2021 COMPLIANCE AUDITS

The brave new (and unchartered) world of post-pandemic audits

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University of Rochester
22nd Annual Health Care Compliance Conference
October 22, 2020

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- Robert Trusiak represents hospital and physician clients on regulatory, statutory, and enforcement issues. He separately provides complete health care consulting services for physician providers, hospitals, research labs, skilled nursing facilities, pharmaceutical companies, and durable medical equipment entities and counsels clients on a number of state and federal health care regulatory matters, including HIPAA, HITECH, Shield Act, health care reform, fraud and abuse, Stark Law and health care compliance issues.
- Previously, Robert served as Chief Compliance Officer, Senior Associate General Counsel and Privacy Officer at Kaleida Health where he successfully managed the internal Compliance team, litigation teams of outside counsel, litigated administrative and contractual actions, ensured regulatory and statutory compliance, and resolved matters involving accrediting and enforcement entities as well as individual matters.
- Robert also served as Assistant United States Attorney until his retirement in 2012 as Chief of the Affirmative Civil Enforcement Unit. Robert prosecuted civil and criminal cases on behalf of the United States of America involving health care fraud, Department of Defense fraud, HUD fraud, grant fraud, VA fraud, ERISA violations, Tax fraud, Securities fraud, Customs violations, USDA violations, and all forms of procurement fraud.
- Robert was also an Adjunct Professor, University at Buffalo, SUNY, teaching in 2015 and 2016 a graduate level course entitled Health Care Fraud and Abuse.

CARES Act

BACKGROUND

- On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), creating a $2 trillion stimulus package to address the COVID-19 pandemic costs to businesses, universities, and certain groups of individuals.
- The CARES Act also established the Paycheck Protection Program ("PPP") that expanded the Small Business Administration's ("SBA") loan guaranty program to help businesses retain workers during the COVID-19 crisis. If borrowers meet certain requirements, some portion of these PPP loans can be eligible for forgiveness. These loans are subject to requirements and self-certifications that could lead to investigations if the government suspects that misrepresentations occurred in the application process.

BACKGROUND (continued)

- The CARES Act establishes three oversight mechanisms to ensure the funds are disseminated appropriately:
  1. It provides for the appointment of a Special Inspector General;
  2. It establishes the Pandemic Response Accountability Committee to oversee the funds made available under the Act; and
  3. It establishes a Congressional oversight committee.
- In June 2020, Congress introduced the COVID-19 Whistleblower Protection Act to address the misuse of federal funds spent in combatting COVID-19 by instituting strong whistleblower protections for employees or former employees of recipients of funds under the CARES Act.
  - Specifically, the whistleblower bill protects disclosures related to gross mismanagement, danger to public health or safety, abuse of authority, or violation of laws, rules or regulations.
  - It also creates a legal framework providing administrative relief, giving the US Department of Labor the ability to investigate whistleblower retaliation claims from non-federal employees or contractors.

BACKGROUND (continued)

In addition to the specific mechanisms established related to COVID-19, the federal government already has a variety of criminal, civil, and administrative tools at its disposal to address procurement fraud.

- Perhaps the most potent weapon is the civil False Claims Act (FCA).
- The most common violation that results in civil FCA litigation is where a company or individual "knowingly presents, or causes to be presented, to a Government official a false or fraudulent claim for payment or approval." This is typically triggered upon submission of a false or incorrect invoice to the government for work performed but can be triggered under a variety of other scenarios as well.

BACKGROUND (continued)

On September 10, 2020, Acting Assistant Attorney General Brian Rabbitt, in remarks delivered at the PPP Criminal Fraud Enforcement Action press conference, reiterated the Department of Justice's (DOJ) commitment to aggressively pursue and prosecute CARES Act-related fraud.

- As of that date, the DOJ had already charged 57 people with fraudulently obtaining more than a combined $175 million in loans through the CARES Act's Payroll Protection Program.
- " . . in many cases these defendants didn't stop at simply making false statements, but rather tried to back up their alleged lies with fake documents, like falsified tax records, dummy payroll and revenue records, and in some cases even stolen personal information from unsuspecting third parties."
- "To bring these cases as quickly as we have, and to sort through the volume of loans made by the SBA, the Fraud Section and its partners deployed the first-in-class data analytics capabilities they have developed and employed to great effect in other criminal investigative areas, such as health care fraud and market manipulation."
- "The Fraud Section has truly become a market leader in its use and development of these techniques, and here again we see their potential."

AREAS OF RISK FOR CARES ACT FUNDS RECIPIENTS

- In order to obtain CARES Act funds, individuals and business are required to make certain certifications and representations—either express or implied—as to their eligibility to receive those funds.
- Such a situation should raise a heightened awareness with regard to potential false claims risk, as the FCA recognizes both express and implied certifications as a cognizable theory of recovery.
- In all cases, a provider would be required to present evidence that the expenses and/or lost revenues are indeed the result of COVID-19. For example, under the required attestation the provider must represent that "[t]he Recipient certifies that the Payment will only be used to prevent, prepare for, and respond to coronavirus, and that the Payment shall reimburse the Recipient only for health care related expenses or lost revenues that are attributable to coronavirus."
- Additionally, the attestation lists a number of un-related legal provisions that must be followed, but further provides that it "is not an exhaustive list and you must comply with any other relevant statutes and regulations, as applicable." General compliance attestations such as this one frequently become the basis for FCA and/or other health care fraud allegations.

SPECIFIC FALSE CLAIMS ACT RISK

- The Select Subcommittee on the Coronavirus Crisis released on September 1, 2020 a preliminary staff report on the Paycheck Protection Program (PPP) showing that billions of dollars in PPP loans may have been diverted to fraud, waste, and abuse. See https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2.
- There will be a wave of FCA suits for PPP funding given the government report. A few highlights:
  - Over $1 Billion in Loans Went to Companies That Received Multiple Loans.
  - More Than 600 Loans Totaling Over $96 Million Went to Companies Excluded From Doing Business With the Government.
  - More Than 350 Loans Worth $195 Million Went to Government Contractors With Significant Performance and Integrity Issues.
  - Federal Database Raises Red Flags for $2.98 Billion in Loans to More Than 11,000 PPP Borrowers.
  - SBA and Treasury Approved Hundreds of Loan Applications Missing Key Identifying Information About the Borrower. T

JUST LISTEN TO THE SBA INSPECTOR GENERAL

- While the enforcement activity that has become public thus far has been criminal, SBA Inspector General Hannibal "Mike" Ware has described these cases as the "smallest and tiniest tip of the iceberg".
- While criminal charges to date have focused on alleged phony businesses, creation of nonexistent employees, and purchases of Lamborghinis and other exotic items, civil enforcement under the FCA will likely be less flashy but result in far more taxpayer recovery.
- This is so for several reasons.
  - First, the government must only establish that a defendant acted with reckless disregard under the FCA, a much lower burden for intent than under most criminal statutes.
  - Second, the government must only prove its case by a preponderance of the evidence, rather than the higher criminal standard of proof beyond a reasonable doubt.
  - Third, rather than simply recovering restitution, the FCA allows the government to recover treble damages, plus hefty penalties per violation. Civil FCA cases under the PPP will likely focus on alleged false statements in connection with eligibility under SBA regulations, size-based standards, affiliation rules, need-based certifications and other more technical violations.
- See https://www.nytimes.com/2020/08/28/business/ppp-small-business-fraud-coronavirus.html.
- See also https://www.law360.com/newyork/articles/1320884/calculating-fca-damages-from-ppp-fraud-may-be-tricky-?nl_pk=d5a47e8e-d8e2-4df8-a42a-10613bf9f904&utm_source=newsletter&utm_medium=email&utm_campaign=newyork?copied=1.

COMPLIANCE RECOMMENDATIONS

Recipients of CARES Act and other stimulus funds should consider maintaining a file that contains, at a minimum, the following:

- The application
- Evidence of the applicant's diligence that the statements made in the application were truthful, accurate, and appropriately complete
- Award documents (if any) from the government
- Evidence of the use of federal funds for proper and approved purposes
- A compliance matrix - a cross-referencing tool to help ensure compliance with the funding requirements
- Evidence the compliance matrix is followed
- Communications with the award official about award performance—especially if any difficulties arise during performance and how those difficulties were resolved
- Evidence of any modifications of performance or other funding requirements
- Close out documentation from the government (if applicable)

RECOMMENDATIONS (CONTINUED)

Audits and investigations by federal and state regulators are inevitable. Indeed, one of the CARES Act program requirements is that once the Fund is exhausted, there is to be a governmental audit. A successful strategy for answering government questions in audits and investigations is showing candor in any interactions with the government.

- If circumstances change, if a company's understanding of the facts change, or if compliance steps are missed, failing to communicate any of this to the government can cause auditors or investigators to escalate their concerns, including to prosecutors.
- On the contrary, explaining the issues, how they were discovered, and what is being done to address the issues can help the government decide to focus its enforcement efforts elsewhere.

RECOMMENDATIONS (CONTINUED)

Recipients of any of the government funds should consider taking the following measures to help ensure compliance with requirements for receipt of such funds and avoid FCA exposure as enforcement actions ramp up in the coming months:

1. Stay informed of any government clarifications, guidance documents, and new regulations to ensure that any inaccuracies in information previously submitted are identified and corrected immediately.

RECOMMENDATIONS (CONTINUED)

2. Employ special accounting techniques for COVID-19-related funds and expenses, including:
    a. Documenting a relevant nexus between COVID-19, lost revenue or expenses, and each use of the funds (especially salary/payroll of retained employees);
    b. Clear tracking and detailed descriptions of COVID-19 expenses and losses with as close to real-time adjustments and updates as possible;
    c. Separating incoming funding streams, including by using distinct bank accounts or special general ledgers, to avoid "double dipping" and document overlapping uses;
    d. Tracking lost revenue and expenses by payor and provider type;
    e. Being pro-active in self-auditing finances and revising policies and procedures to account for new requirements; and
    f. Implementing internal controls, including "hard stop" protocols, which must be satisfied prior to internal release of COVID-19-related grant funds.

RECOMMENDATIONS (CONTINUED)

3. Thoroughly vet all subcontractors to whom COVID-19-related funds are distributed for compliance with applicable laws, regulations, Terms and Conditions, certifications, and attestations.
4. Educate both decision-makers and supporting staff on the relevant steps necessary to ensure organizational compliance, including recurring status checks and regular updates related to COVID-19 compliance.
    - Keep an iterative memorandum rather than a *set it and forget it* approach to compliance.
        - For ex., on June 19, HHS released a frequently asked question defining lost revenue as "any revenue that … a health care provider lost due to coronavirus." It stated that hospitals could "use any reasonable method of estimating the revenue during March and April 2020 compared to the same period had COVID-19 not appeared. On Sept. 19, HHS issued a new definition of lost revenue, stating that it was "represented as a negative change in year-over-year net patient care operating income." It specified that after covering the cost of COVID-19-related expenses, hospitals generally only will be able to apply Provider Relief Fund payments toward lost revenue up to the amount of their 2019 net patient operating income.
5. Regularly consult and document advice received from counsel and accounting firms to corroborate internal practices and lend credence to compliance measures taken.
6. Report to the board of directors or managing members regularly on the receipt and use of COVID-19 funds, compliance progress, and potential risks.

RECOMMENDATIONS (CONTINUED)

The CARES Act also created the Public Health and Social Services Emergency Fund (the "Provider Relief Fund" or "PRF") to which it allocated grant money to be distributed to hospitals and other health care providers affected by the public health emergency. In addition to the generally-applicable best practices previously discussed, recipients of PRF Funds should implement the following additional measures to help ensure compliance with PRF Terms and Conditions and avoid FCA exposure related to PRF Funds:

1. Separate all bills that have been or will be charged to patients seen during the public health emergency (after January 31, 2020), and review such bills for compliance with attestations and certifications regarding balance billing practices. This may include rendering a preliminary internal determination of whether any such patient is likely to be considered, based on clinical indicators, a "presumptive or actual" COVID-19 patient.

RECOMMENDATIONS (CONTINUED)

2. Employ heightened record-keeping and support for staff whose salaries exceed $197,300, and consider reviewing salary inputs for such staff, as applicable, to ensure that inputs from PRF grants are in line with the pro rata cap.
3. Diligently track the number of jobs created or retained by project or activity supported by the use of PRF grants and other COVID-19-related funds, in addition to other relevant metrics required to be tracked by recipients of grants over $150,000.

Telehealth

BACKGROUND

- Pre-pandemic, telehealth comprised a fraction of a percentage of Medicare spending. The story was essentially the same for state Medicaid programs and commercial health plans.
- The root cause was Section 1834(m) of the Social Security Act, which defines the scope of the Medicare telehealth benefit. The statute imposes five requirements for coverage:
  - The **geographic** requirement. The beneficiary must reside in a rural area.
  - The **location** requirement. The beneficiary must be physically present at a healthcare facility when the service is provided.
  - The **service** requirement. The service provided must be listed as an approved telehealth service (as defined by CPT® or HCPCS code).
  - The **technology** requirement. The service must be provided using a telecommunications technology with audio and video capabilities that permit real-time interactive communication.
  - The **provider** requirement. The service must be furnished by an eligible provider, including physicians, non-physician practitioners, clinical psychologists, clinical social workers, registered dieticians, and nutrition professionals.

BACKGROUND (CONTINUED)

- In the last few years, Congress approved some exceptions to the Section 1834(m) requirements:
  - **Telestroke**. Effective 01/01/2019, geographic and location requirements do not apply to services furnished to diagnose, evaluate, or treat symptoms of acute stroke.
  - **Substance Use Disorder**. Effective 07/01/2019, geographic and location requirements do not apply to services relating to SUD and co-occurring behavioral health conditions.
  - **End-Stage Renal Disease**. Effective 01/01/2019, geographic and location requirements do not apply to ESRD services relating to home dialysis.
  - **Medicare Advantage**. For 2020 plan year, the MA plan may eliminate geographic and location requirements.

BACKGROUND
(CONTINUED)

- CMS also approved specific exceptions for providers participating in the Medicare Shared Savings Program and Center for Medicare & Medicaid Innovation initiatives.
- While the Section 1834(m) restrictions apply only to Medicare, other payers also have resisted fee-for-service reimbursement for telehealth services.

PANDEMIC

- In its initial response to the COVID-19 pandemic, Congress gave CMS authority to waive Section 1834(m)'s **geographic** and **location** requirements for the duration of the public health emergency (PHE).
- With this waiver authority and through the publication of two interim final rules, CMS has significantly expanded telehealth Medicare fee-for-service reimbursement.
- State Medicaid programs and commercial plans followed suit, temporarily providing expanded telehealth coverage and reimbursement.
- On October 14, 2020, CMS expanded the list of telehealth services that Medicare Fee-For-Service will pay for during the PHE by adding 11 new services to the Medicare telehealth services list. The new telehealth services include certain neurostimulator analysis and programming services, and cardiac and pulmonary rehabilitation services. The list of the newly added services is available at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes

POST-PANDEMIC

- When the declaration of the national COVID-19 public health emergency expires, Medicare's temporary expansions of telehealth coverage and reimbursement will expire with it. Significant legislative and regulatory changes will be required to re-capture any gains made during the pandemic.
- With Medicare viewed as the "leader" for health care policy, state programs and private payers are likely to model their telehealth approaches after Medicare.

POST-PANDEMIC (CONTINUED)

- For years, regulators have heavily scrutinized health care services furnished via telecommunication and remote technologies. Moving forward, regulators will certainly increase their focus on rooting out fraud and abuse involving telehealth.
- While regulators have many tools to root out fraud and abusive practices, they are also likely to expand use of analytics technology to facilitate fraud detection.

RECOMMENDATIONS

- Telecommunication and remote technologies present serious potential liabilities, such as privacy risks for patients, providers and insurance companies, as well as the risk of cyberattacks.
- If you want no part of health care fraud investigations or audits, or the tremendous penalties they carry, regulatory compliance will be critical. Consider the following:
    1. Evaluate physician employment contracts and billing agreements;
    2. Assess the security of telehealth technologies and vendors' HIPAA security compliance;
    3. Consider how telehealth platforms function across connected devices with electronic health record systems;
    4. Create or amend agreements with vendors who may have, or may be able to gain, access to protected health information, and ensure protections for any security breaches – including indemnification, internal processes for reporting, and cyber liability;

RECOMMENDATIONS (CONTINUED)

5. Train employees on compliant billing practices and fraud assessment and reporting strategies;
6. Perform comprehensive security assessments of IT systems and technologies in use or under consideration for adoption.
7. Safeguard Internet Protocol (IP) with a remote workforce;
8. Remain vigilant for fraudulent schemes that target telehealth physicians;
9. Be mindful of potential pitfalls that can create exposure to FCA liability – such as upcoding and diagnostic code errors, billing for unapproved COVID-19 treatments, etc.

TELEWORKING

- The COVID-19 pandemic forced businesses to rapidly change from having a largely office-based workforce to allowing employees to work from home to reduce the risk of infection.
- The Department of Homeland Security Cybersecurity and Infrastructure Security Agency (CISA) has published a Telework Essentials Toolkit to help business leaders, IT staff, and end users transition to a more permanent teleworking environment.
- The CISA Toolkit is intended to provide support to organizations to help them re-evaluate and strengthen their cybersecurity defenses and fully transition into a long-term teleworking solution.
- The Toolkit includes three personalized modules that include best practices for executive leaders, IT professionals and teleworkers, and include the security considerations appropriate to each role.
- The Toolkit can be accessed at https://www.cisa.gov/sites/default/files/publications/20-02019b%20-%20Telework_Essentials-08272020-508v2.pdf

Current Procedural Terminology (CPT)

CPT E&M CODES CHANGES

- CPT, published by the American Medical Association (AMA), is the medical code set used to report medical services and procedures (surgical and diagnostic) for reimbursement.
- Providers, payers, coders and auditors will be challenged on January 1, 2021, because the American Medical Association (AMA) still has to issue CPT clarifications in some very key areas.
- The AMA does not process or pay claims and as such, they are not the final word on billing policies or payment guidelines, so CMS and other payers will also need time to comment on any changes, adjust to those changes and/or clarifications, or even push changes back on the AMA should they disagree with the AMAs position.

WHAT WE DO KNOW ABOUT CPT CHANGES

- Actual CPT Evaluation & Management (E&M) changes are set to go into effect January 1, 2021. They effect only Office or Other Outpatient Services (99201-99205 and 99211-99215) codes. The AMA may, however, make additional modifications.
- What we know:
  - Code 99201 for the evaluation and management of a new patient will be deleted due to low utilization.
  - The history and exam elements will no longer be factored into office/outpatient E&M code selection, though they will be necessary to report the office/outpatient E&M service.
  - Time associated with 99202-99215 has been changed from "typical face-to-face time" to "total time spent on the day of the encounter."
  - The medical decision making (MDM) chart has been revised for 2021.

CPT CHANGES FOR OTHERS

- What do these changes mean for hospital observation, hospital inpatient, consultations, emergency department, nursing facility, domiciliary, rest home, custodial care, and home E&M services?
- The answer is they won't change, not in 2021 at least.
- CMS views the 2021 changes to office/outpatient E&M codes as something of a test run to determine whether the changes should be applied to other E&M code groups in the future.

QUESTIONS?

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