Hot Compliance and Enforcement Topics Regarding COVID-19

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AGENDA

1. Enforcement Initiatives
2. Provider Relief Fund (PRF)
3. Telefraud and Telehealth Fraud
4. Potential Enforcement Policy Changes

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Enforcement Initiatives

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OIG INITIATIVES

- Pandemic Response Accountability Committee (PRAC) of CIGIE
  - Strategic goals include preventing and detecting FWA and mismanagement; that is, mitigating major, cross-cutting risks and holding wrongdoers to account.

- U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG)
  - Strategic goals include protecting people by fighting fraud that endangers beneficiaries, and protecting funds by preventing/detecting/remedying waste or misspending of COVID-19 response/recovery funds.
  - In response to the COVID-19 Pandemic, OIG has engaged in the following initiatives:
    - Partnership with CMS, DOJ, FBI, HFPP, NHCAA
    - Cross component work within OIG: OI, OEI, OAS
    - Sharing of Division of Data Analytics work product:
      - Lab billing, pharmaceuticals, diagnostic codes
      - Telemedicine billing by NPI taxonomy, dollar amounts, codes utilized, billed categories, HCPCS modifiers, etc.
    - Review schemes from OIG Hotline
    - Reviewing nursing home safety

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OIG INITIATIVES

- Office of Inspector General (OIG)
  - OIG Work Plan covers:
    - PRF distributions,
    - Inpatient discharges of beneficiaries with COVID-19,
    - Hospital utilization,
    - Telehealth,
    - COVID-19 testing data, and
    - Lab billing for COVID-19 add-on testing.
  - OIG has stated separately that it is conducting significant oversight to ensure telehealth services are not compromised by fraud. (Principal Deputy Inspector General Grimm on Telehealth, 2.26.2021).
  - Industry Guidance
    - Guidance to health care community regarding OIG's enforcement authorities for arrangements directly connected to the COVID-19 public health emergency.
    - Minimize burdens.

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DOJ STATEMENTS ON ENFORCEMENT

- U.S. Department of Justice (DOJ)
  - Criminal Division (6.9.20 Senate Judiciary Testimony)
    - Part of working group with FBI, OIG; fraud section assigned 25 prosecutors to pursue COVID-19 cases, directed its data analytics group to focus on COVID-19 related billing schemes, and retained SMEs.
  - Civil Division (6.26.20 U.S. Chamber of Commerce Speech)
  - "Providers who receive [PRF] funds must agree to a number of terms and conditions … [w]here a provider knowingly violates these requirements, the [FCA] may come into play."
  - "[W]ill not pursue companies that made immaterial or inadvertent technical mistakes in processing paperwork or that simply and honestly misunderstood the rules, terms and conditions, or certification requirements."
  - Civil Division (12.6.2020 Remarks of Michael D. Granston)
    - "The Civil Division is working closely with various Inspector Generals and other agency stakeholders to identify, monitor, and investigate these potential violations, and these efforts are expected to translate into significant cases and recoveries."
  - Civil Division (2.17.2021 Remarks of Brian M. Boynton)
  - The Civil Division is concerned with six areas that it views as priorities: Pandemic-Related Fraud, Opioids, Fraud Targeting Seniors, Electronic Health Records, Telehealth, and Cybersecurity.
  - Stimulus programs passed by Congress will be the source of FCA claims and "[t]hese schemes will likely include false representations regarding eligibility, misuse of program funds, and false certifications pertaining to loan forgiveness."

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PUBLIC ENFORCEMENT ACTIONS

- PRAC Data as of 9.30.20 (from 10.29.20 Semiannual Report)
  - HHS OIG: 8 pub. investigations, 10 indictments/crim. complaints, 10 arrests
  - Medicare Fraud: 4 pub. investigations, 4 indictments/crim. complaints, 2 arrests

- DOJ Enforcement Actions
  - *U.S. v. Santos* (D.N.J. 3.30.2020) and *U.S. v. Hoobler* (N.D.Ga. 5.15.20). Defendants allegedly solicited and received kickbacks for referrals of genetic tests regardless of medical necessity, as well as COVID-19 tests bundled w/ more costly respiratory pathogen panel (RPP) tests.
  - *U.S. v. Schena* (N.D.Cal. 6.9.20). President of medical technology company allegedly paid kickbacks to recruiters for referrals of allergy tests regardless of medical necessity, and then made misrepresentations to investors about the company's bundled COVID-19 test.
  - *U.S. v. Goyal* (S.D.N.Y. 6.24.20). Ophthalmologist allegedly defrauded the U.S. Small Business Administration by applying for Paycheck Protection Program Relief intended to help small business during the pandemic, even though he was not eligible due to previously healthcare fraud charges.
  - *U.S. v. Shibley* (W.D. Wash. 06.29.20). Doctor allegedly submitted fraudulent PPP loan applications by misrepresenting his payroll expenses, number of employees and his prior criminal history.
  - *U.S. v. Belone* (S.D.Fla. 7.10.20). Owner of DME company allegedly submitted fraudulent PPP loan applications, received and used funds to further Medicare fraud schemes, and transferred some funds to his personal account.

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PUBLIC ENFORCEMENT ACTIONS

- *U.S. v. Nobbe* (S.D. Fla. 7.29.20). Chiropractor allegedly obtained PPP relief and used that money to pay personal expenses, and "orchestrated a conspiracy to submit false and fraudulent claims for reimbursement to Medicare and CareCredit, and to defraud his own patients by charging them thousands of dollars … under false pretenses."
- *National Telehealth Takedown* (09.30.20). Defendants involved in $100 million telemedicine scheme allegedly paid kickbacks for prescription medication or durable medical equipment.
- *Dr. Milan Chakrabarty and Hemet Endoscopy Center Settlement* (OIG 12.04.20). Doctor and endoscopy center allegedly knowingly made, used, or caused to be made false statements in a document submitted to receive PRF funds.
- *U.S. v. SlideBelts, Inc.* (E.D. Cal. 1.12.21). Internet retailer entered into civil settlement with United States (paying $100,000 in damages and penalties) to resolve alleged fraudulent inducement of $350,000 PPP loan.
- *U.S. v. Abbas* (E.D. Mich. 02.11.21). Owner of home health company allegedly misappropriated PRF funds by issuing checks to family members for personal use. Her company was not operating during the pandemic.
- *U.S. v. Joseph* (D. Col. 03.17.21). A physician is alleged to have transferred around $118,000 in COVID-19 relief funding from his medical business account to his personal account.
- U.S. v. Scott (M.D.Fla. 4.14.21). Telemarketer sentenced to 10 years in prison for misrepresenting coverage of laboratory tests to Medicare beneficiaries and then paying kickbacks in return for doctor's orders authorizing the tests.
- CARES Act matters pursued by Fraud Section of DOJ Criminal Division compiled at https://www.justice.gov/criminal-fraud/cares-act-fraud (last visited 4.8.21).

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QUI TAM RELATORS' BAR

- "In the health care sector that HHS oversees, the bar has assembled COVID-19-related teaching tools regarding: pharmaceuticals, biologics and devices; clinical trials; and current good manufacturing practices (i.e. manufacturing quality)." (Neil Getnick, *FCA Whistleblowers Are More Important Than Ever Before*, Law360, 01.06.2021).
- "Whistleblowers have long been essential in policing the pharma industry and exposing misconduct that is hidden from regulators." (Erika Kelton, partner at Phillips & Cohen, *Whistleblower Cases Are A Warning To Covid-19 Vaccine Makers*, Forbes.com, 11.20.20).
- Taxpayers Against Fraud Education Fund has established a COVID-19 Anti-Fraud Task Force "assist federal and state law enforcement in deterring, detecting, and exposing fraudulent business practices targeting taxpayer dollars."
- The task force includes relator's attorneys, former government officials, and technical experts

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PROVIDER RELIEF FUND (PRF)

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Overview

- Coronavirus Aid, Relief and Economic Security Act (CARES Act) – Creation of Provider Relief Fund and initial $100 billion
- Subsequent legislation added billions to Provider Relief Fund
- Health Resources and Services Administration (HRSA) to manage the Provider Relief Fund
- UnitedHealth Group (UHG) to facilitate payments
- HHS information on PRF available at: www.hhs.gov/coronavirus/cares-act-provider-relief-fund/

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HHS Terms and Conditions

- Generally, PRF recipients must attest to receipt of payment and applicable Terms and Conditions (T&Cs) within 90 days
- T&Cs include certain certifications regarding:
  - PRF eligibility,
  - limitations on use of PRF funds,
  - reporting and compliance requirements, and
  - accuracy and completeness of submitted documentation
- Certifications include language about materiality

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PRF Eligibility

- "Eligible Healthcare Providers" defined as:
  - ''[P]ublic entities, Medicare or Medicaid enrolled suppliers and providers, and such for-profit entities and not-for-profit entities not otherwise described in this proviso as the Secretary may specify, within the United States (including territories), that provide diagnoses, testing, or care for individuals with possible or actual cases of COVID– 19" H.R. 748, 116th Cong. (2020)
- Under the statute, eligibility turns on:
  - Eligible health care provider submitting "to the Secretary of Health and Human Services an application that includes a statement justifying the need of the provider for the payment and the eligible health care provider shall have a valid tax identification number" *Id*.
- HRSA has imposed additional criteria by distribution

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Limitations on Use

- Payment must be used to "prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus." H.R. 748, 116th Cong. (2020).
- "[T]hese funds may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse." *Id.*
- Additional restrictions in FY 2020 Consolidated Appropriation, such as abortions, lobbying, gun control advocacy, Executive Level II Salary Limits ($197,300)
- Under T&Cs, for all care for a presumptive or actual case of COVID-19, recipient agrees to not seek to collect out-of-pocket cost-sharing greater than in-network obligation

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FAQs and Other PRF Guidance

- HHS has previously said that communications on its website "cannot, by themselves, impose binding new obligations on regulated entities."

> Divisions of HHS commonly use websites, blog entries, and social media posts to issue communications with regulated parties. While these communications may provide the public with helpful information they cannot, by themselves, impose binding new obligations on regulated entities.

- OMB has issued similar statement:

> **IV. Other Information**
>
> Guidance documents on HRSA webpages on the HHS.gov website, such as those listed under "Availability of Other Program Information," are provided only to clarify the applicable laws, regulations, and terms and conditions of the award. Such guidance documents do not create new compliance requirements. However, non-federal entities in substantial compliance with the guidance applicable in these guidance documents at the time of a transaction are considered in compliance with the underlying compliance requirements.

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January 15 Reporting Requirements

- HHS issued revised Notice of Reporting Requirements on 1.15.21
  - Report using normal method of accounting (cash or accrual basis)
- First: Report on unreimbursed health-care related expenses attributed to COVID-19, including:
  - General and Administrative
  - Healthcare-related Expenses
- Second: Apply remaining PRF funds to patient care lost revenues
- Other Assistance Received
- Non-financial Data

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Enforcement

- Enforcement Tools
  - Administrative
  - False Claims Act
    - False Statements
    - Reverse False Claims
  - Criminal Prosecutions
- Potential Defenses
  - Deemed attestations insufficient
  - Strict compliance with T&Cs immaterial
  - No intent given complexity of program and evolving guidance

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TELEFRAUD AND TELEHEALTH FRAUD

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Telehealth Fraud v. Telefraud

- Past Cases
  - *U.S. v. HealthRight LLC*, 2:18-cr-00133 (E.D.Tenn. filed Sept. 14, 2018) (pending criminal prosecution of telehealth provider for conspiracy to commit health care fraud and wire fraud, based on scheme to obtain reimbursement for drugs in excess of AWP through manipulation of patients and physicians, and brokering of prescriptions to pharmacies)
  - *U.S. ex rel. Bearden v. Arizona Medical Supply, LLC, et al.*, No. 2:13-cv-01127 (D.Utah filed Dec. 26, 2013) and *U.S. ex rel. Boucher v. KPM Capital, LLC, et al.*, No. 2:14-cv-00092 (D.Utah filed Feb. 11, 2014) (settled FCA actions alleging that telemarketers made direct telephone solicitations with no legitimate medical referrals to induce beneficiaries to purchase durable medical equipment)
  - Key issues included direct solicitation of beneficiaries; bait-and-switch sales tactics during direct solicitations of beneficiaries; charges for telehealth visits that never occurred; inducement of physicians to prescribe services or items; charges for services or items that are unnecessary or unreasonably priced.

- OIG Recently Distinguished "Telefraud" from Telehealth Fraud (Grimm Statement 2.26.20)
  - Telefraud schemes "inappropriately leverage[] the reach of telemarketing schemes in combination with unscrupulous doctors conducting sham remote visits to increase the size and scale of perpetrator's criminal operations."
    - "In many cases, the perpetrators did not bill for the sham telehealth visit. Instead, the perpetrators billed fraudulently for other items or services, like durable medical equipment or genetic tests."
  - OIG emphasized that it "is conducting significant oversight work assessing telehealth services during the [PHE]. Once complete, these reviews will provide objective findings and recommendations that can further inform policymakers … ."

COVID-19 and Telehealth Flexibilities

- CMS Telehealth Policy Before Public Health Emergency (PHE)
  - Before COVID-19, Medicare could only pay for telehealth on a limited basis: when the person receiving the service was in a designated rural area and when they left their home to go to a clinic, hospital, or other facility for the service.
  - In 2019, Medicare also started paying for virtual check-ins, plus e-visits with clinicians under Part B.

- CMS Telehealth Policy Changes for PHE
  - Under Section 1135 waiver (3.6.2020), Medicare pays for office, hospital, and other visits furnished via telehealth across the country and including in patient's residence. A range of providers—including MDs, PAs, NPs, LCPs, and LCSW—may furnish the telehealth.
  - The provider must use an interactive audio and video telecommunications system that permits real-time communication between the distant site and the patient at home. To the extent Section 1135(g)(3) requires that a patient have a prior established relationship with a practitioner, HHS has exercised enforcement discretion and will not audit compliance with that requirement.

OIG Enforcement Discretion
- On 3.17.2020, OIG announced that it is exercising enforcement discretion and will not enforce AKS, related CMP and exclusion laws, or prohibition on inducements to beneficiaries against providers that reduce or waive beneficiary cost-sharing for telehealth visits.

- Amended PREP Act Declaration
  - On 12.8.20, HHS announced a fourth amendment to the Secretary's Public Readiness and Emergency Preparedness Act (PREP Act) declaration. The amendment purports to preempt state laws that limit cross-border practice of medicine via telehealth.

COVID-19 and Telehealth Flexibilities

- Annual CMS Physician Fee Schedule Final Rule (issued 12.1.20)
  - Adds more than 60 services to the Medicare telehealth list that will continue to be covered beyond the end of the PHE.
  - Commissions a study of the telehealth flexibilities provided during the COVID-19 PHE. The study will explore new opportunities for services where telehealth and virtual care supervision, and remote monitoring can be used to more efficiently bring care to patients and to enhance program integrity, whether they are being treated in the hospital or at home.
  - Recognizes that Medicare does not have the statutory authority to pay for telehealth to beneficiaries outside of rural areas or, with certain exceptions allow beneficiaries to receive telehealth in their homes.

- Pending Federal Legislation
  - Numerous bills pending in the U.S. House, including the Telehealth Modernization Act (S. 368, H.R. 1332), which would:.
    - Remove the originating and geographic site restrictions for telehealth;
    - Give the Secretary authorities to expand the provider types that can deliver telehealth to beneficiaries;
    - Allow face-to-face requirements for hospice care and home dialysis;
    - Enable CMS to use sub-regulatory guidance to add telehealth services; and
    - Extend FQHC and RHC distant site ability as authorized under the CARES Act.

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Enforcement

- Enforcement Tools
  - Administrative, False Claims Act, Criminal Prosecution
- Additional Cases
  - *U.S. v. Andrews, et al.* (D.N.J. 7.9.20). Four men indicted for running pharmacy that paid kickbacks to marketing firms for prescriptions for compounded drugs issued without a doctor-patient relationship, and for routinely waiving copayments.
  - *U.S. v. Curty* (D.N.J. 9.23.20). Co-owner of marketing company indicted for paying individuals to obtain prescriptions for compounded drugs regardless of medical necessity, and then fill the prescriptions at pharmacies that paid kickbacks to the marketing company.
  - *U.S. v. Belter, et al.* (D.N.J. 9.30.20). Six individuals charged in prescription medication and DME telefraud scheme in which beneficiary information and kickbacks were provided in return for prescriptions, which were given to pharmacy in return for kickbacks.

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Enforcement

- Additional Cases
  - *U.S. v. Ogon* (D.N.J. 1.27.21). Doctor sentenced to prison for prescribing compounded medications without a doctor-patient relationship and in return for kickbacks.
  - *U.S. v. Wolfe* (S.D. Fla. 2.4.21). Operator of DME companies pleaded guilty to conspiracy to commit healthcare fraud, and settled FCA claims, based on telefraud scheme where doctors were bribed to submit claims without any underlying doctor-patient relationship.
  - *U.S. ex rel. Thornton v. Nat. Compounding Co.* (M.D. Fla. 3.16.21). Marketers settled FCA claims based on scheme to solicit patients via telemarketing, and then submit prescriptions for compounded to pharmacies in return for kickbacks.
- Compliance Considerations
  - Marketing strategies
  - Legitimate physician-patient relationship
  - Compliance program applied to marketing, compensation

ENFORCEMENT POLICY CHANGES

ENFORCEMENT POLICY INITIATIVES FROM 2020

- Granston Memorandum Implementation
  - "[F]ollowing the memo, [DOJ] has moved to dismiss around 50 qui tams," after dismissing roughly 45 qui tams in the prior 30 years.
  - "We may also take a look at qui tams that try to hold companies liable for doing what the government said was ok to do … [i]f a business in good faith took advantage of the regulatory flexibility granted by federal agencies … it may not be appropriate to impose [FCA] liability." (DOJ 6.26.20 Speech).
- HHS OGC FCA Working Group (announced 12.4.20)
  - Purpose is to strengthen "partnership with DOJ and OIG on using [FCA] to pursue bad actors and protect taxpayer funds."
  - HHS announcement stated that "[t]he vast majority of private individuals and organizations have used [COVID-19 relief] funds in good faith to combat the pandemic and maintain and strengthen our healthcare system."
- HHS OGC Good Guidance Final Rule (finalized 12.3.20)
  - Guidance documents that are not posted in HHS guidance repository are rescinded.
  - Creates procedure to petition HHS to withdraw or modify guidance documents; HHS must respond.
  - Affirms principle that a guidance document cannot establish independent legal obligations unless a contract specifically incorporates it; any new guidance document must contain a disclaimer.
  - The Secretary must sign significant and certain non-significant guidance documents; significant guidance documents must issue through a notice-and-comment process involving OIRA.

ENFORCEMENT POLICY CHANGES IN 2021?

- Executive Order on Revocation of Certain Executive Orders Concerning Federal Regulation (Jan. 20, 2021)
  - Revokes Executive Order 13891 of October 9, 2019 (Promoting the Rule of Law Through Improved Agency Guidance Documents)
  - Directs OMB and heads of agencies to "promptly take steps to rescind any orders, rules, regulations, guidelines, or policies, or portions thereof, implementing or enforcing [EO 13891] … ."
- Senator Grassley
  - Raised concerns about Granston memorandum and dismissals based on agency resources in letter to former AG Barr on 3.4.2019.
  - Raised similar concerns and asked for technical support on new FCA legislation in letter to AG Garland on 2.24.2021. ("I have no objection to the Justice Department dismissing meritless or parasitic cases, however, it is up to the courts, through a hearing, to determine whether or not a case lacks merit")

THANK YOU/ QUESTIONS?

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