False Claims Act Exposure for Beneficiaries of the Public Health and Social Services Emergency Relief Fund: Mitigating Risks of Ambiguous Terms & Conditions

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I. Introduction

The CARES Act allocated $100 billion in relief funds to hospitals and other healthcare providers, to be distributed by the Department of Health and Human Services ("HHS") through the Public Health and Social Services Emergency Relief Fund (or "Provider Relief Fund"). Many healthcare providers across the country have received payments from the Fund, beginning with an initial tranche of $30 billion distributed in mid-April, and many more will be receiving additional funding in coming weeks.

These funds provide critical support to hospitals, physician-owned practices, and other providers who face significant financial challenges caused by the dual shocks of preparing to treat COVID-19 patients while simultaneously losing revenue because of suspension of elective procedures. But the relief funds are subject to extensive terms and conditions, and with those conditions comes exposure to potential liability under the False Claims Act ("FCA"). This exposure is particularly acute given the broad and ambiguous language of some of the terms and conditions, the expectation of intensive government enforcement efforts following distribution of relief funds, and the economic incentives for private relators to commence FCA lawsuits.

Although many providers are understandably rushing to obtain relief funds immediately, it is critical to pay attention to the strings attached to those funds. Prudent providers can and should take steps now to mitigate the risk of potentially costly FCA claims that could arise later.

II. FCA Basics

The False Claims Act, enacted in 1863 to "stop[] the massive frauds perpetrated by large contractors during the Civil War," *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016), imposes liability where a defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"

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to the Government. 31 U.S.C. § 3729(a)(1). A person "knowingly" presents a false claim if he "(1) has actual knowledge of the information," *i.e.*, actually knows the claim is false; "(2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1); *see United States v. Munoz-Escalante,* 2015 U.S. Dist. LEXIS 142167, at * 6 (D.S.D. 2015) (citing *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 767 (8th Cir. 2002)). Upon proving a violation, the Government can recover treble damages plus civil penalties. 31 U.S.C. § 3729(a)(1).

The Government itself may commence an FCA action, or a private relator may do so on behalf of the Government, in which case the Government may or may not choose to intervene in the case. In either case, damages recovered belong to the Government, but the relator is entitled to a share of the proceeds. *See generally United States ex rel. Hunt v. Cochise Consultancy, Inc.*, 887 F.3d 1081, 187 (11th Cir. 2018).

Where, as here, the Government's payment of funds is conditioned on compliance with certain requirements, FCA exposure can arise if the recipient of funds is alleged to have "falsely" certified compliance with the terms and conditions of payment. *See, e.g., Escobar*, 136 S. Ct. at 1995 (confirming the "implied false certification theory can be a basis for liability" under the FCA).

III. Terms & Conditions of Provider Relief Fund Payments

Providers who receive disbursements from the Provider Relief Fund are required to sign an attestation agreeing to the Government's terms and conditions for receipt of the funds. In addition to a prohibition on using relief funds for expenses or losses reimbursed by other sources (*i.e.*, no "double dipping"), and numerous other specific provisions, the terms and conditions prohibit "balance billing" out-of-network patients for "all care for a presumptive or actual case of COVID-19."[1] The terms and conditions also impose a broad limitation on the purposes for which relief funds may be used:

The 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.

The latter two conditions in particular engender the potential for FCA litigation because they are both broadly applicable and ambiguous. For example, the prohibition on balance billing extends to "presumptive" cases of COVID-19, but fails to define a "presumptive" case. As experience with COVID-19 rapidly evolves, providers and public health agencies continually update clinical signs and symptoms of the disease, many of which are nonspecific. Virus test kits remain in short supply. Absent a test confirming a patient's infection with the novel coronavirus, how is a provider to define "presumptive" cases of COVID-19 so as to comply with this condition? The Provider Relief Fund website states that "providers must agree not to seek collection of out-of-pocket payments from a 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" (emphasis added). This suggests that the out-of-pocket limitation applies only to COVID-19-related

diagnosis and care, but ambiguity remains due to the lack of specific guidance.

The broad limitation on use of relief funds is similarly problematic. Given the devastating breadth of the COVID-19 pandemic's medical, economic, and social effects, how are providers to distinguish "expenses or lost revenues" that are "attributable to the coronavirus" as opposed to some other cause? For example, do "health care related expenses . . . attributable to the coronavirus" include only the direct costs of purchasing additional personal protective equipment, ventilators, and other supplies necessary to treat COVID-19 patients? Or does this category include associated administrative costs, costs of training, etc.? Do "lost revenues . . . attributable to the coronavirus" include only revenues from elective procedures cancelled pursuant to government order or by medical necessity? Or could this category also include, for example, procedures that could have gone forward but were cancelled by patients because of perceived infection risk? Could it include loss of business opportunities that are shelved or cancelled because of the broader effects of the pandemic? The Government's decision to distribute a portion of the funds immediately and broadly to all providers that received Medicare fee-for-service reimbursement in 2019 suggests that "attributable to the coronavirus" should include lost revenue caused by the economic downturn attributable to the coronavirus. But again, a lack of guidance on how directly lost revenue must be attributable to the coronavirus pandemic creates ambiguity.

So-called "subregulatory guidance," that thicket of agency memoranda, website "FAQs," and other directives not promulgated through notice-and-comment rulemaking or legislation, compounds the problems raised by ambiguous terms and conditions. Agencies are scrambling to issue new rules, directives, and direction as the COVID-19 pandemic evolves. This scramble is understandable, but it creates significant pressure for agencies to do something—fast—and that urgency does not lend itself to legislative action or the ordinary notice-and-comment rule-making process. From an administrative perspective, Department of Justice trial attorneys have been directed to not pursue FCA cases premised on violations of "sub-regulatory guidance"—this is the so-called "Brand Memo" of January 2018, which was later memorialized in section 1-20.000 of the Justice Manual. Likewise, the Courts have started to express some hostility to FCA cases premised on such violations, particularly in the wake of the June 2019 Supreme Court decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), which underscored the importance of notice-and-comment rulemaking to create substantive legal standards. Nevertheless, agencies will continue to promulgate subregulatory guidance, and it will continue to play a role in litigation, in one form or another.

IV. The Risks of Ambiguous Payment Conditions

As the foregoing examples suggest, there is room for interpretation and debate over the meaning of the broad language used in the terms and conditions attached to the Provider Relief Fund. And where there is room for debate, the potential for litigation increases considerably. This is particularly true where the Government is expected to ramp up enforcement efforts following disbursement of stimulus funds. Indeed, in announcing the allocation of additional funds, HHS Secretary Azar promised "significant anti-fraud and

auditing work . . . by HHS, including the work of the Office of the Inspector General," to enforce the conditions imposed on the disbursements. The Government's efforts likely will focus on clear cases of willful fraud, rather than good-faith disputes over the meaning of ambiguous language in the terms and conditions. But recipients of relief funds cannot rely on good faith and prosecutorial discretion alone, because private relators still have significant financial incentives to pursue FCA claims. Ambiguous terms and conditions provide relators (and creative attorneys) a potential path to generate claims the Government probably would not pursue.

Fortunately for recipients of Provider Relief Fund payments, the federal courts generally hold that a defendant will not face FCA liability for violating a vague or ambiguous law, regulation, or contractual condition if the defendant's interpretation of the condition was objectively reasonable. *See, e.g., United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City*, 833 F.3d 874, 879 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (en banc) (Jones, J., concurring) ("Where there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim."). This principle, which functions as a particularized application of the knowledge or *scienter* requirement of an FCA claim, "helps to ensure that innocent mistakes made in the absence of binding interpretive guidance are not converted into FCA liability, thereby avoiding the potential due process problems posed by 'penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.'" *Purcell*, 807 F.3d at 287 (quoting *Satellite Broad. Co. v. Fed. Commc'ns Comm'n*, 824 F.2d 1, 3 (D.C. Cir. 1987)).

There is an additional nuance, however: Even if a defendant received funds on the basis of an objectively reasonable interpretation of applicable conditions, the defendant still may be liable "if a Relator (or the United States) produces sufficient evidence of government guidance that 'warned [the defendant] away from an otherwise reasonable interpretation' of an ambiguous regulation." *Donegan*, 833 F.3d at 879 (quoting *Purcell*, 807 F.3d at 290).

V. Mitigating FCA Risk Associated with Provider Relief Fund Payments

The foregoing case law should provide a viable defense for Provider Relief Fund recipients who use funds in accordance with good-faith, objectively reasonable interpretations of HHS's terms and conditions. But providers should not simply hope to win the interpretive battle after an FCA claim is filed; there are steps providers can take now to bolster the likely strength of their defenses if litigation occurs.

First, recipients of Provider Relief Fund Payments should carefully monitor and track the uses of these funds, so they can demonstrate compliance with the terms and conditions. (Relatedly, note that the terms and conditions expressly require compliance with federal financial management and record retention regulations, including 45 C.F.R. §§ 75.302 and 75.361-365).

Second, recipients should carefully consider, articulate, and document how particular uses of relief funds meet the HHS conditions. Having supportable financial data to show that the recipient suffered an abnormal loss of revenue that can be attributable to coronavirus will likely be important to defend a recipient's use of relief funds to support its operating expenses during the public health emergency. With respect to uses that may be debatable, providers should think critically and actively now about how those uses fit within the conditions, rather than waiting to generate a *post hoc* explanation after litigation arises. For example, in *United States ex rel. Donegan v. Anesthesia Associates of Kansas City*, the court ascribed some significance to the defendant's reasonable definition of a vague regulatory term, adopted by the defendant's Professional Practice Committee and documented in its Corporate Compliance Plan. 833 F.3d at 879.

Thoughtful and deliberate development of internal definitions and processes not only helps generate more defensible interpretive positions; it also should help to demonstrate that the recipient is acting thoughtfully and in good faith. While there is some disharmony in the case law regarding the legal significance of a recipient's subjective good faith, *see, e.g.,* John T. Boese & Douglas W. Baruch, Civil False Claims & *Qui Tam* Actions § 2.06 (4th ed.), a defendant's good faith will almost always be relevant to the Government's exercise of prosecutorial discretion, and to the judges and juries who ultimately decide cases.

Third, fund recipients should continue to monitor communications and guidance from HHS regarding the terms and conditions and use of funds. Even where agency guidance may not be legally binding, it often remains important as a practical matter and, even if not dispositive, it can play an evidentiary role in FCA litigation.

Fourth, recipients must be vigilant about understanding the nature and purpose of any deposits of Government funds. It is a mistake to take the view that "if HHS deposited the funds in our account, my organization was entitled to them." The FCA's reach is very broad—it is not just limited to affirmative requests for funds, but extends also to the knowing retention of overpayments and so-called "reverse" false claims. *See* 31 U.S.C. § 3729(a)(1)(G).

Finally, recipients should seek the advice of counsel regarding appropriate uses of Provider Relief Fund payments and other applicable conditions and regulatory requirements. Good, proactive legal advice can help mitigate the risk of facing FCA claims, and under certain circumstances can even provide a defense to an FCA claim if litigation occurs. *See, e.g., United States ex rel. Bidani v. Lewis*, 2001 U.S. Dist. LEXIS 260, at *24 (N.D. Ill. 2001) (citing *United States v. Cheek*, 3 F.3d 1057, 1061 (7th Cir. 1993)). It should be noted, however, that the advice-of-counsel defense may not be available to a defendant who "shops around" for a favorable legal opinion or otherwise does not act in good faith. *See United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 792 F.3d 364, 380 (4th Cir. 2015).

VI. Conclusion

The Provider Relief Fund offers crucial support to hospitals, clinics, and other providers

who face dire and immediate financial need. Providers in need of assistance certainly should avail themselves of this support as appropriate, but should be conscious of the attendant risks. Proactive, deliberate compliance actions are the best way to mitigate the risks of costly litigation likely to sweep through the healthcare industry on the heels of the COVID-19 pandemic.

[1] “[F]or all care for a presumptive or actual case of COVID-19, Recipient certifies that it 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.”