The Evolution of *Escobar* in 2017 and the False Claims Act in 2018 and Beyond

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- The False Claims Act
  - What Is It?
  - Why Does it Matter?
- The *Escobar* Decision
- The FCA, Post-*Escobar*
- What to Watch for in 2018
- Take-Aways

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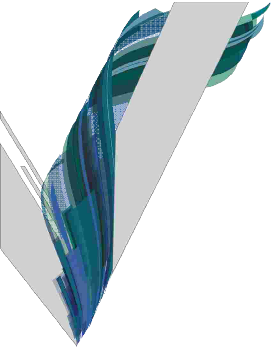
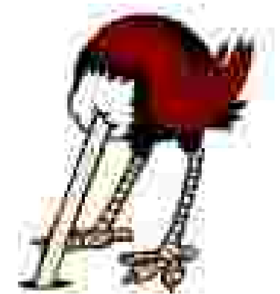


The False Claims Act

What Is It?

- **The Civil False Claims Act provides civil penalties for any person who:**
  - Knowingly presents (or conspires to present) a false or fraudulent claim for payment or approval to an officer or employee of the United States Government.
  - A claim is submitted "knowingly" when the claimant:
    - Has **<u>actual knowledge</u>** of the information;
    - Acts in **<u>deliberate ignorance</u>** of the truth or falsity of the information; or
    - Acts in **<u>reckless disregard</u>** of the truth or falsity of the information.
  - No specific intent to defraud required.
- ***Qui Tam****:* Creates a private right of action (*i.e.*, whistleblower).



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The Implied False Certification Theory

- “Implied false certification” is a theory of liability under the False Claims Act.
- Under this theory, compliance with federal, state, and local law is implied when the contractor delivers products or services. If a contractor submits a claim and omits that it has violated some provision of law, regulation, or contract, then it has made a misrepresentation, and, consequently, the claim is “false or fraudulent” under the False Claims Act.
- Prior to the *Escobar* decision, courts across the country had varied widely on how to determine which laws, regulations, or contract provisions are “material,” such that violating them would constitute fraud.
- Determining whether a statute, regulation, or contractual requirement is "material" was the primary subject of *Escobar*.

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- **Penalties:**
  - Civil penalty between $11,181 and $22,363 **per false claim**;
  - Three times the damages sustained by the government; and
  - The cost of any civil action brought.

- **Collateral Consequences:**
  - Termination of contracts;
  - Suspension and/or debarment.

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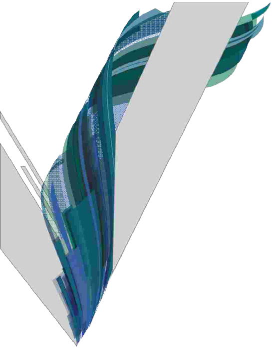
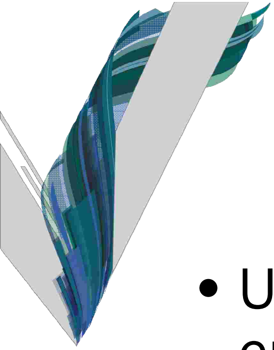


The False Claims Act

Why Does It Matter?



The False Claims Act
Why Does It Matter?

- U.S. Department of Justice statistics continue the trend of heavy enforcement:
- FY 2017
  - Total FCA recoveries → $3.7 billion
  - *Qui tam* recoveries account for $3.4 billion
  - Whistleblower recoveries → $392 million
- Since FY 2009, average approx. $4 billion
- Total recoveries since Jan. 2009 → $35 billion
  - *Qui tam* recoveries since 2009 → $27.8 billion
  - Whistleblower recoveries since 2009 → $3.8 billion

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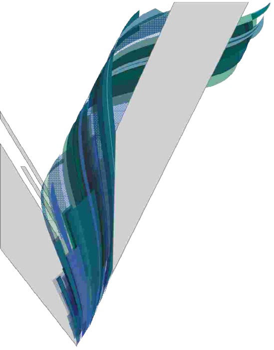
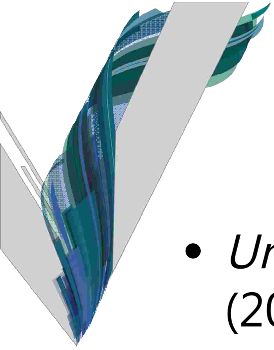


The *Escobar* Decision



The Facts of *Escobar*

- *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016)
- Arbour Counseling Services provided mental health counseling to Rivera, a Medicaid recipient.
- Arbour employees treated Rivera for mental health problems. Rivera had a fatal reaction to medication prescribed by Arbour.
- In obtaining National Provider Identification numbers for the purpose of making reimbursement claims under Medicaid, Arbour employees misrepresented their professional credentials.
- Rivera's parents learned of this and filed a *qui tam* lawsuit under the False Claims Act.

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- The District Court did not recognize the implied false certification theory because Arbour did not violate any provisions that were a specific condition to payment.

- The First Circuit disagreed with the District Court's reading of the False Claims Act.
  - It held that making a claim certifies compliance with express conditions of payment, but also with implicit conditions of payment.
  - Here, the Massachusetts Medicaid regulations listed adequate supervision as an "express and absolute" condition of payment.

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- The Supreme Court upheld the “implied certification” theory of liability under the False Claims Act.
  - “We first hold that the implied false certification theory can, at least in some circumstances, provide a basis for liability.”

- The Court found that claimants *can* be liable if they omit violations when submitting claims:
  - “When…a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided.”

- With respect to when the implied certification theory can be a basis for liability, the Court held that it can occur “at least where two conditions are satisfied”:
  - “[F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided”; and
  - “[S]econd, the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.”

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- However, for a recipient of federal funds to be liable under the False Claims Act, those requirements must be "material."

- Which provisions were "material" is the subject of the Court's analysis.
  - The Court repeatedly emphasized that:

    "Not every undisclosed violation of an express condition of payment automatically triggers liability; [and it is insufficient] for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance."
  - Materiality cannot be found where noncompliance is "minor or insubstantial."
  - The parties' course of conduct can be one way to determine which noncompliances are material. For example:

    "[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, 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."

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- The Supreme Court shifts the analysis from consideration of the conditions for payment within the contract to whether the misrepresentations themselves were *material* to the payment decision.

- The Supreme Court provided some guidance for determining "materiality."
  - The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."
  - "Under any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'"
  - An express condition of payment is relevant but not dispositive of materiality.
  - Minor breaches or noncompliance do not create materiality.
  - A violation is not material under the FCA solely because the federal government could have denied a claim if it had known of the misrepresentation.
  - Evidence for materiality can include prior practice.
  - If the federal government has previously refused claims for certain violations, those violations are likely material.
  - If the federal government has previously granted claims despite knowledge of a certain type of violation, then that violation is likely not material.

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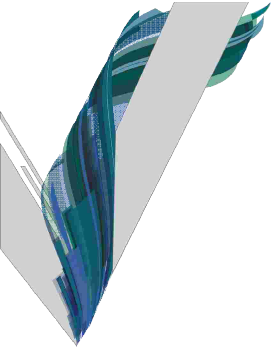

The FCA, Post-*Escobar*

The FCA, Post-*Escobar*

- The Government's decision to pay, despite actual knowledge of a noncompliance, was considered by the *Escobar* Court as a strong indicator of a requirement not being material.

- In the year and a half following *Escobar*, several U.S. Courts of Appeal examined this issue.

- ***U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017)**, *petition for cert. filed* (U.S. Feb. 5, 2018) (No. 17-1108), *docketed* (U.S. Feb. 7, 2018)

  – First Circuit found, in the context of its approval of medical devices, that the FDA "possesses a full array of tools for 'detecting, deterring, and punishing false statements made during . . . approval processes'" and that the FDA's decision "not to employ these tools in the wake of Relators' allegations so as to withdraw or even suspend its approval of the . . . device leaves Relators with a break in the causal chain between the alleged misstatements and the payment of any false claim."
  – Court stated that the FDA's decision not to act "renders a claim of materiality implausible."
  – Quoting the "very strong evidence" language from *Escobar* regarding the Government's continued payment, the First Circuit found compelling that "the FDA allowed the device to remain on the market" despite the Relators' allegations.
  – The First Circuit relied heavily on its decision in *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016), from late 2016 that also focused on Government payment despite full knowledge of violations of requirements.

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- ***U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017)**
  - Relator alleged that Genentech concealed information about a cancer drug's health risks.
  - The Third Circuit affirmed the district court's dismissal, finding that an alleged misrepresentation is not material "when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance."
- ***U.S. ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746 (3d Cir. 2017)**
  - Affirmed the district court's summary judgment in favor of the defendant.
  - The Third Circuit concluded that the claims were not material because the Centers for Medicare & Medicaid ("CMS") specifically knew of the violations at issue (use of dummy identification numbers) and routinely paid despite the use of the dummy numbers.

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The FCA, Post-*Escobar* (cont'd)

- ***Abbott v. BP Exploration & Production*, 851 F.3d 384 (5th Cir. 2017)**
  - Plaintiffs asserted that BP falsely certified compliance with various regulatory requirements with respect to an oil platform in the Gulf of Mexico.
  - In response, the Department of the Interior ("DOI") conducted a full investigation, finding that the allegations were without merit and that no grounds existed to suspend operations on the platform.
  - The Fifth Circuit affirmed in favor of BP, concluding:

    "As recognized in *Escobar*, when the DOI decided to allow…continue[d] drilling after a substantial investigation into Plaintiffs' allegations, that decision represents 'strong evidence' that the requirements in those regulations are not material."

- ***U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645 (5th Cir. 2017)**, *petition for cert. filed* (U.S. Feb. 12, 2018) (No. 17-1149), *docketed* (U.S. Feb. 16, 2018)
  - The Federal Highway Administration ("FHWA") approved defendant's guardrail end terminals and found them eligible for reimbursement despite a flawed crash test report sent to FHWA that had inadvertent omissions about design changes.
  - The Fifth Circuit reasoned that, "though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality."
  - The Fifth Circuit emphasized FHWA's explicit approval of the end terminals and insistence that the changes made did not affect its decision to purchase the end terminals.

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- ***U.S. ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017)**
  - The Ninth Circuit affirmed a district court's grant of summary judgment in favor of the defendant, in part relying on the fact that the Department of Homeland Security ("DHS") knew of the defendant's cost tracking system, approved it, and paid for the work provided.

- ***U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017)**
  - The D.C. Circuit affirmed the district court's grant of summary judgment in favor of the defendant because it found no materiality with respect to violations of requirements through the maintenance of inflated headcounts at U.S. Army recreation centers.
  - The Court relied on the fact that "the DCAA investigated [the] allegations and did not disallow any charged costs" and "KBR continued to receive an award fee for exceptional performance…even after the Government learned of the allegations."
  - The D.C. Circuit found that this was "'very strong evidence' that the requirements allegedly violated by the maintenance of inflated headcounts are not material."

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- Notwithstanding these Circuit Court decisions, as alluded to by the Fifth Circuit in *U.S. ex rel. Harman v. Trinity Industries Inc.*, **the government's decision to pay is not dispositive**.
- The Ninth Circuit made this a reality in ***U.S. ex rel. Campie v. Gilead Sciences, Inc.*****, 862 F.3d 890 (9th Cir. 2017)**, *petition for cert. filed* (U.S. Dec. 26, 2017) (No. 17-936), *docketed* (U.S. Jan. 3, 2018).
  - Gilead Sciences represented in its new drug applications ("NDAs") to the Food and Drug Administration ("FDA") that it would source an ingredient for its drugs from registered facilities in Canada, Germany, the United States, and South Korea, but instead sourced from a Chinese facility.
  - The relators asserted that Gilead had been inserting products from the Chinese facility into its finished drugs for at least two years before it sought approval from the FDA to do so.
  - Relators alleged that "because the drugs paid for by the government contained [an ingredient] sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs."
  - Gilead argued that the continued FDA approval of and payment for the drugs after the FDA knew of the noncompliance made the violations not material to its payment decision.
  - The Ninth Circuit disagreed:

    "It is undisputed that at all times relevant, the drugs at issue were FDA-approved, and that the government continues to make direct payments and provide reimbursements for the sale of the three drugs. Relators thus face an uphill battle in alleging materiality sufficient to maintain their claims."

The FCA, Post-*Escobar* (cont'd)

- ***U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017)** (continued)
  - Despite these statements, the Ninth Circuit instead found persuasive plaintiffs' argument that one should not "read too much into the FDA's continued approval—and its effect on the government's payment decision," for several reasons:
    - "First, to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud."
    - "Second, as argued by Gilead itself, there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs."
    - "Third, unlike *Kelly*, where the government continued to accept noncompliant vouchers, Gilead ultimately stopped using [the ingredient] from [the Chinese facility]. Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance."
  - Relevant to the Ninth Circuit's conclusion was the fact that it was disputed, and there was no evidence before the court, whether and when the FDA had actual knowledge of the violations. Therefore, the Ninth Circuit found that the relators had sufficiently pled materiality and reversed the district court's dismissal of the claims.

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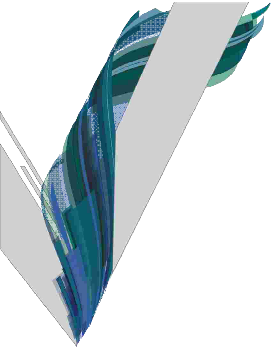

What to Watch for in 2018 and Beyond

The FCA in 2018 and Beyond

- ***U.S. ex rel. Campie v. Gilead Sciences, Inc.*** – Gilead Sciences petitioned the Court to grant certiorari.
  - Gilead contends that the Ninth Circuit misapplied the *Escobar* materiality standard by requiring defendants "to show immateriality, even where the government continued to make purchases."
  - The Ninth Circuit had revived this whistleblower action, citing a dispute between the relators and the defendant about "exactly what the government knew and when," making it unclear whether the Government's acquiescence through continued payments was made knowing Gilead was in noncompliance.
  - In *Gilead*, relators claimed Gilead's requests for payment for FDA-approved drugs impliedly certified that Gilead's drugs were manufactured at approved facilities and not adulterated, when in fact the drugs were not.
  - Though Gilead countered that under *Escobar* the Government's continued payment despite knowledge of the violation demonstrated the violations were not material, the Ninth Circuit decided that the issue raised by the parties was a matter of proof, not law.
  - Gilead's petition has been joined by multiple third parties, including the U.S. Chamber of Commerce, the Coalition for Government Procurement, and others.
  - On April 16, 2018, the Supreme Court issued a one-line opinion inviting the Solicitor General of the United States to "file briefs in this case expressing the views of the United States," which may indicate that the Supreme Court will take up this issue.

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The FCA in 2018 and Beyond (cont'd)

- Another case to follow is ***Rose v. Stephens Institute*, No. 09-CV-05966-PJH, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016)**
  - The relator claims defendant defrauded the U.S. Department of Education ("DOE") by falsely alleging compliance with Title IV of the Higher Education Act.
  - While defendant argued that DOE knew of the violation but continued to make payments, indicating the violation was not material, the district court found that "the DOE's decision to not take action against AAU despite its awareness of the allegations in this case is not terribly relevant to materiality."
  - The district court relied in part on a pre-*Escobar* decision that found compliance with the Title IV requirement at issue was determined to be material.
  - Following the district court's decision, the defendant moved to certify the court's order for interlocutory appeal and oral arguments were held on December 6, 2017.
  - During oral arguments, Judge Graber of the Ninth Circuit commented that there could be many reasons that the Government pays a claim despite knowledge of a violation, and thus Government acquiescence should not be dispositive.
  - Whether or not this comment—or some iteration of it—works its way into a final decision will be of interest as it is a departure from other Circuits who have viewed continued acquiescence as proof of immateriality.
  - The comment, however, harkens back to the Ninth Circuit's decision in *Campie* in which the court stated that "there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs."
  - Will the Ninth Circuit follow the same path in *Rose* as it did in *Campie*?

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The FCA in 2018 and Beyond (cont'd)

- In a recent decision, a district court granted judgment as a matter of law for the defendants for relator's failure to offer proof of materiality and vacated a $350 million jury verdict for the relator.
  - In ***Ruckh v. Salus Rehabiliation, LLC*, No. 8:11-CV-1303-T-23TBM, 2018 WL 375720 (M.D. Fla. Jan. 11, 2018)**, the relator claimed that the defendants filed false claims against the Government by failing to maintain a "comprehensive care plan" as required by Medicaid regulations and by submitting unsigned and undated documents for reimbursement by Medicare.
  - According to the court, however, the relator failed to demonstrate that the Government would have considered either violation material, especially in light of the Government's knowledge of the violations.
  - More importantly, the decision describes *Escobar*'s materiality standard as one that "rejects a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely—multiplied by three—because of some immaterial contractual or regulatory non-compliance."
  - On January 12, 2018, the relator filed an emergency motion for injunction pending appeal to the Eleventh Circuit.

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- Though the Eleventh Circuit has not yet wrestled with the materiality standard under *Escobar*, it did recently revive a pre-*Escobar* whistleblower suit relating to the sale of helicopters under the U.S. foreign military sale ("FMS") program in ***United States ex rel. Marsteller et al. v. Tilton et al.*, 880 F.3d 1302 (11th Cir. 2018)**.
  - The relators alleged that improprieties in the relationship between a U.S. Army procurement official and several military contractors required that the defendants disclose the relationship under FAR 52.203-13, Contractor Code of Business Ethics and Conduct, and the Truth in Negotiations Act, 10 U.S.C. § 2306a.
  - The district court had dismissed relators' claims because none of the contracts in question required compliance with either requirement as an express condition of payment.
  - In reviving the suit, the Eleventh Circuit noted an express condition of payment is no longer dispositive and directed the district court to analyze the allegations under the *Escobar* materiality standard—specifically, whether the alleged violations were "garden-variety breaches" or not.

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The FCA in 2018 and Beyond (cont'd)

- Also impacting the FCA this year and into the foreseeable future has been several positions taken by the Department of Justice when it comes to FCA enforcement.

- Two related memos, issued on November 16, 2017 and January 25, 2018.
  - The first, issued by Attorney General Sessions, prohibits DOJ components from issuing guidance documents that purport to create rights or obligations without such guidance first undergoing the notice-and-comment rulemaking process.
    - As it relates to FCA compliance, this memorandum prohibits DOJ from using these guidance documents to force regulated parties into taking action or refraining from taking action based on applicable statutes or lawful regulation.
  - The Brand memorandum plays off of the Sessions memo by stating that the "principles from the [Sessions memo] are relevant to more than just [DOJ's] own publication of guidance documents [and] also should guide [DOJ] litigators in determining the legal relevance of other agencies' guidance documents in affirmative civil enforcement."

- What this means in practice is that DOJ attorneys should not be imposing guidance documents as establishing binding rules from which to predicate civil enforcement actions.

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The FCA in 2018 and Beyond (cont'd)

- In addition to these Sessions and Brand Memos, on January 10, 2018, Michael Granston, Director of the Commercial Litigation Branch of DOJ's Fraud Section, issued a memorandum explaining that due, in part, to the record number of *qui tam* cases filed in recent years, Department attorneys, when evaluating whether to intervene in a *qui tam* action, should also consider whether the government should seek to dismiss the case altogether.

- Granston explained that this approach is needed because of the resources required to monitor these cases, even those where the Government does not intervene, and the potential for adverse decisions stemming from such cases that could impact the Government's ability to enforce the FCA.

- As a result, Granston lays out a non-exhaustive list of seven factors that DOJ attorneys can use as a basis for dismissal:
  - Curbing meritless *qui tam* cases;
  - Preventing parasitic or opportunistic *qui tam* actions;
  - Preventing interference with agency policies and programs;
  - Controlling litigation brought on behalf of the United States;
  - Safeguarding classified information and national security interests;
  - Preserving Government resources; and
  - Addressing egregious procedural errors.

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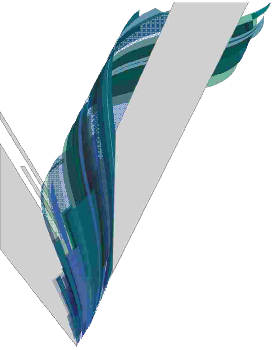
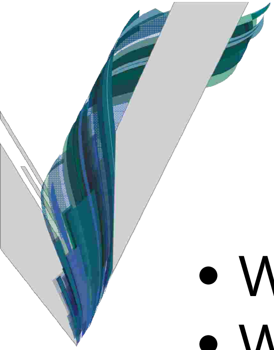


Take-Aways



What Does All of This Mean to Me?

- What federal contracts or grants do we have?
- What triggers payment?
- What else would I consider to be the material provisions of the contract/grant?
- What would my federal partner consider to be the material provisions of the contract/grant?
- What do I do that impacts the material provisions to the contract/grant?
- How can I best ensure compliance with these provisions?
- How can I document compliance with these provisions?

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- Federal Acquisition Regulation clauses applicable to federal contracts, including:
  - Size representations
  - Pricing (*i.e.*, GSA PRC violations)
  - Time reporting
  - Labor qualifications
  - OCI provisions
  - Cost representations
  - Domestic preference compliances (*e.g.*, BAA, TAA, etc.)

- Uniform Guidance Clauses applicable to the grant, including:
  - OCI provisions?
  - Reporting provisions?
  - Procurement provisions?
  - Women- and minority-owned business provisions?

- Company policies and procedures, including:
  - Code of conduct?
  - Timekeeping policies?
  - Subcontract/subgrant monitoring and vetting?

- Laws in other countries
  - Labor laws?
  - Required permits?

- Agency Guidance
  - HUD guidance related to housing programs?
  - Training requirements?

- Statutory Requirements, for example:
  - Stafford Act requirements?
  - Affordable Care Act requirements?

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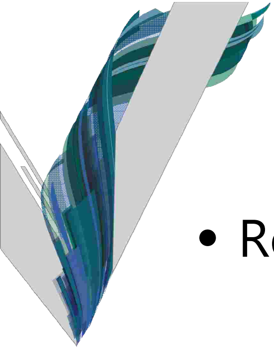

What to Do?

- Review your certification process.
  - Who will be charged with ensuring that the company is up to date on its certification requirements? Are they the right people?
  - What representations are you making, and how could they be wrong, particularly as they relate to the core contract provisions?
- Maintain a written dialogue with your Government customer.
- Develop a plan for potential noncompliance.
- Assess your weaknesses.
  - What are the red flags in your industry?
  - What issues have emerged from audit findings in the past?
  - Revisit your ethics and compliance program on an annual basis.

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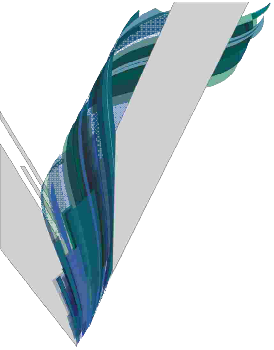

Questions?

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Next Month's Government Contracts Webinar:

Government Cost Audits and Claims

Wednesday, May 30, 2018
12:00pm-1:30pm ET

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