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QUI TAM QUARTERLY

UNCERTAIN RELIEF: NAVIGATING CARES ACT PROVIDER RELIEF FUND GUIDANCE AND FALSE CLAIMS ACT RISKS

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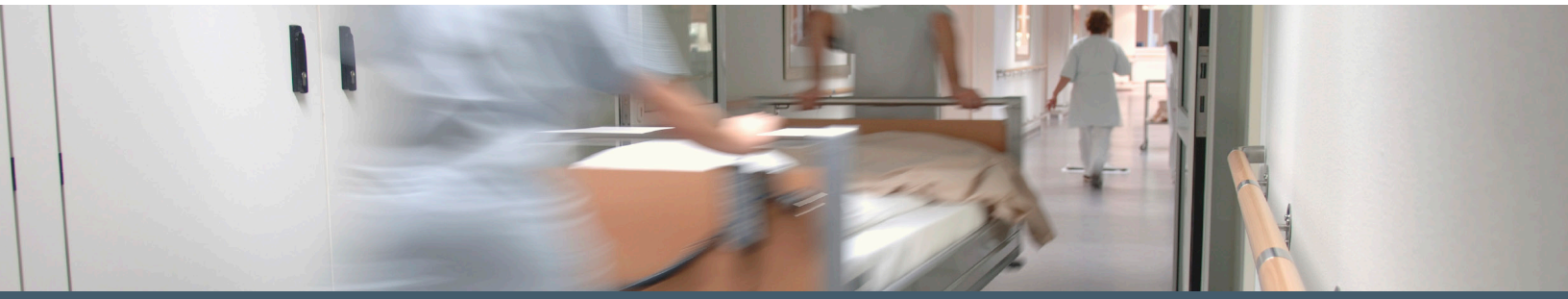

The COVID-19 pandemic created unprecedented strain on the nation's health care system and the economy. To combat the economic side of the pandemic's pervasive impacts, on 27 March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act,[1] which President Donald J. Trump signed into law on the same day. The CARES Act is one of a series of government stimulus packages aimed at buoying the nation's economy during the pandemic. In particular, the CARES Act includes an extensive US$2 trillion federal aid package, which is composed of a combination of funding for public health programs, tax benefits for businesses and individuals, appropriations for government programs supporting pandemic relief efforts, and other items to help stabilize the economy. As has been well-documented since its inception, the CARES Act has resulted in hundreds of billions of dollars in federal stimulus money being paid to recipients with almost unprecedented speed, largely as a result of the Paycheck Protection Program (PPP) and the Provider Relief Fund (PRF).

The speed with which the government has made PPP and PRF payments during the pandemic has raised the specter that certain recipients inside and outside of the health care industry will face substantial civil and criminal enforcement risks. In fact, almost immediately after the government began distributing PPP loans—which were intended to help small businesses continue operating during the pandemic crisis—the U.S. Department of Justice (DOJ) engaged in aggressive criminal enforcement actions across the country against PPP loan recipients for allegedly falsely certifying compliance with PPP loan requirements. Defendants charged to date with PPP-related fraud have allegedly engaged in largely egregious conduct, from intentionally misrepresenting the existence of the business that applied for PPP funds to inflating the number of the business's employees in order to increase the size of stimulus aid received. Indeed, the DOJ's enforcement efforts to date surrounding PPP funds have been characterized largely by a focus on "the low-hanging fruit" or those whose alleged conduct makes potential prosecution clear. Continued criminal enforcement against certain PPP recipients and a related wave of significant civil enforcement, primarily through the federal False Claims Act (FCA), is expected throughout the remainder of 2020 and into subsequent years.

In contrast to the payment of PPP funds, the PRF likely presents a more nuanced enforcement scenario, particularly from a civil and FCA perspective.[2] The PRF is aimed at supporting health care-related expenses or lost revenue attributable to the pandemic and assuring that uninsured Americans are able to receive testing and treatment for COVID-19. The government distributed this funding to providers through multiple rounds of general and targeted allocations and reimbursement, amounting to over US$100 billion distributed to health care providers and suppliers to date. To receive PRF funds, providers were required to sign attestations confirming receipt of the funds and certifying compliance with certain terms and conditions (Terms and Conditions). The government also issued PRF Frequently Asked Questions (FAQs) to supplement the Terms and Conditions. Critically, while they are the primary source of provider guidance for use of PRF funds, the FAQs have

often proven unclear, complicated, and shifting since their issuance. The complexities inherent in the Terms and Conditions and the FAQs—coupled with the attestation and certification requirements—create potentially fertile grounds for significant FCA-related enforcement efforts by the government and relators against recipients of PRF funds for years to come.

This edition of the *Qui Tam Quarterly* focuses on the potential FCA risk areas faced by recipients of PRF funds in the health care industry, as well as the potential defenses to FCA actions based on some of the nuances of accepting PRF funds under the Terms and Conditions and related FAQs. It begins by reviewing the key Department of Health and Human Services (HHS) guidance around the PRF to determine which guidance is more likely to result in enforcement activity. It then considers potential defenses to such activity under the FCA, including the extent to which (1) ambiguous or changing guidance and/or regulations may create enforcement problems where recipients interpreted the regulations in good faith, (2) the materiality element may not be satisfied where HHS knows about provider non-compliance with certain guidance requirements but declines to request reimbursement or initiate an investigation, and (3) the government and relators will be able to establish falsity through relying on the informal and frequently updated FAQ guidance documents. It also considers whether the government may more aggressively move to dismiss *qui tam* actions brought by relators in marginal cases where a provider appears to have acted in good faith pursuant to the guidelines in the so-called "Granston Memo."

CARES Act Provider Relief

Under the CARES Act, the PPP and Health Care Enhancement Act,[3] and the Families First Coronavirus Response Act,[4] the federal government allocated over US$175 billion in payments to be distributed through the PRF to hospitals and other health care providers and suppliers on the front lines of the pandemic response. The PRF is aimed at supporting health care-related expenses or lost revenue attributable to the pandemic and assuring that uninsured Americans are able to receive testing and treatment for COVID-19.[5] HHS has distributed this funding to providers through multiple rounds of general and targeted allocations and reimbursement to health care providers, including US$50 billion in "General Distribution" funding and over US$52 billion in "Targeted Distribution" funding directed to specific types of providers, including skilled nursing facilities; rural health care providers; Medicaid and CHIP providers; safety net hospitals; tribal hospitals, clinics, and urban health centers; dental providers; and hospitals located in COVID-19 "high-impact" areas.

Health care providers receiving distributions and reimbursement under the PRF must sign attestations confirming receipt of the funds and certifying compliance with certain Terms and Conditions, which vary depending on which distribution is received and retained. HHS also issued FAQs to supplement the Terms and Conditions. The FAQs are particularly important, as they are one of the few guidance documents HHS has issued on the receipt and use of PRF funds. Key compliance obligations under the Terms and Conditions include, among others, the following:

- *Use of Funds*. Recipients must attest that the PRF funds will be used only to prevent, prepare for, and respond to COVID-19, and to reimburse the recipient only for health care-related expenses or lost revenues attributed to COVID-19.
- *Prohibition on Double-Dipping*. Recipients are not permitted to utilize PRF funds to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse. Accordingly, recipients also participating in other federal response programs (e.g., PPP, FEMA emergency response funds) must carefully track that expenses or losses are not claimed twice.
- *Reporting Requirements*. Recipients receiving more than US$150,000 must submit quarterly reports detailing certain information on use of the funds. In addition, recipients are required to maintain appropriate records and cost documentation as required by certain regulations under 45 C.F.R. Part 75 (Uniform Administrative Requirements, Cost Principles, and Audit Requirement for HHS Awards).
- *Prohibition on Balance Billing*. Recipients are prohibited from seeking more than in-network cost-sharing amounts from out-of-network COVID-19 patients for all care for possible or actual cases of COVID-19. This requirement is significant given that out-of-network providers are generally not aware of in-network cost-sharing requirements under insurance plans.
- *Audit Requirements*. Certain nonprofit recipients of PRF funds are subject to single audit requirements under 45 C.F.R. Part 75 (i.e., if it reported annual total federal fund expenditures (including PRF funds) equal to or above US$750,000). Similarly, commercial organizations that receive US$750,000 or more in annual awards must either obtain a financial audit conducted in accordance with generally accepted government auditing standards or a single audit under 45 C.F.R. Part 75, Subpart F. Note that this requirement was introduced several months after the first General Distribution allocation and is not included in the Terms and Conditions.

- *Reporting Requirements*. Recipients that receive PRF payments exceeding US$10,000 in aggregate are required to report their use of funds in accordance with guidance issued by HHS in September 2020.
- Most notably, the Terms and Conditions state that the listed provisions are *not exhaustive and recipients must also comply "with any other relevant applicable statutes and regulations*."

It is notable, then, that HHS has not promulgated regulations related to the receipt and use of the PRF funds. Moreover, HHS revised the General Distribution Terms and Conditions on multiple occasions as the distributions were being made[6] and has continued to amend, modify, and revise the FAQs since they were first issued in April 2020. Many provisions of the Terms and Conditions and FAQs are ambiguous, inconsistent, and contradictory, and several FAQs were modified or updated after related deadlines had already passed.

These issues have led to confusion and anxiety among PRF recipients and have potentially created FCA risks as recipients attempt to stay abreast of ever-changing guidance and requirements. The following subsections briefly review several fundamental compliance obligations on recipients—those related to the receipt, retention, and use and reporting of PRF funds—and HHS's evolving guidance related to those requirements.

Receipt of General Distribution Funds

HHS distributed US$50 billion in General Distribution funding to recipients in two waves. On 10 April 2020, HHS distributed the initial US$30 billion (commonly called Tranche 1) to providers who billed Medicare fee-for-service in 2019 in an amount proportional to each provider's share of 2019 Medicare patient revenue. Around 24 April, HHS began distributing the remaining US$20 billion of the General Distribution using a methodology designed to ensure the total US$50 billion distribution was allocated proportional to providers' share of total 2018 net patient revenue. Generally, cost-reporting entities, such as hospitals and skilled nursing facilities, received a Tranche 2 payment automatically, and non-cost-reporting entities were required to submit an application for this second payment. Providers who received additional funding automatically were still required to confirm receipt of the second round of General Distribution funds and submit their revenue information for verification. Payments in Tranche 2 were based on the lesser of 2 percent of a provider's 2018 (or most recent complete tax year) gross receipts or the sum of incurred COVID-19 related losses for March and April.

Immediately, there was confusion and uncertainty regarding the application and attestation process related to the Tranche 2 payments, which has continued through the publication of this article. As an example, HHS instructed that Tranche 2 payments are determined based on "the lesser of 2% of a provider's 2018 (or most recent complete tax year) gross receipts or the sum of incurred losses for March and April 2020." This calculation is inconsistent with FAQs that instruct providers to calculate their total expected payment by specifically referencing the 2 percent of revenue calculation without regard to lost revenue. Furthermore, the criteria is arguably inconsistent with the eligibility criteria to keep PRF funds since HHS has provided that health care providers cannot keep the funds if they do not have lost revenue or COVID-19-related health care expenses that equal to or exceed the payments. Contrary to the FAQs, this indicates that a provider does not have to have lost revenue at all to receive a Tranche 2 payment because it could have expenses that exceed the payment and still meet eligibility criteria to retain the funds.

As another example of the confusion, after many recipients had applied for and received Tranche 2 funds, HHS clarified that only patient care revenues may be included in "gross sales or receipts" or "program service revenue" to be considered in the calculation of Tranche 2 funds. More recent guidance appears to confirm an obligation to review the reported revenue and provide to HHS further detail and identification of what portion of that reported gross revenue on financial documentation qualifies as program service revenue. However, HHS has yet to provide fulsome, specific guidance as to what qualifies as program service revenue and, as such, many recipients continue to question whether the receipt of the PRF funds was appropriate in the first instance.

Attestation and Reallocations Among Affiliates

Many providers that have undergone a sale, acquisition, merger, or other changes of ownership (CHOWs) have struggled with the PRF attestation and application processes, as HHS has slowly issued additional instructions through FAQs to recipients to address the various iterations that CHOWs have presented. Likewise, health systems with parent, subsidiary, and various other affiliate entities—often with complex corporate organizational or financial reporting structures—have grappled with which entity is required, permitted, or practically able to attest to compliance with the Terms and Conditions through the PRF portals.

Additionally, HHS was slow to issue guidance related to a parent organization's reallocation of PRF funds among subsidiaries and affiliated entities; this guidance often

informs recipients whether COVID-19-related expenses or lost revenue are sufficient to justify retention of the funds. While there are currently multiple FAQs on the topic, that guidance still conflicts in several respects. As an example, multiple FAQs support that parent organizations have discretion in allocating PRF funds throughout their health system as long as they are used to support eligible expenses or lost revenue, even if the subsidiaries do not report income with the parent organization on a consolidated basis. A separate FAQ requires parent organizations that wish to control and allocate PRF funds to attest to the Terms and Conditions. However, separate attestation process guidance specifically directs parent organizations not to attest to the Terms and Conditions on behalf of subsidiaries that do not report financials on a consolidated basis. It is this type of conflicting guidance that has recipients wringing their hands over the attestation process.

Use of Funds and Reporting Requirements

Guidance regarding proper use of PRF funds and required reporting obligations is perhaps the best example of HHS's haphazard approach to providing instruction to PRF recipients. The Terms and Conditions require each PRF recipient to certify that the funds 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."[7] HHS was slow to release specific guidance on this broad, minimally instructive mandate, although FAQs were eventually issued that provided brief examples of permissible health care expenses for which PRF funds can be utilized and appropriate general methodologies for calculating lost revenues.[8] In addition, the Terms and Conditions forecasted quarterly reporting requirements for recipients receiving more than US$150,000 in PRF funds, which HHS eventually clarified would not be required due to the availability of a publicly available database outlining PRF funding received by recipients.[9]

On 19 September 2020, HHS did eventually issue formalized long-awaited reporting guidance related to the PRF funds (September Reporting Guidance) that outlined more detailed requirements regarding the allocation of PRF funds to reimbursable expenses and lost revenue, as well as key reporting deadlines.[10] The September Reporting Guidance was noteworthy in that it contained significant differences from previous HHS guidance regarding the proper use of PRF funds. Specifically, the September Reporting Guidance indicated that all recipients must first attempt to allocate the PRF funds received to reimbursable expenses prior to applying the funds to lost revenues and that recipients need to have had an operating margin in prior years to claim losses.[11] Such a mandatory two-step approach had not been forecast in any prior HHS guidance and had created a significant compliance burden associated with calculating reimbursable expenses. And, perhaps unsurprisingly, the FAQs still provided that recipients may use any reasonable method for estimating the revenue, such as the difference between their budgeted revenue and actual revenue, and contains no indication of the new metrics and formula outlined in this new guidance.[12]

As a result of this massive shift in guidance, the September Reporting Guidance was the subject of lobbying efforts on multiple fronts, including from the American Hospital Association, which urged HHS to replace the formalized Reporting Guidance with the "reasonable method" PRF reporting requirements outlined in the FAQs.[13] Meanwhile, PRF recipients were left to await clarification and further guidance from HHS to determine whether PRF funds should be returned as the first reporting deadline approached and many providers were attempting to finalize fiscal-year-end financial statements.

Then, on 22 October 2020, HHS issued revised reporting instructions to restore the broader approach to reporting lost revenues that PRF recipients had expected, clarifying that recipients may use remaining PRF funds to cover any lost revenue, measured as a negative change in year-over-year actual revenue from patient care related sources.[14] In an accompanying policy memo, HHS acknowledged that "the instructions placed a limitation on the permissible use of PRF money that HHS had not previously articulated," while noting that "previous guidance did not preclude the establishment of such a limitation in the future."[15] In response to Congressional and stakeholder feedback, HHS did backtrack and revert to its previous guidance on use of PRF funds to cover lost revenue, but not before PRF recipients spent over a month re-evaluating their use of PRF funds during the prior six-month period.

FCA Issues Triggered by Uncertain PRF Guidance

The confusion and uncertainty surrounding receipt of PRF funds has naturally raised concerns among recipients regarding potential liability exposure under the FCA. The FCA provides, in part, that the federal government—or a private party on behalf of the government—may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent claim for payment; who has made a false statement or used a false record to get a claim paid or to avoid, decrease, or conceal an obligation to pay money to the federal government; or who has knowingly retained an overpayment.[16] As such, recipients that have received PRF funds face potential FCA liability exposure in three main

areas: (1) the execution of attestations certifying compliance with the PRF Terms and Conditions; (2) adherence to PRF-related guidance, primarily in the form of changing and unclear FAQs; and (3) provider retention of PRF funds to which the government might later claim the provider was not entitled.

Based on these potential risk areas for recipients of PRF funds, the following discussion addresses the potential defenses that providers may have to FCA liability in light of the FCA's scienter, falsity, and materiality requirements.

Scienter Requirements and Ambiguous Regulations/Regulatory Guidance

Cases Applying the FCA's Scienter Requirement to Ambiguous Statutory or Regulatory Guidance

The ambiguous and changing nature of the regulatory guidance around PRF payments may create serious hurdles for the government or relator in asserting FCA claims against providers. To make an FCA claim, the government must prove that the defendant acted with at least a degree of intent or recklessness. Specifically, to satisfy this scienter requirement, the plaintiff must show that the defendant had actual knowledge that the claim was false or acted with "deliberate indifference" to or "reckless disregard" for the truth or falsity of the claim.[17] Mere negligence in the submission of a claim is not actionable under the FCA.

Where the government or relator relies on a theory that the defendant's claim is false because it was submitted in violation of a statute or regulation—or falsely certified compliance with a statute or regulation—ambiguous language complicates the ability to prove the scienter element. A provider cannot have acted with actual knowledge or reckless indifference if its claim was consistent with a reasonable interpretation of the statue or regulation, even if the government interprets the provision differently, so long as the government had not warned against the provider's interpretation.

In the seminal *Safeco* case from 2007, the U.S. Supreme Court analyzed whether the defendant had "willfully" violated the Fair Credit Reporting Act.[18] After concluding that the term "willfully" encompassed both actual knowledge and reckless disregard, the Court went on to consider whether the defendant had violated the Act based on noncompliance with an ambiguous provision. In holding that the defendant had not acted willfully because its interpretation of the statute was reasonable, the Court explained that "[w]here . . . the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator."[19] The Court cautioned, however, that if the defendant was "warned . . . away from the view it took" by guidance from a court or the agency interpreting the statute, ambiguity in the underlying statute would not defeat a finding of willfulness.[20]

Several courts have applied this *Safeco* analysis to FCA claims based on ambiguous statutory or regulatory standards. These cases hold that a defendant can defeat the FCA's intent requirement if three factors are satisfied: (1) the standard is ambiguous, (2) the defendant acts in accordance with an "objectively reasonable" interpretation of that ambiguous provision, and (3) there is no guidance to "warn" the defendant away from that interpretation.[21]This rule not only appropriately insulates good-faith claims from FCA liability, but it also "avoid[s] 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.'"[22]

While every court of appeals to has considered ambiguous guidance in the FCA context has adopted this three-factor analysis,[23] courts are less uniform in their conclusions about when and how the defendant's "objectively reasonable" interpretation had to have originated. On the one hand, the D.C. Circuit in *Purcell* held that so long as a defendant's claim was reasonable under an objective reading of the statute, its subjective intent is irrelevant.[24] Under this view, evidence that the defendant had concerns about its interpretation at the time it made its claim, or perhaps considered and rejected other interpretations, would not satisfy the FCA's "reckless indifference" standard.

On the other hand, contradicting Purcell's analysis, at least one district court has held that the inquiry focuses on the defendant's interpretation at the time of the certification or claim, "not to an otherwise reasonable interpretation that was created after-the-fact."[25] Under this analysis, a defendant's assertion of a new post hoc interpretation to justify an earlier claim—even an "objectively reasonable" one—would not save it from potential FCA liability. In any event, a defendant's reasonable interpretation at the time a claim was submitted should not be actionable even if it is self-interested or "opportunistic."[26]

Ambiguous or Conflicting Provisions in the PRF Guidance

As discussed above, the Terms and Conditions, FAQs, and other guidance issued by HHS in relation to the PRF are rife with ambiguities and implicit contradictions that could raise scienter defenses in FCA investigations or litigation. These ambiguities and contradictions have perhaps inevitably resulted from the rushed, emergency nature of the original HHS guidance and the fact that HHS continues to update and modify the guidance. Ambiguities

and contradictory changes can be found in everything from threshold eligibility provisions, to guidance about how funds may or not be used, to audit and reporting requirements. This section addresses only a few of these instances to highlight some of the FCA defenses that might arise from these ambiguities and inconsistencies.

Expenses to "Prevent, Prepare for, and Respond to the Coronavirus"

Perhaps the most obvious example of ambiguity in the PRF guidance is the requirement in the Terms and Conditions for the initial US$30 billion PRF allocation that funds 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."[27] Absent other guidance or clarification, this condition of use is subject to myriad and potentially conflicting interpretations. Without further guidance, what expenses are "attributable to the coronavirus"?

Of course, as discussed above, HHS had issued additional guidance that either explicitly or implicitly informs the interpretation of this basic condition, but potential ambiguities remain. For instance, HHS issued an FAQ concerning the General Distribution funds that provides:

> Who is eligible to receive payments from the Provider Relief Fund? To be eligible for the General Distribution, a provider must have billed Medicare fee-for-service in 2019, be a known Medicaid and CHIP or dental provider **and provide or provided after January 31, 2020 diagnoses, testing, or care for individuals with possible or actual cases of COVID-19, or prevented in the spread of COVID-19. HHS broadly views every patient as a possible case of COVID-19**. (emphasis added).[28]

This FAQ answer implicitly adopts an extremely inclusive interpretation of "healthcare expenses attributable to the coronavirus"—that is, expenses for "diagnoses, testing, or care for individuals with possible or actual cases of COVID-19." At the same time, the FAQ notes that "HHS broadly views every patient as a possible case of COVID-19." Reading these two sentences together strongly suggests that all patient care-related expenses for **any patient** for **any reason**, incurred after 31 January 2020, may be reimbursed with PRF distributions, so long as they were not reimbursed by other sources.

By stating that "HHS broadly views every patient as a possible case of COVID-19," the agency leaves the door open to potentially differing interpretations concerning exactly what expenses might be included as health care expenses "attributable to the coronavirus." This potential ambiguity was reinforced by the Reporting Guidance that HHS issued on 19 September 2020. There, as an example, recoverable expenses for "personnel" are defined as "actual expenses paid to prevent, prepare for, or respond to the coronavirus . . . such as workforce training, staffing, temporary employee or contractor payroll, overhead employees, or security personnel."[29] This definition, it could be argued, is narrower than all personnel expenses incurred for treatment of any patient. Further, despite listing several such specific examples of includable expenses, the Reporting Guidance includes a catch-all provision including "Any other actual expenses, not previously captured above, that were paid to prevent, prepare for, or respond to the coronavirus."[30] This clarifying guidance thus comes full circle to simply restating the same broad, vague definition as the original Terms and Conditions.

Lost Revenues "Attributable to the Coronavirus"

Another approach providers have taken is to simply use the "lost revenues" method of calculating allowable reimbursement with PRF funds. As with the expense definition, the original Terms and Conditions provided no specificity in defining what lost revenue could be included. They simply stated that the funds were to be used for "lost revenues attributable to the coronavirus." Again, however, a subsequent FAQ seemed to provide a relatively straightforward, if broad, specific definition:

> The term "lost revenues that are attributable to coronavirus" means any revenue that you as a health care provider lost due to coronavirus. This may include revenue losses associated with fewer outpatient visits, canceled elective procedures or services, or increased uncompensated care.[31]

The FAQ went on to state that providers could "use any reasonable method of estimating the revenue during March and April 2020 compared to the same period had COVID-19 not appeared."[32]

As explained above, HHS temporarily issued the Reporting Guidance on 19 September 2020 that conflicted with this "reasonable method" guidance.[33] Thankfully for concerned providers, HHS rescinded the conflicting Reporting Requirements a month later, on 22 October, clarifying that recipients may use remaining PRF funds to cover any lost revenue, measured as a negative change in year-over-year actual revenue from patient care related sources.[34]

This kind of back-and-forth conflicting guidance from HHS could create serious problems for government or relator claims based on these HHS pronouncements. Applying the case law discussed above to this example, the more times that HHS imposes new requirements that conflict with earlier administrative guidance, the more likely it will be that a provider defendant in an FCA case will be able to argue that it could not have intentionally submitted false claims to PRF funds, where its use of the funds was

perfectly consistent with at least some version of the guidance. While these arguments will require careful consideration of the precise chronology of a provider's acceptance and expenditure of funds, they will inevitably complicate any effort to claim that the provider's actions were deliberately indifferent to program requirements.

Attestation and Reallocations Among Affiliates

Another example of potentially conflicting guidance surrounds a parent's reallocation of funds among subsidiaries and the extent to which expenses or losses incurred by affiliates should be considered in determining PRF eligibility. As described above, HHS guidance is unclear and conflicting as to whether a parent organization must have consolidated financials with a subsidiary—or must attest to receipt of the PRF funds on behalf of the subsidiary—in order to reallocate use of PRF funds attributed to one subsidiary among other subsidiaries.

These kinds of overt conflicts in HHS guidance could make it very difficult for the government or a relator to successfully assert an FCA claim based on non-compliance with one or more of these directives. Indeed, where the guidance is clearly contradictory or effectively renders compliance impossible, it could present a rare instance where a defendant provider could bring a successful motion to dismiss on the pleadings based on an inability to plead that the defendant's alleged non-compliance was intentional or reckless. It is difficult to imagine a court—let alone a jury—finding liability for violation of an FAQ, for instance, where a different FAQ gives directly conflicting guidance.

Falsity

In order to establish FCA liability against a recipient of PRF funds, the government or a relator will necessarily have to establish falsity. Under the FCA, there are two categories of falsity—factual falsity and legal falsity.[35] Factual falsity can be established when there is an incorrect description of the services or goods provided, or when those services or goods were never actually provided despite contrary representations. In contrast, legal falsity can be established where "the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment."[36] FCA claims concerning PRF funds could implicate theories of both factual and legal falsity. As to factual falsity, a provider could intentionally misrepresent its revenues or expenses in order to wrongfully inflate the calculation of its payment from the fund. However, it seems likely that the lion's share of FCA claims—especially those brought by relators—will be based on a theory of legal falsity. Such allegations may include the fact that a provider falsely certified compliance with the Terms and Conditions or the FAQs interpreting the Terms and Conditions.

As set forth above, the FCA risks associated with the Terms and Conditions and the FAQs largely arise from the ambiguity of both and HHS's frequent modifications of and updates to the FAQs. These characteristics of the Terms and Conditions and the FAQs potentially create space for the government or relators to claim that a provider falsely certified compliance with the Terms and Conditions by using the funds in an improper manner or otherwise failed to satisfy the FAQ guidance. However, because the FAQs are sub-regulatory guidance that was not subject to notice and comment rulemaking, a key focus of FCA actions surrounding receipt of PRF funds will likely be on whether or not the FAQs amount to substantive legal standards that affect a party's entitlement to payment pursuant to the United States Supreme Court's 2019 ruling in *Azar v. Allina Health Services*[37] and the cases that are currently interpreting *Allina's* application. If the FAQs are considered substantive legal standards affecting entitlement to receipt of PRF funds, then providers may have a strong defense to a central aspect of FCA allegations related to PRF funds.

Azar v. Allina Health Services

In *Allina*, the U.S. Supreme Court considered whether HHS was required to undertake notice-and-comment rulemaking under the Medicare Act before it changed an important reimbursement formula for hospitals that treat many low-income patients. HHS's change involved including Medicare Part C patients, alongside Medicare Part A patients, in the "fraction" used to calculate disproportionate share hospital payments.[38] The practical effect of this policy was to significantly reduce the payments that hospitals received for treating Medicare patients.[39]

The Court maintained that the decision hinged solely on whether the alteration of the payment formula "**establishes or changed a substantive legal standard governing . . . the payment for services.**"[40] In its opinion, the Court differentiated between "substantive rules" under the Administrative Procedures Act (APA) and a "substantive legal standard" under the Medicare Act.[41] The Court stated that "substantive rules are those that have the force and effect of law, while interpretive rules . . . merely advise the public of the agency's construction of the statutes and rules which it administers."[42] According to the Court, "the Medicare Act contemplates that 'statements of policy' *can* establish or change a 'substantive legal standard,' § 1395hh(a)(2), while APA statements of policy are not substantive by definition but are grouped with and treated as interpretive rules . . . ."[43]

The Court—in a 7–1 decision—"invalidated the policy, holding that CMS's failure to give notice and a chance to comment was fatal under § 1395hh(a)(2)."[44] Importantly, the Court stated that, assuming that an underlying statute does not speak directly to an issue, "**when the government establishes or changes an avowedly 'gap'-filling policy, it can't evade its notice-and-comment obligations under § 1395hh(a)(2)** . . . ."[45]

The thrust of *Allina's* holding is that the establishment or alteration of a substantive legal standard—one that creates, defines, or regulates the rights, duties, or powers of the parties, particularly as it relates to payment—must go through notice-and-comment rulemaking. Critical here is also *Allina's* position that a gap-filling policy that interprets a broadly worded statute or regulation must go through the rulemaking process to be valid and enforceable. The PRF FAQs are clearly gap-filling under *Allina* and they were not subject to notice-and-comment rulemaking. However, a key question exists as to whether *Allina's* application extends beyond the Medicare Act to the CARES Act. If courts rule that it does so extend, under *Allina*, recipients of PRF funds may be able to argue that the government cannot use a purported violation of the FAQs as the basis for an enforcement action under the FCA.[46] Recent case law interpreting and applying *Allina* in the FCA context underscores its potential impact on FCA claims against recipients of PRF funds.

Allina's Application to FCA Cases

As of October 2020, the *Polanski* opinion was the only federal court to apply *Allina's* analysis to an FCA claim based on sub-regulatory rulemaking. The *Polansky* opinion maintained that the government's FCA claim was subject to dismissal where it was based on an alleged violation of a sub-regulatory rule.[46] In doing so, *Polanski* emphasized that any policy that determines a party's entitlement to, or the amount of, federal reimbursement is a substantive legal standard that requires notice-and-comment rulemaking pursuant to the holding in *Allina*.

In *Polansky*, the "core of [r]elator's theory of liability [was] that Defendant exploited the difference in reimbursement rates for inpatient and outpatient services, causing hundreds of thousands of claims for medical services to be billed as inpatient when they should have been billed as outpatient."[48] At specific issue in the case was a 24-hour CMS reimbursement policy, which was solely contained in the 1989 edition of the Medicare Hospital Manual.

The government moved to dismiss the case under 31 U.S.C. § 3730(c) seven years after the case's initial filing and based this action, in significant part, on the government's "genuine concerns regarding the likelihood that [r]elator [would] successfully establish FCA liability."[49] In addition to granting the government's motion to dismiss on these grounds, the district court proceeded to extensively discuss why dismissing the matter on summary judgment grounds was also appropriate based on the Supreme Court's holding in *Allina*.[50]

In applying *Allina*, the central consideration for the district court was whether the 24-hour CMS reimbursement policy was a substantive legal standard within the scope of § 1395hh(a)(2). "If so, then [r]elator's claims fail[ed] as a matter of law, because it [was] undisputed that the 24-hour policy did not go through notice and comment as required by Section 1395hh(a)(2) for substantive legal standards."[51] In holding that the policy was a substantive legal standard, the district court applied the definition used by the District of Columbia Circuit, which is the only federal circuit court to date to interpret the meaning of the term "substantive legal standard." "According to the District of Columbia Circuit, the term **substantive legal standard 'at a minimum includes a standard that creates, defines, and regulates the rights, duties, and powers of parties**.'"[52]

Polansky expounds upon this meaning further, stating:

> Case law applying the District of Columbia Circuit's formulation of the definition for "substantive legal standard" illuminates a distinction between, on the one hand, rules that determine reimbursement and, on the other, statements that set forth enforcement policies. **If a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a "substantive legal standard" under the Circuit's definition**. Conversely, if a policy does not affect the authority of CMS, but simply provides instructions for enforcement, it is more likely not to be characterized as a "substantive legal standard."[53]

Based on this case law, *Polansky* concluded that the 24-hour policy "must be included within the District of Columbia Circuit's definition for substantive legal standard."[54] Specifically, "**the 24-hour policy delineates the circumstances in which a hospital is entitled to higher inpatient reimbursement**."[55] Importantly, *Polansky* explains, "the 24-hour policy, though only expressed in CMS manuals, 'affects a hospital's right to payment' because it sets the standard by which a hospital's entitlement to the higher reimbursement rate for inpatient claims is assessed."[56] **As such, the court deemed the 24-hour policy as a substantive legal standard and maintained that it followed "that the law required advance public notice and an opportunity to comment prior to implementation of the 24-hour policy**. Because there was no such public notice or a chance to comment, the policy [could not] withstand scrutiny under Allina's interpretation of the Medicare Act."[57]

The potential importance of *Polansky* to the recipients of PRF funds is clear: Pursuant to *Allina*, the government cannot establish an FCA claim when the sole basis for liability is a substantive legal standard that has not been subject to notice-and-comment rulemaking.[58] As such, if courts extend *Allina* beyond application to the Medicare Act, defendants in PRF-related FCA actions may be able to forcefully argue that alleged non-compliance with the Terms and Conditions or the related FAQs cannot form a basis for establishing falsity.

Justice Manual and the Brand Memorandum

It is important to note that *Allina* and its potential application to the falsity analysis in FCA actions surrounding receipt of PRF funds track the policy set forth by the DOJ in the recently enacted Title 1-20.000 of the government's Justice Manual on the "Limitation on Use of Guidance Documents in Litigation" (Justice Manual), which, in turn, largely memorialized the so-called "Brand Memorandum." Both documents advise DOJ attorneys that the government "may not use its enforcement authority to effectively convert agency guidance documents into binding rules."[59]Indeed, the Justice Manual expressly states:

> Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, **not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation**. *See* JM 1-19.000. Thus, the Department should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations. The Department must establish a violation by reference to statutes and regulations. **The Department may not bring actions based solely on allegations of noncompliance with guidance documents**.[60]

Based on this policy and that set forth in the Brand Memorandum, there is a strong argument that the permissible uses of guidance documents in government enforcement actions are inapplicable in the PRF context,[61] particularly in light of *Allina* and *Polansky*. Specifically, the government cannot predicate an enforcement action on lack of compliance with sub-regulatory guidance in and of itself, particularly if that guidance amounts to a substantive legal standard that was not subject to notice-and-comment rulemaking or a clear interpretation of an existing statute or regulation. As such, recipients of PRF funds may also be able to effectively use the DOJ's own policies in arguing that the government or relator cannot establish falsity in an FCA action solely on the grounds that the defendant allegedly failed to comply with the Terms and Conditions and FAQs.

Materiality Considerations

In addition to the falsity and scienter elements, where an FCA claim is based on a false record or statement by the defendant, the FCA also requires that the false statement be "material."[62] The statute defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Since the Supreme Court's 2016 decision in *Universal Health Services, Inc. v. United States ex rel. Escobar* (*Escobar*),[63] defenses in false certification cases often focus on this materiality element. As a general matter, *Escobar* established two key principles in analyzing whether a defendant's false certification of compliance with regulatory or other guidance is material. First, *Escobar* held that the mere fact that compliance with a particular regulatory requirement is designated as a condition of payment does not in itself establish that a violation of that provision is material. Second, *Escobar* held that an agency's knowledge and behavior is relevant to materiality. That is, if the agency regularly pays claims despite having knowledge that they are in violation of some technical rules or requirements, it "is strong evidence that the requirements are not material."[64]

At this point, it is challenging to predict which guidance HHS may or may not deem material as it begins to review PRF claims and audit the uses of PRF funds. The scope of the payments is enormous—both in total dollar amounts and in the number of providers receiving funds. Also, the funds were distributed rapidly while HHS was still developing guidance about how the funds can be used and how providers must account for them. Accordingly, it will take some time for HHS to determine whether compliance with certain guidance in the Terms and Conditions or FAQs might be excusable and in what circumstances.

That said, in instances where HHS has provided inconsistent guidance, or where guidance has changed over time, providers may have good arguments that such guidance was not a material condition of the receipt of PRF funds. One clear example of such guidance is HHS's conflicting guidance on permissible calculations of "lost revenue due to the coronavirus." As explained above, in calculating lost revenues, the original FAQs allowed providers to "use any reasonable method" of estimating lost revenue.[65]Later guidance, however, required a more specific calculation limiting lost revenue to the amount of a provider's 2019 net gain from health care-related sources.[66] These conflicting directions in co-existing guidance documents enable a provider facing an FCA claim to argue that the later-promulgated requirement could not have been material to HHS's payment decision since it was only issued after the payments were made and conflicted with more lenient prior guidance. Providers could make similar materiality arguments concerning any of the guidance discussed above

that was promulgated only after providers had made their original attestations or that conflicts with earlier guidance.

Granston Dismissals of *Qui Tam* Cases

An interesting open question is whether overaggressive FCA claims brought by relators regarding PRF funds will finally compel the DOJ to more aggressively use its authority under 31 U.S.C. § 3730(c) to dismiss frivolous *qui tam* cases. As discussed in the **second edition** of the *Qui Tam Quarterly*, the anticipated rise in affirmative government dismissals of *qui tam* cases under section 3730(c) after the release of the so-called "Granston Memo" in January 2018 has not occurred in a significant way.[67] While the government moved to dismiss approximately 50 *qui tam* cases in the two-plus years since the DOJ issued the Granston Memo, this still represents a very small percentage of the approximately 1,300 *qui tam* cases filed by relators in 2018 and 2019.

It is unsurprising that the government has not moved to dismiss a higher percentage of these cases. A government determination that a *qui tam* case lacks merit generally requires substantial investigative time and resources. Government attorneys responsible for investigating cases, therefore, have a strong incentive in marginal cases that appear to lack merit to simply decline intervention and allow a relator to continue on his or her own, rather than moving to dismiss the case. Simply declining intervention without moving to dismiss relieves the government of the burden of a deeper investigation into the merits of a case, and eliminates the risk of mistakenly dismissing a meritorious claim. These incentives are magnified by the fact that the government has consistently made substantial financial recoveries in non-intervened cases, and the fact that some courts have denied the government's motions to dismiss under section 3730(c) where the government was viewed as having failed to conduct a sufficient investigation.[68]

It is possible, however, that a new wave of qui tam cases alleging fraudulent receipt of PRF and other CARES Act funds by providers acting in good faith could inspire the government to seek dismissal more frequently. Indeed, recent DOJ statements concerning CARES Act enforcement hint that the government may already be seriously considering this more aggressive approach. In a speech from June 2020 concerning the DOJ's approach to CARES Act fraud enforcement, the then Deputy Assistant Attorney General Ethan P. Davis observed that "not every *qui tam* case has merit or should proceed" and reiterated the Granston Memo's delineation of circumstances where affirmative dismissal is appropriate.[69] Mr. Davis further elaborated that, while the government "will continue to use the [dismissal] authority judiciously," it will "consider moving to dismiss qui tams that are based on technical mistakes with paperwork **or honest misunderstandings of the rules**" or if "there was a reasonable attempt to comply with the [agency] guidance."[70]

If the DOJ puts these remarks into practice, this raises the question of how a defendant-provider in a *qui tam* case can convince the government that it received CARES Act funds with the good-faith belief that it was in compliance with applicable CMS guidance and rules. In light of the analysis above, one of the ways to potentially convince the government to seriously consider affirmative dismissal is for a defendant provider to offer concise and credible documentary evidence of its good-faith belief that it was, indeed, in compliance when it made required PRF certifications or made decisions about how to use PRF funds. Such documentation would have to be convincing without requiring a more rigorous government investigation to confirm.

What kind of documentary evidence would best fit this mold? While it remains to be seen exactly what the range of false certification theories relators might allege, the best way to obtain an affirmative dismissal will likely be for a provider to maintain **written documentation of its decision-making processes** about whether to apply for or retain PRF funds, including how the funds were kept, tracked, and spent. The key is to document the process by which the appropriate decision-makers—directors, managers, or board members—considered applicable guidance and made a decision about how to interpret that guidance. If a provider can prove that it made rigorous attempts to ensure it was in compliance, it might be able to persuade the government that the provider is not merely trying to justify a knowing violation of the rules with some kind of *post hoc* rationalization.

While it would be ideal for providers to document these compliance considerations and decisions at the time they were made, even after-the-fact documentation of the decision-making process could be beneficial. So long as a provider clearly documents the interpretive process **before** the government initiates an audit or investigation, and **before** a relator files a *qui tam* complaint, the government could well find such documentation to be persuasive evidence that a provider had a good-faith belief that it was in compliance. This could neutralize any alleged fraudulent intent and give the government comfort that dismissal is appropriate. Another key piece of evidence that might convince the government to dismiss a relator's FCA claim outright is written advice of counsel concerning the interpretation and application of the Terms and Conditions and FAQs. Of course, sharing privileged legal opinions with the government raises serious risks of inadvertent subject matter privilege waivers and should be considered carefully.

Conclusion

In the years following the 2008 financial crisis, government and relator enforcement actions led to record-setting FCA recoveries surrounding the billions of dollars of federal relief payments made under the Troubled Asset Relief Program (TARP). Indeed, FCA actions surrounding TARP accounted for the lion's share of the nearly US$6 billion recovered in fiscal year 2014. Given the nature and extent of CARES Act payments during the pandemic, FCA cases are anticipated to track or exceed those tied to the 2008 financial crisis. The number of *qui tams* filed by relators in 2020 and beyond is expected to be particularly high given the pace with which CARES Act funds were paid and the lack of clarity surrounding the requirements for receipt of such payments. The ambiguous requirements for PRF funds—particularly those associated with the Terms and Conditions and the FAQs—create the type of legal and regulatory "grey areas" that can serve as fertile grounds for FCA matters.

However, these grey areas surrounding PRF funds also potentially arm recipients with powerful defenses that are not always as robust or apparent in FCA cases. As outlined herein, defendants in PRF-related cases have potentially strong scienter and falsity arguments—as well as arguments under the DOJ's own policies—that may dissuade the government from bringing an action or may encourage the government to seek dismissal of, or decline to intervene in, a *qui tam* action. While the specific contours of potential materiality arguments are currently unclear and are likely to evolve in the PRF context, there is likely ample room for defendants in FCA cases to push back in that respect as well.

In light of the complexities related to PRF funds, including the evolving nature of the Terms and Conditions and FAQs, providers who find themselves as the subjects or targets in a government enforcement or FCA matter should consult counsel. Defending FCA actions, in particular, related to PRF funds requires expertise in both FCA matters and CARES Act funding.

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[1] Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020).

[2] Indeed, on 24 August 2020, during the "COVID-19 Health Care Fraud Town Hall" co-sponsored by K&L Gates, the then Acting Assistant Attorney General of the Civil Division of the U.S. Department of Justice, Ethan P. Davis, maintained that DOJ recognizes that the PRF is an important effort to help the private sector cope with the pandemic, and that providers have been overwhelmed in trying to use the funds in a compliant manner. Davis stated that, while DOJ intends to combat fraud surrounding the PRF, DOJ also does not want enforcement efforts to discourage providers from taking advantage of CARES Act initiatives, and that DOJ is not interested in investigating/prosecuting honest mistakes or simple misunderstandings. These comments are similar to those Davis made on 26 June 2020 when he maintained, regarding CARES Act funding, "you can rest assured that the Civil Division will 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." Ethan P. Davis, "Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform" (June 26, 2020), https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

[3] Pub. L. 116–139.

[4] Pub. L. 116–127.

[5] As noted above, the PRF is separate from other funding opportunities related to responding to the pandemic, including Medicare accelerated/advance payment loans, PPP loans, reimbursement of certain expenses through the Federal Emergency Management Agency (FEMA), and multiple federal and state grant programs, among others.

[6] As an example, on 10 April 2020, HHS issued the Terms and Conditions applicable to the first general distribution at the same time the general distribution funds were deposited in providers' accounts, which required that each provider "currently provides diagnoses, testing, or care for individuals with possible or actual cases of COVID-19." By 13 April, HHS had quickly revised the Terms and Conditions to clarify that providers and suppliers that have ceased operation as a result of the pandemic are eligible to receive funding as long as they provided diagnoses, testing, or care for individuals with possible or actual cases of COVID-19, noting that care does not have to be specific to treating COVID-19. Importantly, HHS noted in the updated guidance that it "broadly views every patient as a possible case of COVID-19."

[7] *E.g.*, HHS, Initial $30 Billion General Distribution Terms and Conditions, https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-30-b.pdf.

[8] *See* HHS, CARES Act Provider Relief Fund Frequently Asked Questions, https://www.hhs.gov/sites/default/files/provider-relief-fund-general-distribution-faqs.pdf (last visited Oct. 13, 2020) [hereinafter, HHS, FAQs].

[9] HHS, FAQs ("Recipients of Provider Relief Fund payments do not need to submit a separate quarterly report to HHS or the Pandemic Response Accountability Committee. HHS will develop a report containing all information necessary for recipients of Provider Relief Fund payments to comply with this provision. For all providers who attest to receiving a Provider Relief Fund payment and agree to the Terms and Conditions (or retain such a payment for more than 90 days), HHS is posting the names of payment recipients and their payment amounts on its public website here.")

[10] HHS, General and Targeted Distribution Post-Payment Notice of Reporting Requirements, https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements.pdf (Sept. 19, 2020)

[11] *Id.* The Reporting Guidance notes that PRF funds not fully expended on health care-related expenses attributable to coronavirus may be applied to lost revenues equal to a negative change in year-over-year net patient care operating income less various categories of other assistance received. The Reporting Guidance requires calculation of net income from patient care services based on a detailed outline of revenue from patient care, general and administration expenses, and health care-related expenses. Importantly, the instructions note that recipients may apply payments toward lost revenue, only up to the amount of their 2019 net gain from healthcare related sources, adding that recipients that reported negative net operating income from patient care in 2019 may apply payment amounts to lost revenues only up to a net zero gain/loss in 2020.

[12] *See* HHS, FAQs (explaining that PRF recipients "may use any reasonable method of estimating the revenue during March and April 2020 compared to the same period had COVID-19 not appeared. For example, if you have a budget prepared without taking into account the impact of COVID-19, the estimated lost revenue could be the difference between your budgeted revenue and actual revenue. It would also be reasonable to compare the revenues to the same period last year.").

[13] Am. Hospital Ass'n, Letter to the Hon. Alex M. Azar, II (Sept. 25, 2020). The AHA argued that this sudden shift in guidance after recipients have been operating under existing guidance for several months is unfair and unrealistic and will require many hospitals to return the PRF funds. Similarly, in a letter to HHS Secretary Alex Azar dated October 1, 2020, Senate Majority Leader Mitch McConnell expressed "serious concerns that [the Reporting Guidance] will cause great uncertainty and financial hardship for Kentucky hospitals." U.S. Sen. Mitch McConnell, Letter to the Hon. Alex M. Azar, II (Oct. 1, 2020).

[14] HHS, General and Targeted Distribution Post-Payment Notice of Reporting Requirements, https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements-october-2020.pdf (Oct. 22, 2020).

[15] HHS, Reporting Requirements Policy Update, https://www.hhs.gov/sites/default/files/reporting-requirements-policy-update.pdf (Oct. 22, 2020).

[16] *See* 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B), (a)(1)(G).

[17] *Id.* § 3729(b)(1).

[18] Safeco of Am. v. Burr, 551 U.S. 47 (2007).

[19] *Id.* at 70 n.20.

[20] *Id.* at 70.

[21] *See, e.g.*, United States ex rel. Purcell v. MWI Corp., 807 F.3d 281, 288 (D.C. Cir. 2015).

[22] *Id.* at 287.

[23] United States ex rel. Streck v. Allergan Inc., 746 F. App'x 101, 106 (3d Cir. 2018); United States ex rel. McGrath v. Microsemi Corp., 690 F. App'x 551, 552 (9th Cir. 2017); United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC, 833 F.3d 874, 879-80 (8th Cir. 2016); United States ex rel. Harman v. Trinity Indus. Inc., 872 F.3d 645 (5th Cir. 2017).

[24] *Purcell*, 807 F.3d at 289 (relying on language from Safeco).

[25] United States ex rel. Bahnsen v. Bos. Sci. Nueoromodulation Corp., 2017 U.S. Dist. LEXIS (D.N.J., Dec. 15, 2017).

[26] United States ex rel. Johnson v. Golden Gate Nat'l Senior Care, LLC, 223 F. Supp. 3d 882, 892 (D. Minn. 2016).

[27] HHS, Initial $30 Billion General Distribution Terms and Conditions, https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-30-b.pdf.

[28] HHS, FAQs.

[29] HHS, General and Targeted Distribution Post-Payment Notice of Reporting Requirements, https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements.pdf (Sept. 19, 2020).

[30] *Id.*

[31] HHS, FAQs (updated June 19, 2010).

[32] *Id.*

[33] HHS, General and Targeted Distribution Post-Payment Notice of Reporting Requirements, https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements.pdf (Sept. 19, 2020).

[34] HHS, General and Targeted Distribution Post-Payment Notice of Reporting Requirements, https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements-october-2020.pdf (Oct. 22, 2020).

[35] *See* Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 931–32 (E.D. Pa. 2019).

[36] *Id.* at 931–32.

[37] 587 U.S. ___, 139 S. Ct. 1804 (2019).

[38] *See id.* at 1809–10.

[39] *See id.*

[40] *Id.* at 1810 (emphasis added).

[41] *See id.* at 1810–14.

[42] *Id.* at 1810 (citation omitted).

[43] *Id.* at 1811 (emphasis in original).

[44] Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 933 (E.D. Pa. 2019)..

[45] *Allina*, 139 S. Ct. at 1817, 204 L. Ed. 2d 139 (emphasis added).

[46] Significantly, an October 2019 memorandum issued by the CMS Counsel's Office further underscores the potential import of *Allina* in FCA actions predicated on sub-regulatory guidance. *See* CMS Memorandum, Impact of *Allina* on Medicare Payment Rules (Oct. 31, 2019). In this memorandum, the CMS Counsel's Office maintains that "[w]here [HHS] or [CMS] issued guidance that, under *Allina*, should have been promulgated through notice-and-comment rulemaking, **the Department's ability to bring enforcement actions predicated on violations of those payment policies is restricted**. If [CMS] intends for a particular guidance document to be used in enforcement actions, then the guidance must comply with *Allina*." *Id.* (emphasis added). The memorandum adds that "**[t]he critical question is whether the enforcement action could be brought absent the guidance document. If the answer is no, then the guidance document establishes a norm and, under Allina, is invalid unless issued through notice-and-comment rulemaking.**" *Id.* (emphasis added).

[47] *See Polansky*, 422 F. Supp. 3d 916.

[48] *Id.* at 919.

[49] *Id.* at 932

[50] *Id.* at 930.

[51] *Id.* at 934.

[52] *Id.* (quoting Allina Health Servs. v. Price, 863 F.3d 937, 943 (D.C. Cir. 2017) (emphasis added)).

[53] *Id.* at 934–35.

[54] *Id.*

[55] *Id.*

[56] *Id.* (quoting *Allina*, 139 S. Ct. at 1811).

[57] *Id.* (emphasis added).

[58] The potential difficulties that the government or relators may have in establishing falsity in FCA actions predicated upon violation of PRF FAQs is further affirmed by *Agendia, Inc. v. Azar*, 420 F. Supp. 3d 985 (C.D. Cal. 2019). In *Agendia*, the Central District of California relied on Allina in concluding that a Medicare Administrative Contractor's local coverage determination (LCD) and corresponding policy article were "unlawfully promulgated without notice and comment" under § 1395hh(a)(2). *Agendia*, 420 F. Supp. 3d at 998. In so doing, the court framed its analysis in the case as to whether the LCD was a "**(1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services**.'" *Id.* at 997 (quoting 42 § U.S.C. 1395hh(a)(2)) (emphasis added).

[59] Rachel L. Brand, "Memorandum: Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases" (Jan. 25, 2018).

[60] Department of Justice Manual, Title 1-20.000, Limitation on Use of Guidance Documents in Litigation (Dec. 2018).

[61] The permissible uses of guidance documents range from establishing scienter to the provision of legal or factual context in the government's litigation briefing. *See id.*

[62] P31 U.S.C. § 3729(a)(1)(B), (a)(1)(G), (b)(4).

[63] *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

[64] *Id.* at 2003–04 ("[If] the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.").

[65] *Id.*

[66] HHS, General and Targeted Distribution Post-Payment Notice of Reporting Requirements, https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements.pdf (Sept. 19, 2020).

[67] *Qui Tam Quarterly* (July 2019), https://www.klgates.com/Qui-Tam-Quarterly-The-Department-of-Justice-False-Claims-Act-Policy-Issue.

[68] *See, e.g.,* United States ex rel. Harris v. EMD Serono Inc., 370 F. Supp. 3d 483 (E.D. Pa. 2019) (applying "rational relationship" test from Ninth and Tenth Circuits in considering government motion to dismiss under 31 U.S.C. § 3730(c)); United States ex rel. Cimznhca, LLC v. UCB, Inc., No. 17-CV-765-SMY-MAB (S. D. Ill. Apr. 15, 2019) (denying government motion to dismiss in part due to inadequate investigation and lack of cost-benefit analysis to support argument that investigation would not be worth resource expenditure).

[69] Ethan P. Davis, Speech to U.S. Chamber of Commerce's Institute for Legal Reform, Washington, D.C. (June 26, 2020), https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

[70] *Id.* (emphasis added).

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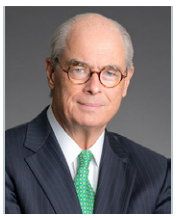

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