v. Bulloch* (Apr. 27, 2020)
  - Price gauging—accumulating, for the purpose of resale at prices in excess of prevailing market prices various scarce materials such as KN95 Masks.

# Current COVID Fraud and Abuse Enforcement Actions

- *Securities fraud / Medicare fraud* filed against Mark Schena / Arrayit Corporation (Jun. 9, 2020)
  - Paid kickbacks to doctors to run ineffective/inaccurate allergy screening tests. Lied to investors to secure funding for purported COVID test
- *United States v. David Adler Staveley* (May 4, 2020)
  - Bank fraud, conspiracy, and aggravated identity theft for fraudulently seeking approx. $550,000 in PPP loans when applicants had little to no employees working for the entities for which they applied
- *United States v. Baoke Zhang* (May 21, 2020)
  - Software engineer charged with wire and bank fraud for allegedly false applications for $1.5 million in forgivable loans
- *United States v. Shashank Shekhar Rai* (May 12, 2020)
  - Submitting false applications for more than $10 million in PPP loans for family company.

# Compliance Tactics

- Maintain careful records regarding accounting and spending of federal funds and reasons for changing arrangements
- Keep records of how organization met relevant participation requirements
- Develop process for unwinding arrangements once PHE is over
- Document deviations from provider policies & procedures
- Document government instructions / explanations
- Update policies and procedures to address changing circumstances
- Make information accessible to personnel on fraud, waste and abuse compliance and provide training to new providers as needed
- Consider whether necessary to build up the internal audit function for claims monitoring
- Evaluate audit plans to take into account changed circumstances during COVID