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Managing Compliance Risk in the COVID-19 Crisis

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How Healthcare Providers Can Manage Compliance Risk in the COVID-19 Crisis

With great crisis comes great compliance risk. We know this from Hurricane Katrina, the 2008 financial crisis, and the BP oil spill.

It is a familiar pattern in which a crisis produces heightened government spending to remedy the suffering and produces public outcry to punish bad actors, both of which in turn produce heightened government enforcement activity.

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- The COVID-19 crisis is already on track to follow the same pattern, and on an even larger scale.
- The Department of Justice has already signaled its intent to once again aggressively investigate during and after the crisis.
- For examples, see the DOJ's Special Inspector General for Pandemic Recovery and the National Nursing Home Initiative.

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By the Numbers

- The Coronavirus Aid, Relief, and Economic Security (CARES) Act is infusing an initial $2.2 trillion in government funds to mitigate the economic effects of COVID-19.
- Healthcare providers — from large hospitals to small practices — are receiving portions of these federal funds. Specifically, the CARES Act set aside $100 billion in emergency relief administered by the U.S. Department of Health & Human Services (HHS) through the Public Health and Social Services Emergency Fund. In addition, the $350-billion PPP adds an additional $75 billion to the fund.

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By the Numbers

- Many healthcare providers will understandably be interested in participating in one or more of the relief programs established by the CARES Act. These programs, however, are conditioned on various eligibility requirements and approved uses of program funds, and require the recipient to make various certifications to the government.
- And of course, healthcare providers continue to bill Medicare amidst the turmoil of treating patients during the pandemic. Submitting claims to federal payors entails its own set of certifications to the government.

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By the Numbers

- Former crises teach us that even before the dust begins to settle, government enforcement actors will aggressively search for fraud in the form of any perceived misrepresentations made to the government to receive any of government funds, invoking the federal False Claims Act (FCA) and seeking treble damages, fines, and criminal referrals.
- There also remains the heightened risk of individuals (especially current and former employees) reporting potential false claims as a whistleblower.

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By the Numbers

- Compliance with all the various requirements and certifications is critical for minimizing exposure to FCA enforcement actions by the government, *qui tam* suits by private whistleblowers, and potential criminal referrals.

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What certifications?

- For Public Health and Social Services Emergency Funds, a recipient must certify that the funds will be used **only to support COVID-19-related expenses or lost revenue due to the cancelation of non-essential elective procedures.**

- A recipient must also agree to not seek collection of out-of-pocket payments from a presumptive or actual COVID-19 patient that are greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network provider.

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What certifications?

- For reimbursement from a government payor (e.g., Medicare) for a medical procedure or service, the provider is certifying many things, including that the procedure or service was medically necessary and accurately described in the claim form.
- These certifications can become tricky when treating an overwhelming new virus in a pandemic.

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What certifications?

- The government says it will be looking for “bad actors” seeking to take advantage of the panic, confusion, big dollars, and fast pace associated with the pandemic relief efforts.
- The Department of Justice has already begun “urging the public to report suspected fraud schemes related to COVID-19” and “directed all U.S. Attorneys to prioritize the investigation and prosecution of Coronavirus-related fraud schemes.” Plaintiffs’ law firms who represent whistleblowers can be expected to follow suit on the whistleblower front. In short, the COVID-19 crisis and CARES Act provide fertile ground for FCA enforcement actions and criminal referrals, heightening healthcare organizations’ associated compliance risk.
- For instance, Attorney General Barr recently said the DOJ will be searching for “medical providers obtaining patient information for COVID-19 testing and then using that information to fraudulently bill for other tests and procedures.”

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But your practice doesn't have any bad actors, so none of this applies . . .

- In shocking news, the government doesn't always get it right.
- Sometimes they ensnare totally innocent actors.
- Plus, the costs of a mere investigation can be massive, and innocent actors who haven't proactively taken measures to put themselves in a strongly defensible position are less likely to be able to quickly convince investigators that they were not bad actors and thereby limit the costs of a government investigation.

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- The reality is, all healthcare providers who submit information to the government in connection with getting any type of funds (e.g., emergency Medicare relief, a Paycheck Protection Program (PPP) loan, a bill for medical services) will face enhanced compliance risk in connection with the FCA and potential criminal enforcement and would be wise to proactively seek to minimize that risk.

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But my state has enacted immunity for providers . . .

- Though many states have enacted or will enact laws or executive orders immunizing healthcare workers and healthcare businesses from lawsuits alleging negligence in exposing the plaintiff to coronavirus, those are no silver bullet, especially with respect to federal scrutiny from CMS or DOJ.

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So that's a lot of scary news, what now?

There ARE steps that you can take to help mitigate these risks.

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Five steps to help mitigate risks

1. Frequently review program rules carefully and develop reasonable and defensible interpretations

- The rules and the government's interpretations are constantly changing. It is not easy to keep track of the changes, and it is often difficult to know exactly what the existing rules mean.
- For instance, healthcare providers that receive emergency relief from the Public Health and Social Services Emergency Fund must certify that the payments will "only be used to prevent, prepare for, and respond to coronavirus, and [will] reimburse the Recipient only for healthcare related expenses or lost revenues that are attributable to coronavirus." Ascertaining exactly what the government will later apply as its test for the required connection between a payment's use and the coronavirus is no easy task.

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Five Steps to help mitigate risks

1. Frequently review program rules carefully and develop reasonable and defensible interpretations

- Likewise, it is not yet entirely clear what the government might **ultimately** say constitutes a false certification in an application for PPP loan funds that "current economic uncertainty makes this loan request necessary to support the ongoing operations of the Applicant."
- The SBA issued FAQ #31 in which it stated that borrowers must show that they cannot "access other sources of liquidity sufficient to support their ongoing operations in a manner that is not significantly detrimental to the business." This FAQ comes ***after*** most applicants had already made the certification, and despite the CARES Act's express waiver of the SBA's usual requirement that borrowers specifically demonstrate they cannot obtain credit elsewhere.

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Five steps to help mitigate risks

1. Frequently review program rules carefully and develop reasonable and defensible interpretations

- Because there are defenses when a payment recipient's conduct is based upon a reasonable interpretation of an ambiguous requirement and the government has not provided any contrary official alternative interpretation, healthcare providers should frequently read program rules and certifications carefully and develop reasonable, defensible interpretations of them, consulting counsel as necessary in the process.

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Five steps to help mitigate risks

2. Evaluate compliance and reporting programs and adopt best practices

- Throughout the COVID-19 crisis and recovery, healthcare organizations should continue to review existing compliance programs and risk-management procedures, and adopt supplemental compliance practices where appropriate to shore up heightened risks posed by the pandemic. If you don't have a compliance program, you **need** to implement one. Counsel can help.
- As a starting point, catalogue all statutory, regulatory and contractual requirements governing providers' claims for government funds, and implement policies and controls around any certifications of compliance with such requirements made to the government. Healthcare entities should then ensure that they have proper accounting and billing procedures in place to track expenditures and services from federal funding for approved purposes.
- Separately, companies should intensify their efforts to maintain effective internal reporting and compliance certification systems.

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Five steps to help mitigate risks

2. Evaluate compliance and reporting programs and adopt best practices

- Finally, healthcare providers should be wary of business relationships in which there is a heightened risk of fraud, waste or abuse, and should conduct due diligence before entering into new business relationships. Failure to perform basic due diligence on business partners could subject companies' conduct to government scrutiny.
- The risk is not hypothetical. Just recently, the DOJ indicted an individual who ran a marketing company that generated leads to testing companies, alleging that he conspired with other healthcare providers to receive kickbacks for COVID-19 tests, provided that those tests were bundled with a much more expensive test that does not identify or treat COVID-19. Committing to an effective compliance and reporting regime on the front-end helps mitigates such risks.

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Five steps to help mitigate risks

3. Keep a record of helpful evidence

- Hospitals and healthcare practices can further reduce exposure to FCA liability by documenting their understanding of the underlying rules, communicating that understanding to the government and tracking their fund expenditures. This includes ensuring that any specific directions from the government are committed to writing, as well as documenting the following:
- Any government modification or waiver of requirements (especially if the government deviation is informal, such as an oral representation)
- The services and items provided by a healthcare provider fund-recipient that are in direct response to the COVID-19 pandemic (to justify reimbursement).
- In fact, any healthcare organization receiving more than $150,000 in CARES Act relief is required to submit to HHS and the Pandemic Response Accountability Committee a report outlining and documenting how those funds were utilized.

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Five steps to help mitigate risks

4. Know thine enemy – (A) Whistleblowers

i. Be on the lookout for potential whistleblowers but do not punish them in any way without consulting counsel.

ii. Appropriately limit written communications about compliance concerns.

iii. Assume you are being recorded.

iv. Be extremely careful discussing profits and losses.

v. Address and correct problems. Do not conceal or ignore.

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Five steps to help mitigate risks

4. Know thine enemy – (B) Government Algorithms

i. Beware outlier status (utilization frequency, upcoding, dollars, outcomes).

ii. Engage counsel if you are subject to a ZPIC, Civil Investigative Demand, or Grand Jury Subpoena.

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Five steps to help mitigate risks

5. Beware billing for new or novel procedures or services

- Many practices have been forced to become creative in the way they treat patients and seek to limit exposure during the pandemic. The government is unlikely to pursue practices for such well-intentioned conduct, even if hindsight suggests such conduct may have been medically unnecessary or even potentially harmful.

- But the government might be less forgiving where practices bill for such conduct, particularly where the billings are lucrative. Before your practice bills for a new or novel practice or procedure it should seek counsel. A legal opinion that the practice can bill for the item is a helpful defense to later scrutiny.

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Questions?

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