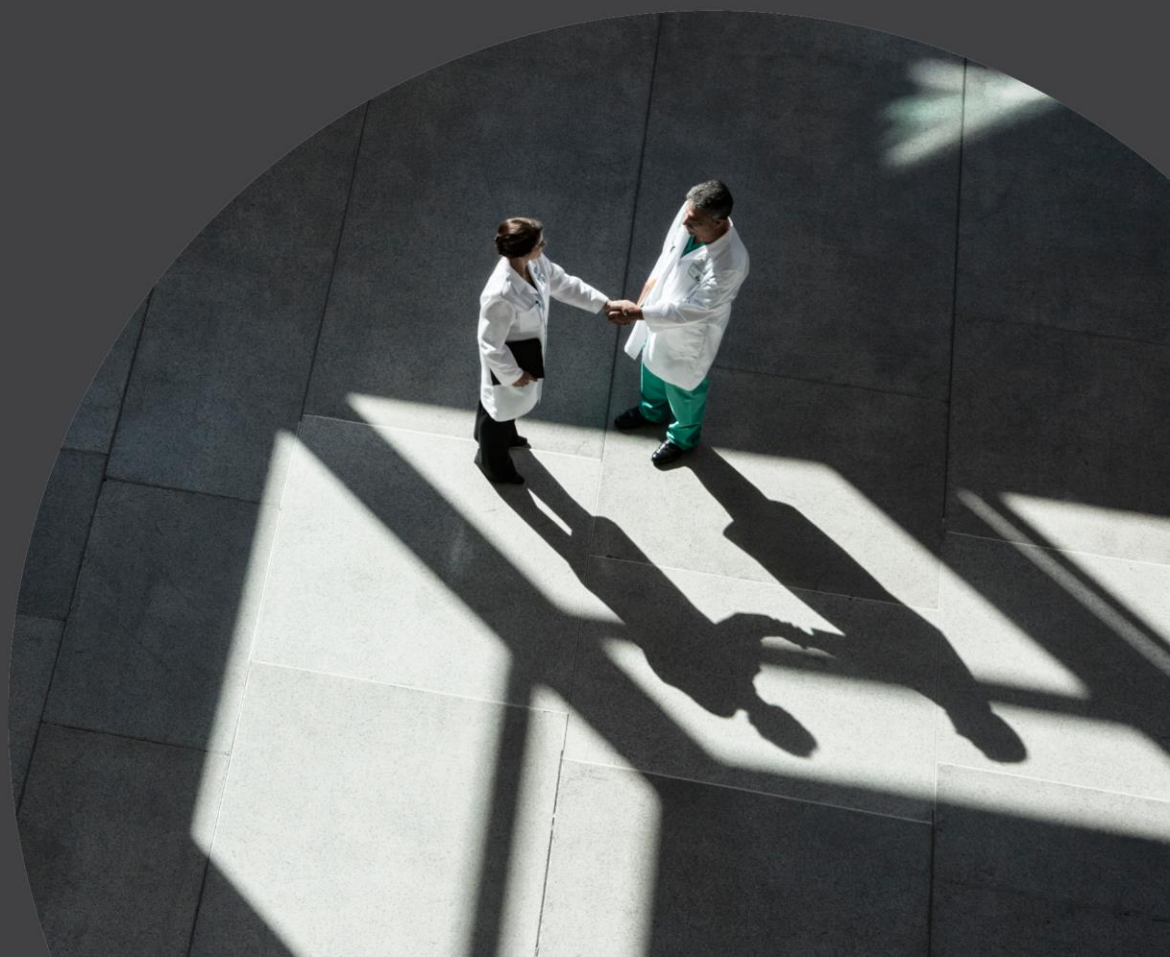
MID-YEAR | JULY 2020

HEALTHCARE ENFORCEMENT MID-YEAR ROUNDUP: 2020



McDermott
Will & Emery

McDermott Will & Emery

MID-YEAR ROUNDUP

TABLE OF CONTENTS

INTRODUCTION In this installment of the *Healthcare Enforcement Roundup* we cover new and longstanding issues impacting the healthcare enforcement landscape. First, we explore the impact of the Coronavirus (COVID-19) on healthcare industry and the heightened risk of enforcement actions, whistleblower complaints and litigation that arise in times of crisis. We also address differing falsity standards that have emerged under the False Claims Act (FCA), the Department of Justice's (DOJ) FCA enforcement priorities – including an overview of the DOJ's updated guidance on corporate compliance – and new developments on the enforceability of sub-regulatory guidance that should all be watched by hospitals, health systems and other industry stakeholders. Finally, this issue features updates on key healthcare enforcement issues to watch from past *Healthcare Enforcement Roundup* reports.

PREPARING FOR THE AFTERMATH OF COVID-19: THE INVESTIGATIONS

In recent months, the federal government has dedicated trillions of dollars to containing and treating the Coronavirus (COVID-19) and stimulating the economy in response to the pandemic. It has also waived many federal health program requirements to grant providers greater flexibility in combatting the virus. During these challenging times, healthcare providers should remember to practice good compliance hygiene to avoid heightened scrutiny and potential allegations of false claims lobbed by governmental actors and whistleblowers.

Impending Governmental Scrutiny

Relators and governmental enforcement authorities have often used the federal False Claims Act (FCA) to bring claims against recipients of federal funds following national crises, and healthcare fraud and abuse has been a primary FCA enforcement focus for many years. Of the $3 billion the US Department of Justice (DOJ) recovered in 2019 from FCA settlements and judgments, $2.6 billion was related to the healthcare, life sciences and pharmaceutical industries, making 2019 the 10th year in a row that healthcare-related recoveries exceeded $2 billion.[1]

This trend likely will continue in 2020 and expand to include COVID-19-related claims as a result of the $2.2 trillion in governmental funds allocated to myriad industries and businesses of all sizes as part of the Coronavirus Aid, Relief and Economic Security (CARES) Act, including $175 billion to healthcare providers through the Provider Relief Fund.

To monitor the use of these allocated governmental funds, the US Department of Health and Human Services (HHS) Office of Inspector General (OIG) received $2 million for oversight of activities supported with funds appropriated to HHS as part of the Coronavirus Preparedness and Response Supplemental Appropriations Act. The CARES Act also established a Special Inspector General for Pandemic Recovery to oversee the spending of government funds in response to COVID-19, as well as the Pandemic Response Accountability Committee and the COVID-19 Congressional Oversight Commission. As there seems to be no shortage of government bodies focused on supervising the use of federal funds related to COVID-19, healthcare providers and all businesses receiving these funds should expect increased scrutiny of how their money is put to use.

[1] *Justice Department Recovers Over $3 Billion From False Claims Act Cases in Fiscal Year 2019*, DOJ (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

Even as COVID-19 continues to spread nationwide, government enforcement bodies have already begun to prosecute alleged bad actors. On March 20, 2020, Attorney General Barr urged the public to report COVID-19-related fraud schemes, and all US attorneys were directed to appoint a COVID-19 fraud coordinator for each district to oversee the investigation and prosecution of COVID-19-related crimes. Almost immediately thereafter, on March 22, 2020, the DOJ filed its first enforcement action in the Western District of Texas against Austin-based operators of "coronavirusmedicalkit.com," alleging that the website was a wire fraud scheme that offered customers access to COVID-19 vaccine kits in exchange for a $4.95 shipping fee. And on March 23, 2020, OIG published a fraud alert warning beneficiaries about "fraudsters" targeting them for fraudulent tests or other services.

Other recent DOJ actions include redistributing more than 500,000 medical supplies confiscated from price gougers,[2] arresting a Georgia man for fraudulently attempting to sell $750 million of personal protective equipment to the US Department of Veterans Affairs,[3] enjoining a Florida entity from selling a bleach product as a miracle cure for COVID-19 and other maladies,[4] arresting a Georgia woman for conspiring to submit fraudulent claims related to COVID-19 tests for Medicare beneficiaries,[5] and charging a California medical technology company president with conspiracy to commit healthcare fraud by submitting more than $69 million in false and fraudulent claims for allergy and COVID-19 testing.[6]

Additional enforcement actions will likely follow, especially in the healthcare industry. On April 22, 2020, HHS Secretary Alex Azar warned Provider Relief Fund recipients that "Congress has entrusted us with an immense amount of money to send to providers, and we will be clear and careful about how we're doing it . . . There will be significant anti-fraud and auditing work done by HHS, including the work of the Office of the Inspector General."

Provider and Contracting Matters

HHS Secretary Azar issued a blanket waiver of Stark Law sanctions in response to COVID-19, allowing greater flexibility in contracting for office space or professional services, among other things. However, the Stark waiver has specific requirements—for example, the purpose of the arrangement must be related to COVID-19 response—and does not waive all Stark Law exception elements. Stakeholders such as the American Hospital Association have recommended that enforcement of the Anti-Kickback Statute (AKS) should be temporarily suspended during these challenging times as well. OIG has thus far stated that it does not intend to issue AKS waivers. Instead, OIG issued a policy statement that it would not impose sanctions under the AKS on

[2] *Department of Justice and Department of Health and Human Services Partner to Distribute More Than Half a Million Medical Supplies Confiscated from Price Gougers*, DOJ (Apr. 2, 2020), https://www.justice.gov/opa/pr/department-justice-and-department-health-and-human-services-partner-distribute-more-half.

[3] *Georgia Man Arrested for Attempting to Defraud the Department of Veterans Affairs in a Multimillion-Dollar COVID-19 Scam,* DOJ (Apr. 10, 2020), https://www.justice.gov/opa/pr/georgia-man-arrested-attempting-defraud-department-veterans-affairs-multimillion-dollar-covid.

[4] *Justice Department Seeks to End Illegal Online Sale of Industrial Bleach Marketed as "Miracle" Treatment for COVID-19*, DOJ (Apr. 17, 2020) https://www.justice.gov/opa/pr/justice-department-seeks-end-illegal-online-sale-industrial-bleach-marketed-miracle-treatment.

[5] *Georgia Woman Arrested for Role in Scheme to Defraud Health Care Benefit Programs Related to Cancer Genetic Testing and COVID-19 Testing*, DOJ (May 15, 2020) https://www.justice.gov/opa/pr/georgia-woman-arrested-role-scheme-defraud-health-care-benefit-programs-related-cancer.

[6] *Medical Technology Company President Charged in Scheme to Defraud Investors and Health Care Benefit Programs in Connection with COVID-19 Testing*, DOJ (Jun. 9, 2020) https://www.justice.gov/opa/pr/medical-technology-company-president-charged-scheme-defraud-investors-and-health-care-benefit.

arrangements that satisfied the Stark blanket waiver. For other arrangements, OIG stated that it would carefully review their purposes and intent during this emergency period. OIG also created an FAQ portal for organizations to ask questions about COVID-19-related arrangements.

For both Stark and AKS compliance purposes, providers should diligently document the reasons for deviating from established compensation practices or making changes to existing arrangements, in anticipation of inevitable future inquiries by the government and relators. Providers should also continue to monitor the changing regulatory landscape to prevent violations of federal requirements that may give rise to future FCA claims. Once the president or HHS secretary declares the end of the public health emergency, the Stark waivers and AKS policy statement may be revoked. In addition, there may be state laws or regulations that are as restrictive, if not more stringent, that may affect the risk analysis of certain actions.

Mitigation Steps

Providers should continue to practice good compliance hygiene at all times but particularly during the COVID-19 pandemic:

- Maintain diligent, contemporaneous records regarding the spending of federal funds.
- Document deviations from policies and demonstrate why such deviations were deemed necessary (*e.g.*, saving lives or no reasonable alternative).
- Follow government instructions. When an instruction or answer to a question is provided, document the details of the conversation contemporaneously, including the name of the government official.
- Adhere to proper billing and coding rules when submitting claims for COVID-19 tests and treatments.
- When possible, revise policies and procedures to address the changing circumstances of COVID-19.
- Make information accessible to employees and contractors on proper fraud, waste and abuse compliance, and provide key compliance training to new providers as needed.
- Build up the internal audit function to monitor claims for appropriateness before submission, and evaluate audit plans to take into account any changed circumstances.

Taking such measures will give providers a road map of the action that they took and why—precisely the type of information that will prove useful to stave off government investigations and whistleblowers.

CIRCUIT SPLIT ON WHEN CLINICAL JUDGEMENTS MAY BE "FALSE" UNDER THE FALSE CLAIMS ACT

Hospice care providers involved in lawsuits under the federal False Claims Act (FCA) now face two different falsity standards. The US Court of Appeals for the Third Circuit's recent decision in *United States v. Care Alternatives*[7] created a circuit split over when a physician's clinical judgment can be deemed "false" in an FCA action. In *United States v. AseraCare, Inc.*,[8] the US Court of Appeals for the Eleventh Circuit held that a reasonable difference of physician opinion is not enough, taken alone, to establish that a clinical judgment is "false."[9] The Third Circuit held the

[7] *United States v. Care Alternatives*, 952 F.3d 89 (3d Cir. 2020).
[8] *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019). For more *AseraCare* analysis, see McDermott's Q4 *2019 Healthcare Enforcement Quarterly Roundup, available at* https://www.mwe.com/insights/healthcare-enforcement-quarterly-roundup-q4-2019/.
[9] *See AseraCare*, 938 F.3d 1278, at 1297.

opposite.[10] Both courts considered the FCA falsity standard in the context of the Medicare hospice benefit, where the controlling condition of payment is a matter of clinical judgment.[11] The falsity standards in these two cases may also have implications for other types of reimbursement claims that involve a provider's clinical judgment. So far, the US Court of Appeals for the Ninth Circuit—considering an FCA claim involving the medical necessity of inpatient hospitalizations—has rejected the Eleventh Circuit's "objective falsehood" standard at the pleading stage.[12] The federal FCA imposes civil liability, including treble damages, on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the federal government or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[13] An FCA claim consists of four elements: the plaintiff must prove that the defendant (1) made a false statement, (2) with scienter, (3) that was material, (4) causing the government to make a payment.[14] A claim can be "false" when the claim's submitter "falsely asserts or implies that it has complied with a statutory or regulatory requirement" when it has not.[15]

Care Alternatives and *AseraCare* involved similar facts. In both cases, former employees of hospice care providers brought *qui tam* actions under the FCA against their former employers, claiming that the providers were certifying patients for the Medicare hospice benefit when those patients were not actually eligible.[16] For a patient to be eligible to receive the Medicare hospice benefit, the patient's attending physician (or the hospice's medical director) must certify that the patient is terminally ill.[17] A terminal illness is one in which the patient is expected to live for six months or less, given the normal course of the illness.[18] A physician must also re-certify the patient for subsequent benefit periods.[19] Reimbursement claims for the Medicare hospice benefit must include medical information and other documentation that support the physician's medical prognosis.[20]

In both cases, the plaintiffs claimed that the hospice care providers' physicians were certifying patients for the Medicare hospice benefit, when the patients' medical records did not support the determination that the patients were terminally ill.[21] These "false" clinical judgments, the plaintiffs argued, made the resulting Medicare reimbursement claims fraudulent.[22]

AseraCare

On September 9, 2019, the Eleventh Circuit held in *AseraCare* that a "mere difference of reasonable

[10] *See Care Alternatives*, 952 F.3d 89, at 95.
[11] *See AseraCare* at 1282-84; *Care Alternatives* at 92-93.
[12] *See* Winter ex rel. United States v. Gardens Regional Hospital, 953 F.3d 1108 (9th Cir. 2020).
[13] 31 U.S.C.S. § 3729(a)(1)(A)-(B). *See also AseraCare* at 1284.
[14] *See AseraCare* at 1284.
[15] *AseraCare* at 1290.
[16] The US government intervened in *AseraCare* but did not intervene in *Care Alternatives*. *See AseraCare* at 1281; *Care Alternatives* at 93.
[17] *See AseraCare* at 1293.
[18] *See Id.*
[19] *See Id.*
[20] *See Id.* at 1295.
[21] *See AseraCare* at 1281; *Care Alternatives* at 91-92.
[22] *See AseraCare* at 1281; *Care Alternatives* at 91-92.

opinion between physicians, without more," is insufficient to create a triable issue of fact regarding the falsity element of an FCA claim.[23] Instead, the Eleventh Circuit adopted an "objective falsehood" standard, requiring the plaintiff to demonstrate more than a reasonable difference of medical opinion.[24] A plaintiff can meet this standard in several ways.[25] A certifying physician's medical opinion can be "objectively false" in any of the following instances:

- The physician fails to review a patient's medical records or otherwise familiarize herself with the patient's condition before asserting that the patient is terminal.
- The plaintiff proves that a physician did not, in fact, subjectively believe that his patient was terminally ill at the time of certification.
- Expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records.[26]

To properly state an FCA claim in the context of the Medicare hospice benefit, the plaintiff therefore must identify facts and circumstances about the certification of terminal illness that are inconsistent with the "proper exercise" of a physician's clinical judgment.[27] In other words, the plaintiff must show something more than the "mere difference of reasonable opinion" about the prognosis.[28] Otherwise, the FCA claim fails as a matter of law.[29]

Care Alternatives

In *Care Alternatives*, the Third Circuit considered the Eleventh Circuit's "objective falsehood" standard in the hospice context and expressly rejected it.[30] Instead, the Third Circuit stated that medical opinions may be "false," and the conflicting opinion of a doctor retained as an expert by the relator can, without more, create a triable issue of fact for the jury regarding the element of falsity.[31] The court emphasized that a reimbursement claim can be legally false when it does not comply with statutory or regulatory conditions for payment.[32]

Under a theory of legal falsehood, the plaintiff would need to show that the hospice care provider failed to meet at least one of the two regulatory requirements for payment of the Medicare hospice benefit: (1) a physician certified the patient as terminally ill, and (2) the certification was accompanied by clinical information and other documentation that *support* the medical prognosis.[33] According to the Third Circuit, disagreement between experts on whether the clinical information "supports" the prognosis can raise a genuine dispute of material fact on falsity under the second requirement.[34]

In the Third Circuit's view, the Eleventh Circuit's "objective falsehood" standard conflates the FCA elements of falsity and scienter, which should remain distinct elements of an FCA claim.[35] The relator's need to demonstrate the element of scienter—by showing that the physician made a *knowingly* false determination about the patient's prognosis—would limit the possibility that hospice providers would be exposed to FCA liability whenever

[23] *AseraCare* 1297.
[24] *See Id.*
[25] *See Id.*
[26] *See Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*

[30] *See Care Alternatives* at 98-99.
[31] *See Id.*
[32] *See Id.* at 95.
[33] *Id.* at 97 (emphasis added).
[34] *Id.*
[35] *See Id.* at 96.

plaintiffs can find an expert who disagrees with the certifying physician.[36] Strict enforcement of the scienter requirement would mitigate concerns that hospice providers would face increased liability, according to this court.[37]

The Ninth Circuit Weighs In: *United States v. Gardens Regional Hospital*

Recently, the US Court of Appeals for the Ninth Circuit considered whether plaintiff-relators must plead an "objective falsehood" to properly state a claim under the FCA at the pleading stage, effectively siding with the Third Circuit. In *Gardens Regional Hospital*,[38] a former hospital director filed a *qui tam* action alleging that her former employer-hospital falsely certified that patients' inpatient hospitalizations were medically necessary.[39] Because medical necessity is a requirement for Medicare reimbursement, the relator argued that the false certifications caused false Medicare claims.[40]

The district court dismissed for failure to state a claim, holding that claims implicating a doctor's clinical judgment can never state a claim under the FCA because "subjective medical opinions" cannot be objectively false.[41] On appeal, the Ninth Circuit reversed and remanded.[42] Noting the broad language of the FCA (which "imposes liability for all false or fraudulent claims" and "does not distinguish between objective and subjective falsity or carve out an exception for clinical judgments and opinions") the court held that a doctor's certification that a patient's inpatient hospitalization is medically necessary *can* be false or fraudulent under the FCA.[43]

To support its decision, the court cited the US Court of Appeals for the Fifth Circuit's holding that "claims for medically unnecessary treatment are actionable under the FCA,"[44] and the US Court of Appeals for the Tenth Circuit's determination that a "medical judgment can be false or fraudulent as proscribed by the FCA."[45] The court agreed with the Third Circuit's rejection of the "bright-line rule that a doctor's clinical judgment cannot be false."[46]

Implications

Under *AseraCare*, relators cannot rely solely on contrary medical expert testimony to survive summary judgment. Instead, relators must demonstrate that the physician did not properly review the patient's records or familiarize herself with the patient, that the physician was lying, or that no reasonable physician would have certified the patient. As a result, relators face a greater evidentiary burden, and the standard generally benefits defendants.

The Third Circuit's standard allows plaintiffs to survive summary judgment on the element of falsity

[36] *See Id.*
[37] *Id.*
[38] Winter ex rel. United States v. Gardens Regional Hospital, 953 F.3d 1108 (9th Cir. 2020).
[39] *See Winter*, 953 F.3d 1108, at 1115-16.
[40] *See Id.*
[41] *Id.* at 1116.
[42] *See Id.* at 1113.
[43] *Id.* at 1117.
[44] *Id.* at 1118 (referencing *United States ex rel. Riley v. St. Luke's Episcopal Hospital*, F.3d 370, 376 (5th Cir. 2004)).
[45] *Id.* (referencing United States ex rel. Polukoff v. St. Mark's Hospital, 895 F.3d 730, 742 (10th Cir. 2018)).
[46] *Id.* at 1118-19.

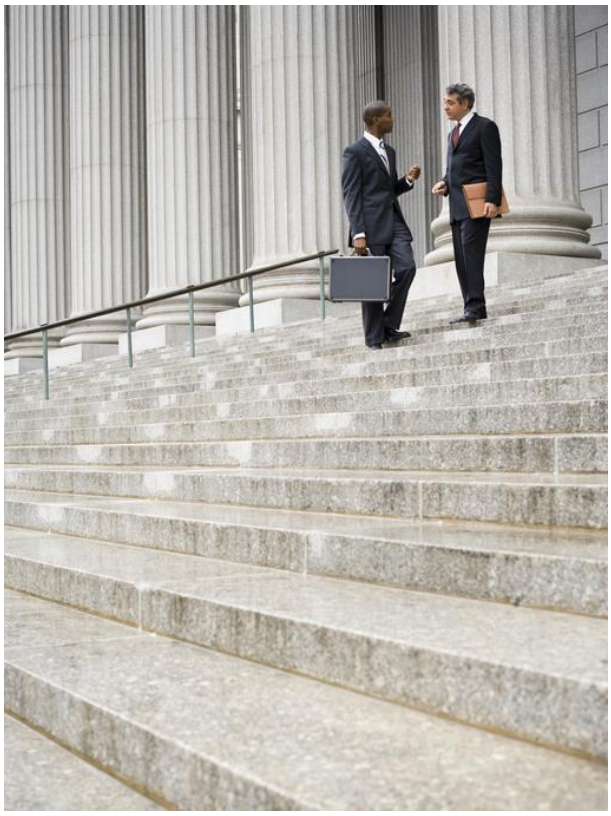
based solely on a medical expert's difference of opinion with the treating physician. While the relator may have an easier road demonstrating falsity in the Third Circuit, the plaintiff must still overcome "strict enforcement" of the scienter element.

The practical effects of the two standards will become more apparent as courts continue to apply them in future cases. The two standards may also be applied in other FCA cases where claims for reimbursement rest on a provider's clinical judgment.

CONTINUED DOJ FOCUS ON COMPLIANCE

As reported in last year's Q2 and Q4 *Roundups*, the US Department of Justice (DOJ) provided significant guidance in 2019 concerning cooperation credit and corporate compliance programs. This trend continued in Q1 and Q2 2020.

On January 27, 2020, Deputy Associate Attorney General Stephen Cox gave the keynote address at the 2020 Advanced Forum on False Claims and Qui Tam Enforcement. During his speech, Cox discussed the DOJ's cooperation policy, stating that "corporate defendants can earn credit—and a reduction in penalties and damages—by voluntarily disclosing misconduct, cooperating with our investigations, and taking remedial measures such as improving corporate compliance programs." Cox went on to state that for companies that provide "maximum cooperation," the DOJ can provide "a substantial discount down to single damages, plus lost interest, costs of investigation, and in a *qui tam* case, the share that must go to the whistleblower." Cox additionally advised that the DOJ may notify the appropriate regulatory agency of a company's



cooperation so that the agency may consider it in connection with administrative proceedings. Further, in some cases, the DOJ will publicly acknowledge the cooperation in resolving *qui tam* litigation. Finally, Cox said that the DOJ will take into account the "nature and effectiveness" of a compliance system in determining whether the False Claims Act (FCA) is the appropriate remedy, reminding the audience that scienter is a key element of the FCA and that "a robust compliance program executed in good faith could demonstrate the lack of scienter." Nonetheless, Cox warned that a "paper tiger" compliance program could demonstrate the opposite, landing companies in hot water.

With this continued focus on cooperation and the relevance of compliance efforts to DOJ's decision-making, companies should ensure that they go above

and beyond to create and maintain strong compliance programs.

On June 1, 2020, the DOJ's Criminal Division issued updated guidance on the "Evaluation of Corporate Compliance Programs," which lays out a series of factors, in the form of questions, for DOJ attorneys to consider when assessing the effectiveness of corporate compliance programs as part of the process of making charging decisions and negotiating resolutions. Companies should bear in mind that the updated guidance is not a checklist, but instead is a framework for the design and implementation of a compliance program.

While much of the guidance is consistent with its previous iterations, several revisions provide insight into the DOJ's current focus when evaluating the effectiveness of a corporate compliance program. At the outset, the updated guidance places more emphasis on tailoring compliance programs to the organization's risk profile and updating and adapting the program as the organization's risks change. For example, in the introductory section, the updated guidance directs prosecutors to "make a reasonable individualized determination in each case" regarding the effectiveness of the program, and lays out specific factors that a risk assessment should consider. These factors include "the company's size, industry, geographic footprint, regulatory landscape" and other "internal and external" factors that might affect the compliance program. The fact that DOJ issued this update amid the COVID-19 pandemic, when "external" factors are reshaping many organizations' risk profiles, is telling. DOJ expects the compliance program to be designed around an organization's risks, and if those risks change, the compliance program should adapt as well.

When considering the effectiveness of a program, prosecutors are directed to focus not only on the program at the moment in time when they are reviewing it, but to go back in time to understand why the program was designed in the way that it was and how and why it evolved. The revisions to the guidance clarify that DOJ expects compliance programs to undergo continuous review and evolution, with companies adapting compliance programs based not only "on lessons learned from [their] own misconduct" but also on the misconduct of "other companies facing similar risks." In other words, companies are expected to keep an eye on enforcement trends and consider adjustments to the compliance program based on those trends.

The updated guidance also highlights DOJ's increasing focus on the granular details of compliance programs—from whether and how the company tracks access to various policies and procedures as a method of determining which policies attract the most attention, to the company's mechanisms for allowing employees to ask questions during both in-person and online trainings. The revisions to the guidance also demonstrate a renewed focus on compliance resources. For example, a question directed at the effectiveness of the program, which previously asked whether the compliance program was "implemented" effectively, now asks whether the program is "adequately resourced and empowered to function" effectively. The updated guidance also includes a new subsection on data resources and access. This subsection specifically asks whether the compliance team has access to the data it needs to do its job, whether there are impediments to such access, and, if so, what the company is doing to address them.

Perhaps in recognition of the fact that middle management has the largest impact on the greatest number of employees revisions, the updated guidelines explicitly state that the "culture of

compliance" should be embraced and implemented not only by senior leadership, but by middle management as well.

In sum, the updated guidance makes clear that compliance programs must be tailored to each organization's risk profile and must evolve as that risk profile changes, and that technological and other resources must be made available to the compliance function. DOJ also recognizes that while the "culture of compliance" may start with the tone set at the top, that culture must be embraced throughout the organization.

ADDITIONAL DOJ FALSE CLAIMS ACT ENFORCEMENT PRIORITIES FOR 2020: EHR & MEDICARE ADVANTAGE

On February 27 and 28, 2020, Joseph H. Hunt, former Assistant Attorney General for the US Department of Justice (DOJ) Civil Division, and Michael Granston, Deputy Assistant Attorney General, Commercial Litigation Branch, highlighted the DOJ's priorities for False Claims Act (FCA) enforcement in 2020 at the Federal Bar Association's annual Qui Tam Conference in Washington, DC.[47] DOJ priorities include alleged fraud arising in the context of electronic health records (EHRs) and alleged fraud involving Medicare Advantage plans.[48]

Electronic Health Records

Government and whistleblower allegations have led to several EHR lawsuits and investigations, with varying outcomes, including the following:

- On June 11, 2020, a federal judge dismissed a lawsuit against Community Health Systems (CHS) involving allegations that CHS submitted false claims to the government related to CHS's adoption of EHR technology and adherence to the meaningful use program (now known as the promoting interoperability program).[49]
- On January 27, 2020, Practice Fusion Inc. resolved criminal and civil investigations relating to clinical decision support functionality in its EHR software for $145 million.[50]
- On February 6, 2019, Greenway Health LLC settled allegations that it caused users to submit false claims to the government by misrepresenting the capabilities of its EHR product and providing unlawful remuneration to

[47] Joseph H. (Jody) Hunt, Remarks to the Federal Bar Association 2020 Qui Tam Conference (Feb. 27, 2020) (https://www.justice.gov/civil/speech/assistant-attorney-general-jody-h-hunt-delivers-remarks-federal-bar-association-2020); *see also;* Christopher Denig, Matthew Dunn & Krysten Rosen Moller, *Senior DOJ Attorneys Speak About FCA Enforcement Priorities, Dismissal, and Cooperation*, Inside Government Contracts (Mar. 3, 2020), https://www.insidegovernmentcontracts.com/2020/03/senior-doj-attorneys-speak-about-fca-enforcement-priorities-dismissal-and-cooperation/.

[48] *Id.*

[49] *United States ex rel. Lewis v. Cmty. Health Sys., Inc.*, No. 18-20394-CIV, 2020 WL 3103994, at *1 (S.D. Fla. June 11, 2020)

[50] *Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations*, DOJ (Jan. 27, 2020), https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0.

users to induce them to recommend the EHR product, for $57.25 million.[51]

- On January 30, 2019, Inform Diagnostics, formerly known as Miraca Life Sciences Inc., settled allegations that it paid kickbacks to referring physicians in the form of subsidies for EHR systems and free or discounted technology consulting services for $63.5 million.[52]

Medicare Advantage

The primary areas of government and whistleblower focus on Medicare Advantage organizations relate to risk adjustment generally and chart reviews in particular. Medicare Advantage organizations also are experiencing Risk Adjustment Data Validation audits by the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG).

More specifically, there is substantial litigation activity related to Medicare Advantage risk adjustment, including ongoing litigation that vacated CMS's rule defining what constitutes a risk adjustment overpayment.[53] DOJ's statement that Medicare Advantage plans are an enforcement priority comes at a time when key elements of the risk adjustment framework are hotly contested, forming a backdrop of uncertainty.

Within this context, several recent FCA lawsuits and settlements illustrate DOJ's prioritization of Medicare Advantage risk adjustment:

- On March 27, 2020, the DOJ filed a lawsuit against Anthem, Inc., alleging that Anthem falsely certified the accuracy of the diagnosis data it submitted to CMS for risk-adjustment purposes under Medicare Part C and knowingly failed to delete inaccurate diagnosis codes in connection with chart reviews.[54]
- On August 8, 2019, Beaver Medical Group L.P. and one of its physicians settled allegations that they reported invalid diagnoses to Medicare Advantage plans and thereby caused those plans to receive inflated payments from Medicare for approximately $5 million.[55]
- On April 12, 2019, Sutter Health LLC and affiliated entities settled allegations that the affiliated entities submitted inaccurate information about the health status of beneficiaries enrolled in Medicare Advantage Plans for $30 million.[56]

[51] *Electronic Health Records Vendor to Pay $57.25 Million to Settle False Claims Act Allegations*, DOJ (Feb. 6, 2019), https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-5725-million-settle-false-claims-act-allegations; *see also United States v. Greenway Health, LLC*, 2:19-CV-20 (D. Vt.).

[52] *Pathology Laboratory Agrees to Pay $63.5 Million for Providing Illegal Inducements to Referring Physicians*, DOJ (Jan. 30, 2019), https://www.justice.gov/opa/pr/pathology-laboratory-agrees-pay-635-million-providing-illegal-inducements-referring?utm_medium=email&utm_source=govdelivery.

[53] *See UnitedHealthcare Insurance Co., et al. v. Azar et al.*, 330 F. Supp. 3d 173 (D.D.C. 2018); *c.f. UnitedHealthcare Insurance Co., et al. v. Azar et al.*, Case No. 18-5326 (D.C. Cir.); *see also United States ex rel. Poehling v. UnitedHealth Group Inc. et al.*, Case No. 2:16-cv-08697 (C.D. Cal.), March 28, 2019, Civil Minutes.

[54] *Manhattan U.S. Attorney Files Civil Fraud Suit Against Anthem, Inc., for Falsely Certifying the Accuracy of Its Diagnosis Data*, DOJ (Mar. 27, 2020), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-files-civil-fraud-suit-against-anthem-inc-falsely-certifying; Complaint, *United States v. Anthem, Inc.*, 1:20-cv-02593 (S.D.N.Y. Mar. 26, 2020), https://www.justice.gov/usao-sdny/press-release/file/1262841/download.

[55] *Medicare Advantage Provider and Physician to Pay $5 Million to Settle False Claims Act Allegations*, DOJ (Aug. 8, 2019), https://www.justice.gov/opa/pr/medicare-advantage-provider-and-physician-pay-5-million-settle-false-claims-act-allegations; *see also United States ex rel. David Nutter v. Sherif F. Khalil, M.D., Beaver Medical Group, L.P. et al.*, No. CVC17-02035-PSG-KKX (C.D. Cal.).

[56] *Medicare Advantage Provider to Pay $30 Million to Settle Alleged Overpayment of Medicare Advantage Funds*, DOJ (Apr. 12, 2019), https://www.justice.gov/usao-ndca/pr/medicare-advantage-provider-pay-30-million-settle-alleged-overpayment-medicare; *see also United States ex rel. Ormsby v. Sutter Health, et al.*, Case No. 15-CV-01062-JD (N.D. Cal.).

PRACTICE NOTE

To mitigate DOJ and OIG scrutiny, healthcare providers and EHR vendors should develop a robust and well documented compliance program to address risk areas associated with EHR adoption and use.

Medicare Advantage Organizations should become familiar with ongoing litigation that could affect their compliance obligations, and should develop legal and compliance strategies for addressing key risk areas.

FURTHER INTERPRETATION REGARDING ENFORCEABILITY OF SUB-REGULATORY GUIDANCE

Following the Supreme Court of the United States' decision in *Azar v. Allina Health Services, et al.*[57], open questions remain about the extent to which Medicare sub-regulatory guidance—*i.e.*, guidance that was *not* adopted after notice-and-comment procedures—is enforceable. Since that decision, lower courts have attempted to distinguish what Medicare guidance is enforceable and what is not. Four recent cases have weighed in on this question.

First, the US District Court for the Central District of California held in *Agendia, Inc. v. Azar* that a local coverage determination (LCD) and related policy articles by a Medicare Administrative Contractor were not enforceable. According to the court, those guidance documents constituted "substantive legal standards" that were "unlawfully promulgated without notice and comment."[58] An appeal is pending before the US Court of Appeals for the Ninth Circuit.[59]

Second, the US District Court for the Middle District of Tennessee declined to hold that all LCD determinations are unenforceable. In *United States v. Anesthesia Servs. Assocs., PLLC,* defendants were accused of not complying with an LCD and sought dismissal of the False Claims Act (FCA) claim by arguing that the LCD was "not promulgated in accordance with notice and comment procedures."[60] Noting that the parties did not fully brief the issue, the court nonetheless held that "an LCD may give rise to an FCA claim" and refused to dismiss.[61] Given the lack of briefing, the court may not have known that LCDs are not binding on the US Department of Health and Human Services and that the Centers for Medicare & Medicaid Services (CMS) Office of General Counsel (OGC) has instructed CMS that LCDs do not establish or change substantive legal standards, and therefore cannot support enforcement actions. We discussed the OGC memo in our Q4 2019 report.

Third, in *Polansky v. Exec. Health Res., Inc.*, the US District Court for the Eastern District of Pennsylvania granted summary judgment in favor of the defendants.[62] The relator alleged that defendants failed to comply with guidance published in the Medicare Hospital Manual that instructed physicians to admit individuals as inpatients only if the physician believed the patient would be in the hospital for longer than 24 hours, known as the "two-midnight" rule. The court determined that the Medicare Hospital Manual guidance, which did not go through formal notice-and-comment rulemaking, was a "substantive

[57] 139 S. Ct. 1804 (2019). Notably, several other hospitals and health systems were parties in filing this lawsuit.
[58] 420 F. Supp. 3d 985, 998 (C.D. Cal. 2019).
[59] *Id.* at 998.
[60] No. 3:16-cv-0549, 2019 WL 7372510, at *15 (M.D. Tenn. Dec. 31, 2019).
[61] *Id.* at *16.

legal standard" under the Social Security Act because the guidance "affects a hospital's right to payment."[63] The court granted defendants' summary judgment motion, and the relator's appeal is pending in the US Court of Appeals for the Third Circuit.[64]

Finally, in *Dobson v. Azar*, the US District Court for the Southern District of Florida ruled that the Medicare Appeals Council may uphold an administrative law judge (ALJ) decision to deny a Medicare beneficiary drug coverage based in part on sub-regulatory guidance from the Prescription Drug Benefit Manual (PDBM).[65] Citing *Allina*, the court held that the PDBM "does not carry the force of law but still clarified what 'medically accepted indication' entails."[66] The court also found that "[a]lthough the PDBM does not bind ALJs and the Council, they must be accorded substantial deference if they are applicable to a particular case."[67]

[62] No. 12-CV-4239, 2019 WL 5790061 (E.D. Pa. Nov. 5, 2019).
[63] *Id.* at *15 (quoting *Allina*, 139 S. Ct. at 1811).
[64] *Id.* at *19.
[65] No. 4:18-CV-10038, 2020 WL 3268357 (S.D. Fla. Mar. 31, 2020).
[66] *Id.* at *8.
[67] *Id.*

RECURRING UPDATES

CASES INTERPRETING MATERIALITY AND REASONABLE DIFFERENCES OF OPINION UNDER *ESCOBAR*

As most recently reported in the Q4 2019 *Roundup*, courts continue to interpret the False Claims Act's (FCA's) requirements under *Escobar*.[68]

In *U.S. ex rel. Janssen v. Lawrence Memorial Hospital*,[69] the relator alleged that the defendant violated the FCA by falsifying medical data and falsifying compliance with the Deficit Reduction Act in order to receive Medicare reimbursement from the government. The defendant moved for summary judgment and argued that the relator failed to prove the materiality standard of the FCA.[70] The US Court of Appeals for the Tenth Circuit explained that *Escobar* required the lower courts, when determining materiality, to focus on the reaction of the recipient of the false claim, *not* on the reaction of a reasonable person.[71] Applying this standard, the Tenth Circuit held that the government's decision whether to continue payment once it becomes aware of the false records is relevant to the materiality determination in an FCA claim.[72] Here, even after learning of the issues, CMS continued to pay the defendant's Medicare claims.[73] Therefore, the inaccurate reporting was not material to the government's decision to pay the defendant's claims.[74]

Most recently, in *United States ex rel. Ruckh v. Salus Rehabilitation, LLC, et al.*, a case previously discussed in the Q1 2018 *Roundup*, the US Court of

[68] *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016).
[69] No. 949 F.3d 533, 535 (10th Cir. 2020).
[70] *Id.*
[71] *Id.* at 541.
[72] *Id.*
[73] *Id.* at 541-45.
[74] *Id.* at 545.

Appeals for the Eleventh Circuit reinstated a $85.1 million jury verdict on Medicare claims in favor of the relator.[75] The district court originally overturned the verdict after finding that the relator "failed to introduce evidence of materiality and scienter at trial."[76] The court found that the fact that the government continued to pay the nursing homes' claims for reimbursement, despite knowledge of the alleged billing violations, evidenced that the violations were not material.[77] The Eleventh Circuit distinguished between two sets of allegations in the case, those affecting Medicaid claims, which concerned failures to maintain "comprehensive care plans" for each resident, and those affecting Medicare claims, which concerned upcoding and "ramping" allegations, asserting that the defendants timed treatments and used inappropriate reimbursement codes to falsely elevate payment levels.[78]

As to the Medicaid claims, the Eleventh Circuit affirmed, agreeing with the district court that the allegations were immaterial.[79] Under *Escobar*'s "'demanding' bar," the relator failed to demonstrate that a failure to create and maintain care plans was material.[80] The court highlighted a lack of evidence that the state enforced the requirement, as it continued to pay claims and did not seek recoupment after the nursing homes self-reported, and the relator introduced no evidence that the state ever declined to reimburse or otherwise sought to enforce this kind of violation.[81] As to the Medicare claims, however, the Eleventh Circuit reinstated the verdict, explaining that the "upcoding and ramping" allegations were both material.[82] The Eleventh Circuit dismissed the district court's conclusion that the allegations amounted to "a handful of paperwork defects," stating that the jury was not required to find the defendants' theory at trial credible—*i.e.*, that the codes used were accurate, but underlying documentation of the services provided were missing or, because of clerical error, had not been recorded.[83] Without this explanation, the court held that upcoding is "[a]t its core . . . a simple and direct theory of fraud," with "plain and obvious materiality."[84]

In another recent case, *U.S. ex rel. Porter v. Magnolia Health Plan Incorporated*, the US Court of Appeals for the Fifth Circuit reinforced FCA requirements articulated in *Escobar*.[85] The relator alleged that the defendant violated the FCA by staffing licensed professional nurses for care and case management, instead of registered nurses.[86] The defendant was a third party that contracted with the Mississippi Division of Medicaid "to co-administer the state's Medicaid program through a program commonly known as MississippiCAN."[87] The district court dismissed the relator's complaint because she did not meet the materiality standard, and the Fifth Circuit affirmed. The Fifth Circuit held that the defendant's contracts with the government did not require employment of a registered nurse as a care or case manager as the relator suggested.[88] While the contracts did contain a provision that required the defendant to "strictly adhere to all applicable federal and state law (statutory and case law), regulations and standards . . . including . . . the policies, rules, and regulations" of Mississippi and the Medicaid program

[75] No. 18-10500, 2020 WL 3467393, at *1 (11th Cir. June 25, 2020).
[76] *Id.* at *6.
[77] *Id.*
[78] *Id.* at *2.
[79] *Id.*
[80] *Id.* at *15.
[81] *Id.*
[82] *Id.* at *11-*12.
[83] *Id.* at *12.
[84] *Id.*
[85] No. 18-60746, 2020 WL 1887791, at *1, *3-4 (5th Cir. Apr. 15, 2020).
[86] *Id.* at *1.
[87] *Id.*

(even assuming for argument's sake that the relator's characterizations of those laws and regulations were correct), the Fifth Circuit emphasized that *Escobar* rejected that such broad provisions could be sufficient for FCA liability.[89] As the court in *Escobar* explained, "a misrepresentation cannot be deemed material merely because the [g]overnment designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment."[90] The Fifth Circuit also noted that even after learning that the defendant staffed care and case manager positions with licensed nurse practitioners instead of registered nurses, and even after the relator's complaint was unsealed, the government continued to pay claims and even renewed its contract with the defendant.[91]

UPDATE: VARYING OUTCOMES ON DOJ'S AUTHORITY TO DISMISS *QUI TAM* ACTIONS

As discussed in the Q1 2019 *Roundup*, there is a circuit split on whether the US Department of Justice (DOJ) has "unfettered discretion" or must satisfy the "rational relationship" test in order to dismiss *qui tam* actions. Two recent decisions have perpetuated the split.

First, the US District Court for the Eastern District of Pennsylvania declined to take a side in the circuit split in *Polansky v. Executive Health Resources, Inc.* Jesse Polansky filed a *qui tam* action against Executive Health Resources, Inc., a physician advisor company, alleging that it caused its client hospitals to fraudulently bill Medicare and Medicaid by falsely designating patient admissions as inpatient. The DOJ moved to dismiss, and the district court granted the motion. Acknowledging the circuit split, the district court stated that it "need not decide whether the *Sequoia* rational relationship standard or the *Swift* unfettered discretion standard applies, because under either the Government is entitled to dismissal."[92] The district court nevertheless applied the rational relationship test because it is "slightly more demanding."[93] Accordingly, the district court found that the government's decision to move for dismissal was properly based on its determination that the litigation burden was no longer justified and dismissal was rationally related because it would eliminate the burden. Polansky filed a notice of appeal with the US Court of Appeals for the Third Circuit on December 4, 2019.

Second, the Supreme Court of the United States rejected the opportunity to resolve the circuit split through *United States ex rel. Laurence Schneider v. JPMorgan Chase Bank National Association, et al.* Laurence Schneider initially filed the *qui tam* action in 2013 in the US District Court for the District of Columbia, alleging that the bank falsely claimed compliance with the 2012 National Mortgage Settlement. The DOJ moved to dismiss the action, and the district court granted the motion, citing the DOJ's "unfettered discretion."[94] The US Court of Appeals for the DC Circuit affirmed the dismissal, and Schneider filed a petition for a writ of *certiorari* with the Supreme Court. In his petition, Schneider argued that the Supreme Court should resolve the circuit split and require the DOJ to show that the dismissal served a valid governmental purpose. The DOJ argued in opposition that the dismissal met both standards. The DOJ also trivialized the circuit split,

[88] *Id.* at *4.
[89] *Id.*
[90] *Id.* (quoting *Escobar*, 136 S.Ct. at 2003).
[91] *Id.*

[92] *Polansky v. Executive Health Res., Inc.*, 12-CV-4239, 2019 WL 5790061, at *8 (E.D. Pa. Nov. 5, 2019). Citing *U.S. ex rel., Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998); *Swift v. United States*, 318 F.3d 250 (D.C. Cir. 2003).
[93] *Id.*

stating that "slight differences between the standards applied by the various courts of appeals should very rarely if ever be outcome-determinative." The Supreme Court denied the petition for a writ of *certiorari* on April 6, 2020.

[94] *United States ex rel. Laurence Schneider v. JPMorgan Chase Bank Nat'l Ass'n et al.*, No. 19-68, 2019 WL 1060876, at *3 (D.D.C. Mar. 6, 2019).

CONTRIBUTORS

JAMES CANNATTI
PARTNER
jcannatti@mwe.com
Tel + 1 202 756 8866

ANKUR GOEL
PARTNER
agoel@mwe.com
Tel + 1 202 756 8234

MICHAEL KIMBERLY
PARTNER
mkimberly@mwe.com
Tel + 1 202 756 8901

TONY MAIDA
PARTNER
Tmaida@mwe.com
Tel + 1 212 547 5492

LAURA MCLANE
PARTNER
lmclane@mwe.com
Tel + 1 617 535 4410

PAUL THOMPSON
PARTNER
pthompson@mwe.com
Tel + 1 202 756 8032

SARAH WALTERS
PARTNER
swalters@mwe.com
Tel + 1 617 535 4031

TED ALEXANDER
ASSOCIATE
talexander@mwe.com
Tel +1 202 756 8422

BRITTANY BELL
ASSOCIATE
bbell@mwe.com
Tel +1 212 547 5716

ADAM CAMIEL
ASSOCIATE
acamiel@mwe.com
Tel +1 617 535 4058

LAUREN EVANS
ASSOCIATE
levans@mwe.com
Tel +1 202 756 8864

GREG FOSHEIM
ASSOCIATE
gfosheim@mwe.com
Tel +1 312 984 7511

LAUREN KNIZNER
ASSOCIATE
lknizner@mwe.com
Tel +1 202 756 8252

CHRISTINA LAM
ASSOCIATE
clam@mwe.com
Tel +1 617 535 4073

SOPHIA LUBY
ASSOCIATE
sluby@mwe.com
Tel +1 202 756 8758

DREW ELIZABETH MCCORMICK
ASSOCIATE
dmccormick@mwe.com
Tel +1 617 535 4105

MARIKA MILLER
ASSOCIATE
mmiller@mwe.com
Tel +1 312 984 6977

RACHEL MOORE
ASSOCIATE
rmoore@mwe.com
Tel +1 202 756 8146

ANDREA OKORO
ASSOCIATE
aokoro@mwe.com
Tel +1 617 535 4067

CAROLINE REIGART
ASSOCIATE
creigart@mwe.com
Tel +1 202 756 8548

CATHY REN
ASSOCIATE
cren@mwe.com
Tel +1 310 788 4152

ANNABEL RODRIGUEZ
ASSOCIATE
arodriguez@mwe.com
Tel +1 617 535 4063

KATRINA ROGACHEVSKY
ASSOCIATE
krogachevsky@mwe.com
Tel +1 617 535 4006

WINNIE ULUOCHA
ASSOCIATE
wuluocha@mwe.com
Tel +1 312 984 2753

OFFICE LOCATIONS

ATLANTA
1372 Peachtree Street
Atlanta, GA 30309
USA
Tel +1 404 260 8535
Fax +1 404 393 5260

BOSTON
28 State Street
Boston, MA 02109-1775
USA
Tel +1 617 535 4000
Fax +1 617 535 3800

BRUSSELS
Avenue des Nerviens 9 - 31
1040 Brussels
Belgium
Tel +32 2 230 50 59
Fax +32 2 230 57 13

CHICAGO
444 West Lake Street
Chicago, IL 60606-0029
USA
Tel +1 312 372 2000
Fax +1 312 984 7700

DALLAS
2501 North Harwood Street
Suite 1900
Dallas, TX 75201-1664
USA
Tel +1 214 295 8000
Fax +1 972 232 3098

DÜSSELDORF
Stadttor 1
40219 Düsseldorf
Germany
Tel +49 211 30211 0
Fax +49 211 30211 555

FRANKFURT
Feldbergstraße 35
60323 Frankfurt a. M.
Germany
Tel +49 69 951145 0
Fax +49 69 271599 633

HOUSTON
Two Allen Center
1200 Smith Street
Suite 1600
Houston, TX 77002-4403
USA
Tel +1 713 653 1700
Fax +1 972 232 3098

LONDON
110 Bishopsgate
London
EC2N 4AY
Tel +44 20 7577 6900
Fax +44 20 7577 6950

LOS ANGELES
2049 Century Park East
Suite 3200
Los Angeles, CA 90067-3206
USA
Tel +1 310 277 4110
Fax +1 310 277 4730

MIAMI
333 SE 2nd Avenue
Suite 4500
Miami, FL 33131-2184
USA
Tel +1 305 358 3500
Fax +1 305 347 6500

MILAN
Via Dante 15
20123 Milan
Italy
Tel +39 02 36575701
Fax +39 02 36575757

MUNICH
Nymphenburger Str. 3
80335 Munich
Germany
Tel +49 89 12712 0
Fax +49 89 12712 111

NEW YORK
340 Madison Avenue
New York, NY 10173-1922
USA
Tel +1 212 547 5400
Fax +1 212 547 5444

ORANGE COUNTY
18565 Jamboree Road
Suite 250
Irvine, CA 92612-2532
USA
Tel +1 949 851 0633
Fax +1 949 851 9348

PARIS
23 rue de l'Université
75007 Paris
France
Tel +33 1 81 69 15 00
Fax +33 1 81 69 15 15

SAN FRANCISCO
415 Mission Street
Suite 5600
San Francisco, CA 94105-2533
USA
Tel +1 628 218 3800
Fax +1 628 218 3900

SILICON VALLEY
275 Middlefield Road
Suite 100
Menlo Park, CA 94025-4004
USA
Tel +1 650 815 7400
Fax +1 650 815 7401

WASHINGTON, DC
The McDermott Building
500 North Capitol Street, NW
Washington, DC 20001-1531
USA
Tel +1 202 756 8000
Fax +1 202 756 808

WILMINGTON
1007 North Orange Street
4th Floor
Wilmington, DE 19801
USA
Tel +1 202 756 8950
Fax +1 202 756 8087

mwe.com |