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an interview with Ryan Meade
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by Michael A. Morse, Esq.

2016 False Claims Act review: A truly extraordinary year

» Since 1986, the federal FCA has been used by the government and whistleblowers to recover more than $31 billion in taxpayer funds from healthcare-related cases.

» In 2016, some of the major healthcare-related recoveries were in the areas of skilled nursing, home health, medical necessity, kickbacks, hospital admissions, and extended stays.

» The U.S. Supreme Court's decision in *UHS v. Escobar* will play a prominent role in future healthcare-related FCA cases.

» The use of statistical sampling as evidence in FCA cases continues to be a major battlefront, and major new court decisions are expected in 2017.

» As of August 1, 2016, the mandatory civil monetary penalties for each violation of the FCA nearly doubled.

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As we head into the second quarter of an already turbulent 2017, it is worth reflecting on the truly extraordinary events of 2016. Of course, there was the hotly-contested, historic election in November, which may usher in sweeping changes to our nation's healthcare system. Although the potential impact of these future changes remains to be seen, one thing is clear: 2016 was an extraordinary year for all those who work in healthcare compliance. In particular, 2016 was a truly historic year for the federal False Claims Act (FCA), and one that should be carefully reviewed by the entire healthcare compliance community.

2016: The FCA's "pearl" anniversary

This year the FCA celebrated a historic milestone, marking the passage of 30 years since the *qui tam* whistleblower provisions were added by Congress in 1986. During that time, the FCA has become widely-recognized as the government's most potent weapon to combat fraud, waste, and abuse involving taxpayer funds. Since 1986, the government has recovered more than $48 billion in FCA cases, $31 billion of which came from healthcare-related cases.[1] Of the $31 billion in healthcare recoveries, $25 billion came from cases filed by whistleblowers, and whistleblowers received more than $3.6 billion in awards for reporting the fraud. Since 1986, there have been more than 6,100 whistleblower cases related to healthcare filed under the FCA.

Morse

Senator Charles Grassley (R-IA), one of the principle architects of the 1986 FCA amendments, recognized the 30-year milestone by commenting that: "Thirty years' worth of recoveries shows that we did the right thing. The False Claims Act is, hands down, the most effective tool the government has to fight fraud against the taxpayers."[2] Senator Grassley's staunch support of the FCA is important to note, as he

was just re-elected to his seventh term, and he serves as the Chairman of the Senate Judiciary Committee. With Senator Grassley at the helm, there is every reason to believe that FCA will remain an important part of the government's fraud-fighting arsenal for years to come.

2016: Major FCA recoveries continue in healthcare

This past year, however, was not extraordinary simply due to the 30-year anniversary of the 1986 FCA amendments. The government continued its trend of using the FCA to make substantial recoveries for taxpayers in healthcare-related cases. Although the Department of Justice has yet to release its final statistics for fiscal year 2016, recoveries associated with FCA cases resolved in 2016 total over $4.7 billion. The larger recoveries in healthcare in 2016 include:

- In January 2016, Kindred/Rehabcare, the nation's largest nursing home therapy provider, agreed to pay $125 million to resolve FCA allegations that they caused skilled nursing facility customers to submit claims for medically unnecessary services or services not provided.
- In February 2016, 51 hospitals in 15 states agreed to pay $23.75 million to resolve FCA allegations related to the implant of cardiac devices in Medicare patients in violation of coverage requirements.
- In March 2016, Olympus Corp. of the Americas, the nation's largest distributor of endoscopes, agreed to pay $632.2 million to resolve criminal and FCA allegations related to a scheme to pay kickbacks to doctors and hospitals. Those kickbacks included consulting payments, foreign travel, lavish meals, millions of dollars in grants, and free endoscopes.
- In May 2016, Pfizer/Wyeth agreed to pay $785 million to resolve FCA allegations that they failed to report discounts to Medicaid that they were offering to hospitals for two of their stomach acid reducing drugs, Protonix IV and Protonix Oral.
- In September 2016, Vibra Healthcare LLC, a national hospital chain, agreed to pay $32.7 million to resolve FCA allegations related to admissions and extended stays that were not medically necessary.
- In October 2016, Tenet Healthcare, and two of its Atlanta-area subsidiaries agreed to pay $513 million to resolve criminal and FCA allegations related to the payment of kickbacks in exchange for patient referrals.
- In October 2016, Life Care Centers of America Inc., agreed to pay $145 million to resolve an FCA suit alleging that they caused skilled nursing facilities to submit Medicare and TRICARE claims for rehabilitation services that were not reasonable, necessary, or skilled.[3]

These significant recoveries in 2016 demonstrate that the government and *qui tam* whistleblowers continue to use the FCA against a diverse set of healthcare entities, and for a wide-variety of improper practices. Based on the record over the past 30 years, the recoveries in 2016 are no anomaly, and the FCA should continue to net the government and whistleblowers substantial recoveries in 2017 and beyond.

2016: Major FCA court decisions

This past year also saw significant FCA decisions from the U.S. Supreme Court and a number of federal Courts of Appeals. These decisions have the potential to impact the FCA, and healthcare FCA cases in particular, for years-to-come. Paying careful

attention to these decisions, and the lessons they provide, is essential for all healthcare compliance professionals.

Universal Health Services v. Escobar

In June, the United States Supreme Court issued a unanimous decision recognizing that the FCA may be violated when a claim is submitted to the government that impliedly certifies compliance with an underlying government statute, regulation, or contractual requirement that is material to the government's decision to pay that claim.[4] The Court emphasized that the materiality standard is "demanding," and looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation. The Court emphasized the government's decision to expressly identify a requirement as a condition of payment is relevant, but does not automatically prove materiality. Significantly, the Court added that "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."

There is little dispute that the *Escobar* decision will play a prominent role in future FCA cases. Already, the meaning and impact of *Escobar*, most notably determining the level of proof required to establish materiality, has been hotly contested in federal Courts of Appeals and District Courts. For example, on November 22, 2016, the First Circuit ruled that "courts are to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive.[5]" If other federal courts follow suit, the standard for materiality, and whether the allegations/evidence in a particular case establish materiality, will remain a core litigation issue in future healthcare FCA cases, as many are based on the implied certification theory. Healthcare compliance professionals should watch closely in the future as courts and litigants continue to wrestle, the wake of *Escobar*, with the issue of which statutes, regulations, or contractual requirements are material to the government's decision to pay healthcare claims.

Statistical sampling disputes

For several years, there has been a growing debate in the federal courts about the use of statistical sampling in FCA cases to prove both liability and damages. The government and whistleblowers argue that statistical sampling has been accepted in a wide-variety of cases, including criminal cases, to prove liability and damages in cases where there are simply too many fraudulent claims to prove on a claim-by-claim basis. Defendants have often countered that, because the FCA involves allegations of fraudulent claims and can trigger treble damages and civil fines, the government and/or whistleblower should not be permitted to use statistical sampling as a shortcut for claim-by-claim proof. Federal courts have reached conflicting decisions as to whether, and to what extent, to allow the use of statistical sampling in FCA cases. That debate continued in 2016, and will likely remain for years to come.

In 2014, a federal district court in Tennessee, in a case against Life Care Centers, opened the door to the use of statistical sampling to both calculate damages and to establish the underlying FCA violation.[6] By contrast, in 2015, a federal district court in South Carolina, in a case against Agape Senior Communities, ruled that statistical sampling evidence isn't allowed under the FCA unless it is "the only way" for the government or relators to prove their allegations.[7] The *Agape* decision is presently on appeal before the Fourth Circuit Court

of Appeals, which just heard oral argument in the case at the end of October. On February 14, 2017, the Fourth Circuit issued its opinion in *Agape* and surprised many by side-stepping the issue of the use of statistical sampling in FCA cases. Instead, the Court of Appeals affirmed the district court's decision on unrelated grounds. Additionally, in early October, the Third Circuit Court of Appeals allowed FCA allegations that were based on statistical sampling to proceed to discovery despite the Court's "skepticism" about the validity of the sampling methodology.[8] Because of the important role that statistical sampling plays in FCA cases involving allegations of nationwide fraud or fraud involving thousands of claims, the continuing debate playing out in federal courts in 2016 and early 2017 should be closely watched.

Medicare Advantage and "blind coding"

In August 2016, the Ninth Circuit Court of Appeals, in the case of *U.S. ex rel. Swoben v. United Healthcare Insurance Company et al.*, reinstated a *qui tam* case alleging that various Medicare Advantage (MA) organizations violated the FCA by using biased review procedures designed to avoid identifying erroneously reported diagnosis codes.[9] The defendants were alleged to have conducted retrospective medical record reviews designed to identify only diagnosis codes that would trigger additional payments by CMS, and that they concealed previously submitted diagnosis codes from coders conducting the retrospective reviews (a practice known as "blind coding"). The Court stated that when MA organizations:

> design retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with reasonable diligence, they can no longer certify, based on best knowledge, information, and belief, the accuracy, completeness and truthfulness of the data submitted to CMS.

The Court, however, cautioned that blind coding is not "necessarily a suspect practice," but that it "cannot be squared with the good faith required [] when it is employed as a means of avoiding or concealing overreporting errors." This decision could have a potential impact throughout government-funded risk-adjusted health programs, where retrospective reviews of medical records are common.

Public disclosure bar

In 2016, nine different Courts of Appeals issued decisions regarding the FCA's "public disclosure bar," which in certain circumstances requires courts to dismiss FCA claims that are substantially similar to information previously disclosed in several specified public sources, unless the whistleblower qualifies as an "original source" of the information.[10] Although these decisions cover a variety of legal and factual issues, it bears noting that federal courts focused substantial effort in 2016 on defining the legal parameters of the public disclosure bar, an issue which frequently arises in *qui tam* whistleblower cases. As a practical matter, however, public disclosure issues arise primarily in litigation and do not typically involve the day-to-day work of healthcare compliance professionals.

2016: Increased civil monetary penalties for FCA violations

As of August 1, 2016, the mandatory civil monetary penalty for each violation of the FCA increased to $10,781 – $21,563. This increase, the first since 1986, represents a near doubling of the previous

civil monetary penalty amounts under the FCA. It remains to be seen whether this increase will re-ignite old arguments about whether the FCA imposes excessive fines in violation of the United States Constitution.

2017: Change may be on the horizon, but the FCA will endure

Although 2016 was a year dominated by historic milestones and recoveries under the FCA, 2017 looks to be a year of transition. As a result of the 2016 election, there will be new leadership at the Department of Health & Human Services, the Centers for Medicare & Medicaid Services, and the Department of Justice. New leadership is also expected in nearly every one of the 94 United States Attorney's Offices that are responsible for investigating and prosecuting FCA cases on behalf of the government. Additionally, legislative, regulatory, and policy changes are anticipated for both the Medicare and Medicaid programs. Despite these significant transitions, the FCA should continue to endure in 2017 as a powerful force in the world of healthcare compliance. However, the battle lines drawn in 2016 by the *Escobar* decision and the continuing debate on statistical sampling should continue to capture the focus of the healthcare compliance community in 2017.

1. U.S. Department of Justice: Fraud Statistics – Overview. November 23, 2015. Available at http://bit.ly/2kJrptj
2. Chuck Grassley: "Grassley: False Claims Act is Our Most Important Tool to Fight Fraud against Taxpayers" April 28, 2016. Available at http://bit.ly/2m9Pw1e
3. Department of Justice website: 2016 FCA settlements can be found by searching keywords at http://bit.ly/2mjqf4a.
4. 136 S.Ct. 1989 (June 16, 2016).
5. 2016 WL 6872650 (1st Cir. Nov. 22, 2016).
6. 2014 WL 10937088 (E.D.Tenn. Sept. 29, 2014).
7. 2015 WL 3903675 (D.S.C. June 25, 2015).
8. 839 F.3d 242 (Oct. 5, 2016)
9. 832 F.3d 1084 (9th Cir. Aug. 10, 2016).
10. 31 U.S.C. § 3730(e)(4).