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## *False Claims Act Exposure Risks for Industries Fighting COVID-19*

May 29, 2020

***This is the second in a series of client alerts addressing the likely role of the False Claims Act in the wake of the massive federal government response to the COVID-19 pandemic.***

The Coronavirus Aid, Relief, and Economic Security (CARES) Act makes available more than \$2 trillion in federal loans, grants and other financial assistance to a wide range of industries that have been affected by the COVID-19 pandemic.<sup>1</sup> CARES Act funding dwarfs the federal response to the 2007–2008 financial crisis, when approximately \$800 billion of federal stimulus and recovery funds were authorized by Congress.<sup>2</sup> As during the financial crisis,<sup>3</sup> however, the availability of federal aid presents risk for those who seek to participate in these programs, since the Department of Justice (DOJ) has made it a priority to prosecute those who fraudulently obtain CARES Act funding.<sup>4</sup>

Those companies and individuals who participate in CARES Act programs must also be particularly mindful of potential risk under the civil False Claims Act (FCA), 31 U.S.C. § 3729 et seq. The FCA requires companies and individuals seeking federal funds to be truthful and accurate in representations they make about their eligibility for those funds. It imposes treble damages and civil

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<sup>1</sup> Letter from Phillip L. Swagel, Director, Congressional Budget Office, to the Honorable Mike Enzi, Chairman, Committee on the Budget, United States Senate (Apr. 27, 2020), available at <https://www.cbo.gov/system/files/2020-04/hr748.pdf>.

<sup>2</sup> American Recovery and Reinvestment Act, Pub. L. No. 111-5, 123 Stat. 115 (2009).

<sup>3</sup> See WilmerHale Client Alert, *What History Tells Us About the Importance of the False Claims Act in a Time of Pandemic*, Matthew Benedetto and Liz Phillips (May 11, 2020), <https://www.wilmerhale.com/en/insights/client-alerts/20200511-covid-19-what-history-tells-us-about-the-importance-of-the-false-claims-act-in-a-time-of-pandemic>.

<sup>4</sup> On March 20, 2020, the DOJ announced that Attorney General William Barr had directed all US attorneys to prioritize the investigation and prosecution of coronavirus-related fraud. Department of Justice, *Attorney General William P. Barr Urges American Public to Report COVID-19 Fraud* (Mar. 20, 2020), <https://www.justice.gov/opa/pr/attorney-general-william-p-barr-urges-american-public-report-covid-19-fraud>; see also Department of Justice, *Two Charged in Rhode Island with Stimulus Fraud*, Press Release (May 5, 2020), <https://www.justice.gov/opa/pr/two-charged-rhode-island-stimulus-fraud>; Ankush Khardori, *The Wayward Hunt for Stimulus Fraud*, Opinion, THE WALL STREET JOURNAL (May 11, 2020).

penalties of \$11,463 to \$23,331 per false claim (when adjusted for inflation),<sup>5</sup> and it offers rewards for insiders who file claims on behalf of the government (known as qui tam plaintiffs).

This alert identifies how the CARES Act creates potential exposure under the FCA for industries responding to COVID-19.

### **Small Business and Lender Risk Under the Paycheck Protection Program**

Title I of the CARES Act established the Paycheck Protection Program (PPP), which is administered by the US Small Business Administration (SBA). The PPP created a fund of \$659 billion to provide forgivable loans to eligible small businesses that spend the money on enumerated expenses, including payroll, rent and utilities. To participate in the PPP, borrowers and lenders alike must make multiple certifications to the SBA and thus face potential risk of FCA liability. For instance, a borrower or lender may run afoul of the FCA if it knowingly makes a false certification that it is compliant with the PPP's eligibility rules.<sup>6</sup> But the scope and meaning of those rules have been a source of widespread industry confusion.<sup>7</sup> What's more, the PPP has been rolled out very quickly in an effort to contain the rapid escalation of the COVID-19 crisis and its effect on small businesses.<sup>8</sup> The SBA, in turn, has issued multiple rounds of guidance in the form of Frequently Asked Questions (FAQ) to help participants in the PPP understand and mitigate various risks,<sup>9</sup> but that guidance was in certain instances provided after loan applications were submitted and loan proceeds were disbursed. The guidance provided by the SBA and the Treasury Department may provide some comfort to PPP participants that government regulators are unlikely to second-guess participants' conduct, and the FCA itself requires more than an honest mistake for liability to attach.

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<sup>5</sup> 15 CFR § 6.3(a)(3) (Jan. 15, 2020).

<sup>6</sup> 31 U.S.C. § 3729(a)(1)(B). Under the FCA, "knowledge" is defined as (i) "actual knowledge of the information"; (ii) "deliberate ignorance of the truth or falsity of [] information"; or (iii) "reckless disregard of the truth or falsity of [] information." *Id.* § 3729(b)(1)(A). It requires "no proof of specific intent to defraud." *Id.* § 3729(b)(1)(B).

<sup>7</sup> See, e.g., Anne Sraders, *The new PPP loan forgiveness application is causing lots of confusion. Here's what to know so far*, FORTUNE (May 20, 2020), <https://fortune.com/2020/05/20/sba-ppp-loan-forgiveness-application-confusion/>; Paul Davidson, *Coronavirus PPP loans leave small firms confused, wary and rushing to secure cash to survive*, USA TODAY (Apr. 13, 2020), <https://www.usatoday.com/story/money/usaandmain/2020/04/13/coronavirus-small-businesses-scramble-secure-federal-ppp-loans/5133984002/>.

<sup>8</sup> David Baumann, *Problems Revealed for CUs as Quick Rollout of Paycheck Protection Program Begins*, CREDIT UNION TIMES (Apr. 3, 2020), <https://www.cutimes.com/2020/04/03/problems-for-cus-as-quick-rollout-of-paycheck-protection-program-begins/?slreturn=20200420163111>.

<sup>9</sup> The SBA has continued to update its FAQs, the most recent of which is available at the following link: [https://www.sba.gov/sites/default/files/2020-05/Paycheck-Protection-Program-Frequently-Asked-Questions\\_05%2019%2020.pdf](https://www.sba.gov/sites/default/files/2020-05/Paycheck-Protection-Program-Frequently-Asked-Questions_05%2019%2020.pdf).

But both borrowers and lenders must be prepared for scrutiny down the road. Such SBA guidance, for instance, does not preclude the filing of FCA lawsuits by private plaintiffs.<sup>10</sup>

✓ Certifications to SBA

Under the PPP, borrowers must certify in good faith at the time of loan origination (1) that the loan request is “necessary” to “support ongoing operations” in light of current economic conditions; (2) “that funds will be used to retain workers and maintain payroll or make mortgage payments, lease payments, and utility payments;” (3) that the borrower does not already have a PPP loan application pending with SBA; and (4) for the period from February 15, 2020, to December 31, 2020, that the borrower has not already received a PPP loan.<sup>11</sup>

In addition, lenders that participate in the PPP must also, at the time of loan origination, certify to the SBA that they have confirmed borrower eligibility, as well as that they comply with the Bank Secrecy Act.<sup>12</sup> Both the PPP Interim Final Rule and subsequent SBA guidance have made clear that lenders may rely on borrower attestations, although lenders must “review” payroll documentation submitted by borrowers in support of their loan application.<sup>13</sup> The scope of the term “review” remains open to interpretation.

The PPP’s loan forgiveness procedure allows a PPP loan to be forgiven if 75 percent of the amount of the loan was dedicated to payroll expenses.<sup>14</sup> Borrowers must therefore make several additional certifications when applying for loan forgiveness. For example, the borrower must truthfully and accurately complete a loan forgiveness calculation.<sup>15</sup> The borrower must also certify, among other things, that the funds were used properly and that the borrower has verified the payments for both payroll and nonpayroll expenses.<sup>16</sup>

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<sup>10</sup> These private plaintiffs, called “relators,” may receive a cut of the government’s total recovery, ranging from 15 to 30 percent depending on whether the US intervenes in the case. *Id.* § 3730(d).

<sup>11</sup> CARES Act, Pub. L. No. 116-136 § 1102(a)(2)(G).

<sup>12</sup> The lender is permitted to rely on the certifications of the borrower to “determine the eligibility of the borrower and use of loan proceeds and to rely on specific documents provided by the borrower to determine qualifying loan amount and eligibility for loan forgiveness.” *Business Loan Program Temporary Changes; Paycheck Protection Program*, 85 Fed. Reg. 20811, 20812 (Apr. 15, 2020); *see also* Department of the Treasury, *Paycheck Protection Program (PPP) Information Sheet: Lenders*, <https://home.treasury.gov/system/files/136/PPP%20Lender%20Information%20Fact%20Sheet.pdf>.

<sup>13</sup> *See* PPP FAQ No. 1, as of May 19, 2020 (“[A]s the PPP Interim Final Rule indicates, lenders may rely on borrower representations, including with respect to amounts required to be excluded from payroll costs”).

<sup>14</sup> *Business Loan Program Temporary Changes; Paycheck Protection Program*, 85 Fed. Reg. 20811, 20813–14 (Apr. 15, 2020).

<sup>15</sup> DEPARTMENT OF TREASURY, PAYCHECK PROTECTION PROGRAM LOAN FORGIVENESS APPLICATION 3, <https://home.treasury.gov/system/files/136/3245-0407-SBA-Form-3508-PPP-Forgiveness-Application.pdf>.

<sup>16</sup> *Id.*

✓ Potential FCA Risks

These certification requirements, both at loan origination and forgiveness, raise multiple issues that are relevant to potential FCA exposure. We discuss a few prominent concerns here. First, businesses seeking PPP loans must certify that the loan is “necessary” to support “ongoing operations” due to current economic conditions. Businesses may be uncertain about the exact meaning of the term “necessary,” and the meaning of that term itself may change in the weeks or months ahead. In an attempt to clarify this important term, the SBA, in consultation with the Treasury Department, stated in recently issued guidance that any borrower receiving a PPP loan with an original principal amount under \$2 million may enjoy a safe harbor from SBA audits, enforcement and criminal referral.<sup>17, 18</sup> A borrower seeking a loan under this amount “will be deemed to have made the required certification concerning the necessity of the loan request in good faith.”<sup>19</sup>

While this safe harbor certainly provides some comfort in terms of a potential SBA audit or enforcement action, it would not eliminate potential FCA risk for a few reasons. *First*, the safe harbor itself does not mention the FCA. *Second*, this particular FAQ does not preclude the filing of FCA lawsuits by *private persons* against entities that received a PPP loan under \$2 million. *Third*, agency guidance documents do not have the same binding legal effect as do agency rules, and because these FAQs likely constitute only guidance, the FAQs would not provide a complete shield to FCA liability. It is DOJ policy that guidance documents neither create binding requirements that do not already exist by statute or regulation nor can be used by DOJ litigators, where a defendant is noncompliant with such guidance, to prove liability under the FCA.<sup>20</sup> But such enforcement policies would not similarly limit private plaintiffs (or in fact the DOJ itself if the source of the alleged noncompliance was the CARES Act or its implementing regulations).

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<sup>17</sup> Department of Treasury, *Paycheck Protection Program Frequently Asked Questions* at Question 46 (May 13, 2020), <https://home.treasury.gov/system/files/136/Paycheck-Protection-Program-Frequently-Asked-Questions.pdf>.

<sup>18</sup> In addition, the SBA promulgated an interim rule that provides a safe harbor to borrowers who paid off their loans by May 14, 2020, and that deadline was subsequently extended to May 18, 2020. 13 C.F.R. § 120, available at [https://www.sba.gov/sites/default/files/2020-05/Interim-Final-Rule-on-Extension-of-Limited-Safe-Harbor-with-Respect-to-Certification-Concerning-Need-for-PPP-Loan-Request\\_05%2013%2020.pdf](https://www.sba.gov/sites/default/files/2020-05/Interim-Final-Rule-on-Extension-of-Limited-Safe-Harbor-with-Respect-to-Certification-Concerning-Need-for-PPP-Loan-Request_05%2013%2020.pdf); Department of Treasury, *Paycheck Protection Program Frequently Asked Questions* at Question 47 (May 13, 2020), <https://home.treasury.gov/system/files/136/Paycheck-Protection-Program-Frequently-Asked-Questions.pdf>.

<sup>19</sup> *Id.*

<sup>20</sup> Memorandum from the Associate Attorney General, U.S. Dep’t of Justice to Heads of Civil Litigating Components, United States Attorneys (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download>.

This safe harbor of course does not insulate borrowers who receive loans greater than \$2 million. Those borrowers must have an “adequate basis” for the loan.<sup>21</sup> And the potential FCA risk is only amplified by Treasury Secretary Mnuchin’s recent comments that companies receiving more than \$2 million will face close scrutiny.<sup>22</sup>

The PPP’s loan forgiveness procedure presents FCA risk as well. Although the PPP Interim Final Rule includes a safe harbor for lenders in connection with loan forgiveness requests, this safe harbor also omits reference to potential FCA liability.<sup>23</sup> On top of this, the borrower forgiveness calculations are quite complex, which amplifies risks for borrowers and raises questions about the degree of due diligence, if any, that a lender must undertake upon receiving those calculations—even with the safe harbor in place.<sup>24</sup> The safe harbor is also silent on the due diligence that a lender may be required to undertake if a loan forgiveness request triggers a lender’s internal anti-money laundering monitoring system; the failure to follow up on such internal red flags may also create FCA liability.

#### **Business Loans Under Title IV**

In addition to the small business loans made available under Title I of the CARES Act, businesses are also eligible to receive loans under Title IV. A business that is eligible to receive a loan under Title IV is defined broadly as any “United States business that has not otherwise received adequate economic relief in the form of loans or loan guarantees provided under this Act.”<sup>25</sup> Loans made under Title IV cannot be reduced through loan forgiveness.<sup>26</sup>

##### ✓ Federal Reserve Facilities

The CARES Act permits the Treasury Secretary to use \$454 billion for direct loans and other investments in programs or facilities established by the Federal Reserve.<sup>27</sup> The purpose of these

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<sup>21</sup> Department of Treasury, *Paycheck Protection Program Frequently Asked Questions* at Question 46 (May 13, 2020), <https://home.treasury.gov/system/files/136/Paycheck-Protection-Program-Frequently-Asked-Questions.pdf>.

<sup>22</sup> Andrew Kragie, *Small-Biz Loans Over \$2M Up For Review, Mnuchin Warns*, LAW360 (Apr. 28, 2020), <https://www.law360.com/articles/1268416/small-biz-loans-over-2m-up-for-review-mnuchin-warns>.

<sup>23</sup> Business Loan Program Temporary Changes; Paycheck Protection Program—Requirements—Extension of Limited Safe Harbor With Respect to Certification Concerning Need for PPP Loan Request, 85 Fed. Reg. 29845, 29846 (2020).

<sup>24</sup> See DEPARTMENT OF TREASURY, PAYCHECK PROTECTION PROGRAM LOAN FORGIVENESS APPLICATION 7-8, <https://home.treasury.gov/system/files/136/3245-0407-SBA-Form-3508-PPP-Forgiveness-Application.pdf>.

<sup>25</sup> CARES Act § 4002(4).

<sup>26</sup> *Id.* § 4003(d)(3).

<sup>27</sup> CARES Act § 4003(b)(4).

loans is to “provid[e] liquidity to the financial system that supports lending to eligible businesses, States, or municipalities.”<sup>28</sup>

Among the facilities established by the Federal Reserve is the Main Street Lending Program, which is intended to provide credit support to small and medium-sized businesses.<sup>29</sup> The Main Street Lending Program includes three facilities: the Main Street New Loan Facility, the Main Street Priority Loan Facility and the Main Street Expanded Loan Facility. Each of the three facilities uses the same lender and borrower eligibility criteria, and under each, the lenders and borrowers must make a number of certifications, presenting wide risks for FCA liability in the event that any false certifications are made knowingly.

For example, under the Main Street New Loan Facility, the lender must attest that the proceeds of the loan will not be used to repay or refinance pre-existing loans or lines of credit made by the lender to the borrower and that the lender will not “cancel or reduce any existing lines of credit outstanding” to the borrower.<sup>30</sup> The borrower, in turn, must make a number of attestations about its eligibility, including that the loan proceeds are “necessary” in light of current conditions and that they will be used to “make reasonable efforts to maintain its payroll and retain its employees” during the term of the loan; that the borrower will not use the loan proceeds to repay other loan balances; and that it will not repay other debt of equal or lower priority until it has repaid the loan in full.<sup>31</sup>

A mid-sized business (defined as one with between 500 and 10,000 employees) receiving assistance under Federal Reserve programs must make certain certifications beyond the “necessity” and workforce-retention certifications discussed above.<sup>32</sup> For instance, the mid-sized borrower must certify that it is a US-domiciled business; that it will not offshore or outsource any jobs for the term of the loan plus two years; and that it will remain “neutral” in any union organizing effort for the term of the loan.<sup>33</sup> It is noteworthy that only mid-sized businesses must make

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<sup>28</sup> CARES Act § 4003(b)(4).

<sup>29</sup> Federal Reserve, *Main Street Lending Program Frequently Asked Questions* (Apr. 30, 2020), at A.1, <https://www.federalreserve.gov/monetarypolicy/files/main-street-lending-faqs.pdf>. Other facilities established by the Federal Reserve include the Municipal Liquidity Facility; the Commercial Paper Funding Facility; the Primary Dealer Credit Facility; the Money Market Mutual Fund Liquidity Facility; the Primary Market Corporate Credit Facility; the Secondary Market Corporate Credit Facility; the Term Asset-Backed Securities Loan Facility; Paycheck Protection Program Liquidity Facility; Central Bank Liquidity Swaps; and the Temporary Foreign and International Monetary Authorities Repo Facility. *See* Federal Reserve, *Coronavirus Disease 2019 (COVID-19) Funding, Credit, Liquidity, and Loan Facilities*, <https://www.federalreserve.gov/funding-credit-liquidity-and-loan-facilities.htm> (last accessed May 22, 2020).

<sup>30</sup> Federal Reserve, *Main Street New Loan Facility Term Sheet* (Apr. 9, 2020), <https://www.federalreserve.gov/newsevents/pressreleases/files/monetary20200409a7.pdf>.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* § 4003(c)(3)(D)(i).

<sup>33</sup> *Id.* § 4003(c)(3)(D)(i).

certifications regarding union organization. And only mid-sized businesses must agree not to outsource or offshore jobs. Thus, it seems that mid-sized businesses bear the weight of certain congressional policy goals also advanced by the CARES Act.

The Federal Reserve does not require a mid-sized business borrower to in fact restore its workforce. Failure to restore a workforce, however, could be used as evidence that the borrower made a false certification to obtain the loan—even if the borrower did in fact intend to restore the workforce when the certification was made but intervening circumstances made such restoration financially impracticable.

✓ Loans to Air Carriers and Businesses Critical to National Security

Title IV of the CARES Act also provides a total of \$46 billion in funds to make loans to air carriers and businesses critical to maintain national security.<sup>34</sup> The Treasury Secretary must ensure that any loan agreement with these businesses contains various provisions.<sup>35</sup> For instance, the agreement must provide that, until 12 months after the loan or loan guarantee is not outstanding, the business will not purchase an equity security listed on a national securities exchange of the business and the business will not pay dividends or make capital distributions.<sup>36</sup> The business must also agree that, “to the extent practicable,” until September 30, 2020, it will not reduce its employment levels by more than 10 percent of what the level was as of March 24, 2020.<sup>37</sup> Finally, the Secretary must determine that “the continued operations of the business are jeopardized.”<sup>38</sup>

These requirements pose slightly different FCA risks. For example, the Secretary is tasked with determining that the business has incurred or is expected to incur losses that jeopardize the business, on the basis of information provided by the business. The Treasury Department has not clarified how exactly the Secretary will make these determinations. But there can be no question that any false statement made knowingly by a borrower to the Treasury Department could be the basis for a criminal referral or a potential FCA action.

Also notable under Title IV is that the Secretary is “authorized to designate financial institutions, including but not limited to depositories, brokers, dealers, and other institutions, as financial agents of the United States” in order to perform “all reasonable duties as the Secretary determines necessary to respond to the coronavirus.”<sup>39</sup>

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<sup>34</sup> *Id.* § 4003(b)(1)-(3).

<sup>35</sup> *Id.* § 4003(c)(2).

<sup>36</sup> *Id.* § 4003(c)(2)(E)-(F).

<sup>37</sup> *Id.* § 4003(c)(2)(G).

<sup>38</sup> *Id.* § 4003(c)(2)(I).

<sup>39</sup> *Id.* § 4003(g).

The financial institutions will be paid with federal funds.<sup>40</sup> Therefore, in addition to the potential exposure arising from lending conduct, as described above, financial institutions may also face FCA liability if they are designated as agents of the United States and do not perform their duties truthfully.

## Healthcare Programs

Title III of the CARES Act focuses on the country's healthcare system and creates opportunities for companies to contract with the government to combat COVID-19. The act expands the ability of healthcare companies that manufacture medical devices and diagnostics to contract with the government for COVID-19-relief innovation, and it also provides over \$100 billion to healthcare providers for expenses or lost revenue attributable to the pandemic. These programs are designed to reinforce the country's healthcare system and promote innovation to fight the virus. But they also present additional risk for FCA liability.

### ✓ Healthcare Innovation

Title III expands the ability of the Secretary of Health and Human Services (HHS) to enter into agreements with the private sector to foster "flexible, strategic partnership[s] between the government and industry" in support of coronavirus-related biomedical innovation.<sup>41</sup> The CARES Act expands the ability of the HHS Secretary to enter into these agreements to combat a public health emergency.

This expansion provides additional opportunities for healthcare innovators to partner with the government, and HHS has been actively soliciting proposals for development and licensure of coronavirus diagnostics, vaccines and medicines.<sup>42</sup> Indeed, it has already entered into a number of multimillion-dollar partnerships for development of coronavirus vaccines. Those who seek to enter into a partnership with the government are asked to submit a "brief description of [the] product or technology, accompanied by a slide deck, manuscript, publications, or other non-confidential information."<sup>43</sup> Any false statements made by a prospective innovation partner regarding its bona fides, its product or its technology, which the company knows would be material to the

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<sup>40</sup> *Id.* § 4003(g)(2).

<sup>41</sup> Department of Health and Human Services, Public Health Emergency, *Other Transaction Agreements*, <https://www.phe.gov/about/amcg/otar/Pages/default.aspx> (last accessed May 22, 2020).

<sup>42</sup> Department of Health and Human Services, *HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus* (Mar. 6, 2020), <https://www.hhs.gov/about/news/2020/03/06/hhs-solicits-proposals-for-development-of-medical-products-for-novel-coronavirus.html>.

<sup>43</sup> Department of Health and Human Services, *Request a USG Coronawatch Meeting*, <https://www.medicalcountermeasures.gov/Request-BARDA-TechWatch-Meeting/> (last accessed May 17, 2020).



government's decision to enter into the partnership, may subject the healthcare innovator to FCA risk.

This sort of partnership with HHS also raises a different type of FCA risk than that presented by the loan programs discussed above. We have already discussed how a false statement made knowingly to the SBA or to the Treasury Department that is material to the government's decision to approve a CARES Act loan may present FCA risk, and that risk analysis would be the same here. However, this sort of entrepreneurial private-public partnership also raises questions about the ultimate efficacy of the proposed innovation and the sorts of representations by an ambitious innovator that could potentially run afoul of the FCA. Specifically, some courts have recognized the "worthless services" theory of FCA liability, which "allows a *qui tam* relator to bring claims for violations of the FCA premised on the theory that the defendant received reimbursement for products or services that were worthless."<sup>44</sup> If, for instance, a biotech or pharmaceutical company received funding through this HHS partnership and ultimately developed and manufactured a test, drug or device that did not work, that company could find itself on the wrong end of an FCA lawsuit under a "worthless services" theory. The United States or a private plaintiff could allege not only that the test, drug or device did not work, but that it had "no medical value" and was "so deficient that for all practical purposes [it was] the equivalent of no performance at all."<sup>45</sup> Title III of the CARES Act promotes biotech innovation, but it does not sanction healthcare fraud.

✓ Funding for Healthcare Providers

The CARES Act also appropriated \$100 billion to a "CARES Act Provider Relief Fund" for "eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus."<sup>46</sup> Healthcare provider recipients of such payments, including hospitals and doctors, have mandatory reporting requirements and must sign an electronic attestation confirming receipt of funds and their agreement to certain terms and conditions.<sup>47</sup>

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<sup>44</sup> *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 709 (7th Cir. 2014).

<sup>45</sup> *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011).

<sup>46</sup> CARES Act Title VIII, Department of Health and Human Services. On April 24, 2020, the President signed a law that provided an additional \$75 billion for this purpose. *See* Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020).

<sup>47</sup> Department of Health and Human Services, *CARES Act Provider Relief Fund*, <https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html> (last accessed May 18, 2020).

The terms and conditions, in turn, require healthcare providers to make a number of certifications. These certifications include that the provider billed Medicare in 2019; provides diagnoses, testing or care for individuals with “possible or actual cases of COVID-19;” and is not currently terminated or excluded from participating in Medicare or other federal healthcare programs.<sup>48</sup> The provider must also certify that the funds “will only be used to prevent, prepare for, and respond to coronavirus,” and not to pay other unrelated expenses.<sup>49</sup> There is no required certification concerning actual funding needs.

It remains unclear how HHS will determine whether a healthcare provider has used CARES Act funds “to prevent, prepare for, and respond to coronavirus” or whether HHS will require additional documentation to substantiate such a certification. Moreover, the ambiguity of the phrase “possible or actual cases of COVID-19” presents further FCA risk because the terms and conditions do not define what it means to be a “possible case” of COVID-19. To mitigate these risks, a healthcare provider should carefully document all treatment for which he or she seeks reimbursement under the CARES Act.

These are just a few examples of the ways that various industries that are responding to the COVID-19 pandemic may risk FCA exposure if they choose to seek CARES Act funding. Companies that are considering participating in any of these or similar programs should be mindful of these risks and take care to ensure that any certifications or representations made to the government are truthful.

With a team of veteran litigators, prosecutors, and former Justice and Defense Department lawyers, WilmerHale brings significant knowledge and experience to defending against FCA litigation brought by relators, the DOJ and state attorneys general. Please reach out to the authors of this alert or your WilmerHale contacts should you have any questions.

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<sup>48</sup> Department of Health and Human Services, *Acceptance of Terms and Conditions*, <https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-20-b.pdf> (last accessed May 18, 2020).

<sup>49</sup> *Id.*

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