

**HEALTHCARE ENFORCEMENT  
COMPLIANCE INSTITUTE**

**W2 MANAGED CARE FRAUD  
ENFORCEMENT & COMPLIANCE**

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**AGENDA**

- Recent False Claims Act enforcement trends affecting managed care organizations
- Navigating regulatory challenges in a managed care environment
- Role of an SIU (or Compliance Department) in managed care

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**Overview**

- Managed Care Overview
- Regulatory Landscape
  - ❖ Federal
  - ❖ State
- Enforcement Mechanisms
- Compliance Program Effectiveness
  - ❖ Providers
  - ❖ Managed Care Organizations (MCOs)

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### False Claims Act Recoveries in 2016

- The Department of Justice (DOJ) announced that in fiscal year 2016, it recovered more than \$4.7 billion in settlements and judgments involving fraud and false claims.
- \$2.5 billion came from claims related to the healthcare industry.
- The number of DOJ-initiated healthcare False Claims Act (FCA) actions jumped from 26, in fiscal year 2015, to 69, in fiscal year 2016.
- On August 1, 2016, the per claim penalties under the FCA increased from \$5,500-\$11,000 to \$10,781-\$21,563.

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### False Claims Act Recoveries in 2016

DATE	ENTITY	FALSE CLAIMS ACT ALLEGATIONS	RECOVERY AMOUNT
January 12, 2016	Kindred Healthcare Inc.	Kindred was providing more therapy than the treating therapists thought necessary, and also providing therapy that was not supported by the conditions of the patients.	\$125 million
March 1, 2016	Olympus Corporation of Americas	Olympus had paid millions in kickbacks such as, consulting payments, foreign travel, lavish meals, grants and free endoscopes, in order to induce doctors and hospital executives to buy its endoscopes and other surgical equipment.	\$623.2 million (\$10.8 million civil) (\$12.4 million criminal)
April 27, 2016	Wyeth Pfizer, Inc.	Wyeth (Pfizer had not yet acquired it) knowingly reported to the government false and fraudulent prices on two of its proton pump inhibitor (PPI) drugs. Specifically, the allegations were that Wyeth hid from Medicaid the bundled discounts that they gave to hospitals on the PPI drugs. This led to Wyeth wrongfully avoiding payment of hundreds of millions of dollars in rebates to Medicaid for a five-year period.	\$784.6 million
June 6, 2016	Genentech Inc. and OSI Pharmaceuticals LLC	Genentech and OSI Pharmaceuticals were accused of making false or misleading statements to healthcare providers regarding the effectiveness of a cancer drug, which was promoted by both of the companies.	\$67 million
July 13, 2016	Evercare Hospice and Palliative Care	Evercare was accused of discouraging doctors from recommending the discharge of ineligible patients, that were not terminally ill, from hospice. An additional allegation was that nurses were not being accurate in their recordation practices of the ineligible patients' condition.	\$18 million

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### False Claims Act Recoveries in 2016

DATE	ENTITY	FALSE CLAIMS ACT ALLEGATIONS	RECOVERY AMOUNT
September 28, 2016	Vibra Healthcare	Vibra was alleged to be ignoring the recommendations of their own clinicians and admitting patients into their long term care facilities that did not qualify for admission.	\$32.7 million
October 3, 2016	Tenet Healthcare Corporation	Tenet was alleged to have schemed to defraud the government and pay kickbacks in exchange for patient referrals. Specific allegations were of bribes and kickbacks to the owners and operators of prenatal care clinics in return for the referral of those patients for labor and delivery services. Also alleged, was that Tenet gave the patients the false belief that they had no other choice of hospitals, saying Medicaid would only cover their services at Tenet.	\$368 million (civil) \$145 million (criminal)
October 17, 2016	Omnicare, Inc.	Omnicare was alleged to have solicited and received kickbacks in the form of things such as, grants, or tickets to sporting events etc... from Abbott Laboratories in exchange for Omnicare promoting one of their drugs to nursing home patients. There were also allegations of a rebate scheme from Abbott to Omnicare based on the amount of nursing home residents Omnicare had using the drug in question.	\$28.125 million
October 24, 2016	Life Care Centers of America Inc.	LifeCare had policies and procedures in place to keep as many patients as possible (in their skilled nursing facilities) on the highest level of therapy. The did this for durations longer than the therapists thought necessary and with no regard for the clinical need for the services.	\$145 million

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## False Claims Act Cases in 2016

### Implied False Certification Theory of Liability

*Universal Health Services v. United States ex rel. Escobar*,  
136 S. Ct. 1989 (2016)

The Supreme Court unanimously upheld the "implied certification" theory of liability in some circumstances, holding that liability can attach if the defendant submits a claim for payment that makes "specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement."

The Court limited liability, to circumstances in which the defendant knows that its non-compliance "is material to the Government's payment decision."

The Court emphasized that materiality is a "rigorous" and "demanding" standard, one that cannot be met if "noncompliance is minor or insubstantial."

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## False Claims Act Cases in 2016

### Public Disclosure

*United States ex rel. Winkelman v. CVS Caremark Corp.*,  
827 F.3d 201 (1st Cir. 2016)

The court considered whether the relators' complaint survived the public disclosure bar based on the original source exception.

The court held that the relators were not original sources because they offered no new information materially adding to what previously appeared in public disclosures.

To determine what analysis is used to find what constitutes a material addition was based, in part, on the Supreme Court's recent discussion in *Escobar* of what constitutes materiality under the implied certification liability theory.

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## False Claims Act Cases in 2016

### Knowledge/Scienter Requirement

*United States ex rel. Swoben v. United Healthcare Ins. Co.*,  
832 F.3d 1084 (9th Cir. 2016)

This case involved allegations of Medicare Advantage (MA) organizations reporting skewed data in order to increase capitated payments from the Centers for Medicare and Medicaid. The steps allegedly taken by the MA organizations, if true, rendered their certifications of accurate data false.

Three reasons were given for why the MA organization knew their certifications were false:

- (1) they helped design a template that would not capture disadvantageous errors;
- (2) they were on notice from risk adjustment data validation (RADV) audits that their reported data had a 20% error rate; and
- (3) designed retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted codes that might have otherwise been identified with the diligence required by the applicable regulations.

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## False Claims Act Cases in 2016

### Knowledge/Scienter Requirement (cont.)

*United States ex rel. Swoben v. United Healthcare Ins. Co., 832 F.3d 1084 (9th Cir. 2016)*

The MA organizations argued that their conduct represented an objectively reasonable interpretation of their diligence obligations.

The court disagreed and stated that actual knowledge of any specific unsupported diagnosis codes was not necessary for the finding of the requisite scienter requirement.

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## False Claims Act Cases in 2016

### Pleading Requirements Under Fed. R. Civ. P. 9(b)

*United States ex rel. Eberhard v. Physicians Choice Lab. Servs., LLC, 642 F. App'x 547, 548 (6th Cir. 2016)*

An employee who brought an FCA suit against his former employer failed to satisfy Fed. R. Civ. P. 9(b) because he did not allege the presentation of a specific claim to the government.

The employee was not entitled to relaxation of the Rule 9(b) standard because he did not allege any personal knowledge or any specifics of his employer's submission of Medicare and Medicaid claims, nor did the complaint otherwise provide particular facts, such as times, dates, etc., supporting a strong inference that a false claim was presented to the government.

The court acknowledged that in some limited instances there may be a relaxed pleading standard but declined to find such a situation here.

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## False Claims Act Cases in 2016

### Pleading Requirements Under Fed. R. Civ. P. 9(b) (cont.)

*United States ex rel. Prather v. Brookdale Senior Living Cmty., Inc., 838 F.3d 750, 754 (6th Cir. 2016)*

This case created an exception to the FCA's requirements that specific examples of false claim submission must exist.

The requirement that a relator identify an actual false claim may be relaxed when, even though the relator is unable to produce an actual billing or invoice, he or she has pled facts which support a strong inference that a claim was submitted. The exception could be applied when a relator alleges specific personal knowledge that relates directly to billing practices, as was done here.

The court held that the relator had personal knowledge of the allegations and had given detail that supported a strong inference that false claims had been submitted and therefore her allegations were deemed sufficient under the FCA pleading standard.

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## False Claims Act Cases in 2016

### Elimination of Presentment Requirement

*United States ex rel. Garbe v. Kmart Corp.*,  
824 F.3d 632 (7th Cir. 2016), cert. denied, 2017 WL 69207 (Jan. 9, 2017)

The court held that even if a intermediary or private entity has not directly sought payment from the government, the amendments to the presentment requirements under the Fraud Enforcement Recovery Act of 2009, (FERA) allow suits to go forward against them.

The relator is only required to demonstrate that the entity (public or private) was implementing a government program or using government funds.

This decision brings intermediaries and private entities that use government funds or implement government programs within the reach of the FCA, possibly resulting in a significant expansion of FCA liability.

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## FCA Enforcement Trends

Tweeting about this conference?

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## Enforcement in the News: Government Inquiries

### U.S. probing insurers beyond UnitedHealth over Medicare charges

By Reuters  
11/16/16 10:45 AM EST

March 17 (Reuters) - The U.S. Justice Department disclosed it is investigating four health insurers after a lawsuit accused them of defrauding Medicare by claiming patients were treated for conditions they either did not have or received no treatment for.

The Justice Department revealed the probe of Health Net Inc., United Health Group's Cigna Corp's Braava Health Inc. and Humana Inc. in papers filed on Tuesday in federal court in Los Angeles in a lawsuit filed by a former UnitedHealth Group employee.

The Justice Department last month joined a False Claims Act lawsuit brought by a former Benjamin Franklin, whose whistleblowers said other insurers was filed under seal in 2014.

### Justice Department Joins Whistleblower Suit Accusing UnitedHealth Group of Overcharging Medicare by "Hundreds of Millions"

By THE NATION  
11/16/16 10:45 AM EST

### Scheme Tied to UnitedHealth Overbilled Medicare for Years, Suit Says

By THE NATION  
11/16/16 10:45 AM EST



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## Growing MCO Enforcement and Litigation Focus

Regulatory and enforcement authorities have become attuned to financial incentives associated with MCOs.

The government and the qui tam bar have become more educated and sophisticated on potential enforcement theories.

Congressional pressure has led to CMS and DOJ taking a second look at the MCO industry. Enforcers have been given more tools to investigate fraud & abuse.

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## Civil False Claims Act

### Elements

- Prohibits knowingly presenting a false claim or knowingly making a false record or statement material to a false claim
- "Knowingly" includes acting in reckless disregard or deliberate ignorance of the truth or falsity of the information
- Plan/provider knowledge of allegedly false claim may be pled generally

### Damages, Penalties, and Whistleblowers

- Government may recover treble damages
- Civil penalties of up to \$21,000 per claim
- Qui tam provisions allow individuals (e.g., employees, contractors, providers) to sue and share in ultimate recovery

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## Civil False Claims Act: 60-Day Overpayment Rule

### Background

- The Affordable Care Act requires that overpayments be reported and repaid within 60 days after identification.
- Effective January 1, 2015, identified "overpayments" must be "reported" and "returned" within 60-days, or they may become "obligations" under the False Claims Act (42 C.F.R. § 422.326).
- Pending challenge to Part C regulation (United Healthcare Ins. Co. v. Burwell, No. 16-00157 (D.C.C.))

### CMS Operational Guidance

- "Reporting" satisfied by requesting a Remedy Ticket (for each contract and payment year)
- "Returning" satisfied by submitting data corrections
- "Risk Adjustment Data" vs. "Other"
- No appeals process
- 6-year look-back period

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## Civil False Claims Act: 60-Day Overpayment Rule

**Investigative Steps**

- CMS Guidance requires that MA plans must take affirmative investigative steps related to potential "overpayments":
  - Overpayments can include data inaccuracies that MA plans *"should have determined through the exercise of reasonable diligence"*
  - Reasonable diligence includes *"proactive compliance activities"* and *"investigation... in response to credible information of an overpayment"*
  - Example from Proposed Overpayment Guidance for Parts A & B:  
Compliance hotline complaints create an obligation to timely investigate

**DOJ Position:**  
"an entity 'has identified an overpayment' when it 'has determined, or should have determined through the exercise of reasonable diligence, that [it] has received an overpayment..."

United States ex rel. Kane v. Healthfirst, Inc. (emphasis added)

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## Civil False Claims Act: 60-Day Overpayment Rule

**Congressman Berman**

"Liability for all non-disclosed overpayments of the same type also should be imposed once an organization or other person is on notice that it has been employing a practice that has led to multiple instances of overpayment.

For example, if a corporation learns after-the-fact that it has been violating a billing rule or a contract requirement in its billing, and it nonetheless fails to comply with a legal obligation to disclose the resulting overpayments, this amendment renders the corporation liable under the Act for all overpayments resulting from the violation of the billing rule or contract requirement, even those not specifically identified or quantified.

Source: 155 Congressional Record E1295 (Monday, May 18, 2009) (emphasis added)

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## Qui Tam FCA Actions on the Rise\*

Year	Qui Tam	Non qui tam
1997	350	300
1998	300	300
1999	300	300
2000	300	300
2001	300	300
2002	300	300
2003	300	300
2004	300	300
2005	400	300
2006	500	300
2007	600	300
2008	700	300
2009	600	300
2010	500	300
2011	400	300
2012	500	300
2013	600	300
2014	700	300
2015	800	300
2016	850	300

\* Department of Justice, *Fraud Statistics – Overview, October 1, 1997 – September 30, 2016*  
<https://www.justice.gov/opa/press-release/file/918361/download> (last visited March 23, 2017)

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## Recent FCA Enforcement: Medicare Advantage Risk Adjustment

Tweeting about this conference?

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## The Yates Memo

*September 2015*

**"One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing..."**

- > **Sets forth six principles governing pursuit of individuals for corporate misdeeds**
  - > Corporations must provide all relevant facts relating to the individuals responsible for the misconduct in order to qualify for cooperation credit
  - > Focus on individuals from the inception of criminal or civil corporate investigation
  - > Close coordination between DOJ criminal and civil attorneys
  - > DOJ will not release culpable individuals from civil or criminal liability when resolving a matter (absent extraordinary circumstances or DOJ policy)
  - > Resolution with corporation should not occur without clear plan to resolve related individual cases
  - > Civil attorneys should focus on individuals and evaluate whether to bring suit against individual based on consideration beyond individual's ability to pay
- > **Prosecutions Post-Yates**
  - > Toumey CEO Settlement and Exclusion
  - > NAHC Settlement

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## DOJ Interventions - Swoben

**Timeline**

- > **2009:** James Swoben, former employee of SCAN Health Plan, files Qui tam under seal
- > **2013:** DOJ declines to intervene as to United and other defendants; district court dismisses action
- > **August 2016:** Ninth Circuit revives qui tam on appeal (amended December 2016)
- > **March 6, 2017:** DOJ files motion to intervene as to United
- > **March 13, 2017:** Relator drops all non-United defendants, except Healthcare Partners (DaVita)
- > **March 27, 2017:** DOJ seeks to consolidate Swoben and Poehling cases
- > **May 1, 2017:** DOJ files its Complaint-in-Partial-Intervention ("CPI")
- > **July 14, 2017:** United Defendants file Motion to Dismiss ("MTD") against DOJ's CPI
- > [Today: Court has not reached a decision on the MTD]

**Observations**

- > Under Ninth Circuit/DOJ standard, MAOs submit false certifications if they design and implement chart reviews to locate additional risk adjustment data without undertaking "reasonable efforts" to identify and correct inaccurate risk adjustment data
- > Due diligence standard requires "reasonable efforts," which DOJ will interpret to mean a robust compliance program
- > Swoben makes Ninth Circuit "friendly" to DOJ/qui tam relators

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## DOJ Interventions - *Poehling*

### Timeline

- **2011:** Qui tam filed under seal by UnitedHealth finance employee Benjamin Poehling against UnitedHealth and host of other MAOs
- **December 2016:** Transferred to Central District of California (post-Swoben)
- **February 16, 2017:** DOJ intervention (as to United); complaint unsealed
- **March 27, 2017:** DOJ seeks to consolidate Swoben and Poehling cases
- **May 16, 2017:** Relator files Second Amended Complaint ("SAC"); DOJ files CPI
- **Aug. 29, 2017:** Relator expands his counsel team

### Observations

- Allegations present important themes which provide guidance for risk adjustment compliance programs
  - Executive knowledge of wrongdoing
  - Compliance department answerable to the business rather than independent
  - Targeting codes over accuracy
  - Negligible monitoring
  - Faulty logic and filtering let in false codes

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## Ongoing Risk Adjustment Compliance Standards

### Submit Accurate Risk Adjustment Data

Submit risk adjustment data that is "accurate, complete and truthful" "(based on best knowledge, information and belief)." 42 C.F.R. 422.504(l).

### Report and Return Risk Adjustment Data Identified as Inaccurate

"If an MA organization has identified that it has received an overpayment, the MA organization must report and return that overpayment . . . no later than 60 days after the date on which it identified it received an overpayment . . ." 42 C.F.R. 422.326. Delete erroneous risk adjustment data "as soon as possible." Medicare Managed Care Manual ch. 7 § 40.

### Systematically and Proactively Verify the Accuracy of Risk Adjustment Data

"...[]f through reasonable diligence the comparison between the codes identified by the retrospective reviews and the codes previously submitted to CMS is capable of identifying only under-reporting errors, we assume this would not result in false certifications under current CMS regulations. The due diligence standard requires only reasonable efforts." 9th Cir. Swoben decision (No. 13-56746, 9th Cir.).

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## Ongoing Risk Adjustment Compliance Standards (*cont.*)

### Investigate Potentially Inaccurate Risk Adjustment Data

When plans "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." 9th Cir. Swoben decision (No. 13-56746, 9th Cir.).

### Closely Manage Subcontractors Responsible for Generating Risk Adjustment Data

Have systems in place to "monitor . . . FDRs' compliance with Medicare program requirements." "CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements." Medicare Managed Care Manual ch. 21 § 40.

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### Managed Care Overview

- > Changing World FFS environment to Managed Care
- > Benefits and challenges of the Managed Care Model
- > Some key differences--
  - ❖ Provider Payments
  - ❖ Contracting
  - ❖ Credentialing
  - ❖ Quality

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### Regulatory Landscape

- > Federal & State Programs Key Agencies:
  - ❖ Centers for Medicare & Medicaid Services (CMS) ;
  - ❖ Office of Inspector General (OIG);
  - ❖ US Department of Health & Human Services (DHHS);
  - ❖ State Medicaid Agencies; and
  - ❖ State Attorneys General
- > Governance and Oversight Responsibilities
- > Ramifications

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### Enforcement Mechanisms

- > Identification of Concerns
  - ❖ Industry Monitoring Initiatives
  - ❖ Beneficiary/Provider Complaints (e.g. CTMs)
  - ❖ Audits
  - ❖ Voluntary Disclosures
- > Key Areas
  - ❖ Data Integrity-Universes
  - ❖ Beneficiary Service- Access to cost effective products & services; critical drugs/therapy
  - ❖ Fraud, Waste and Abuse

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