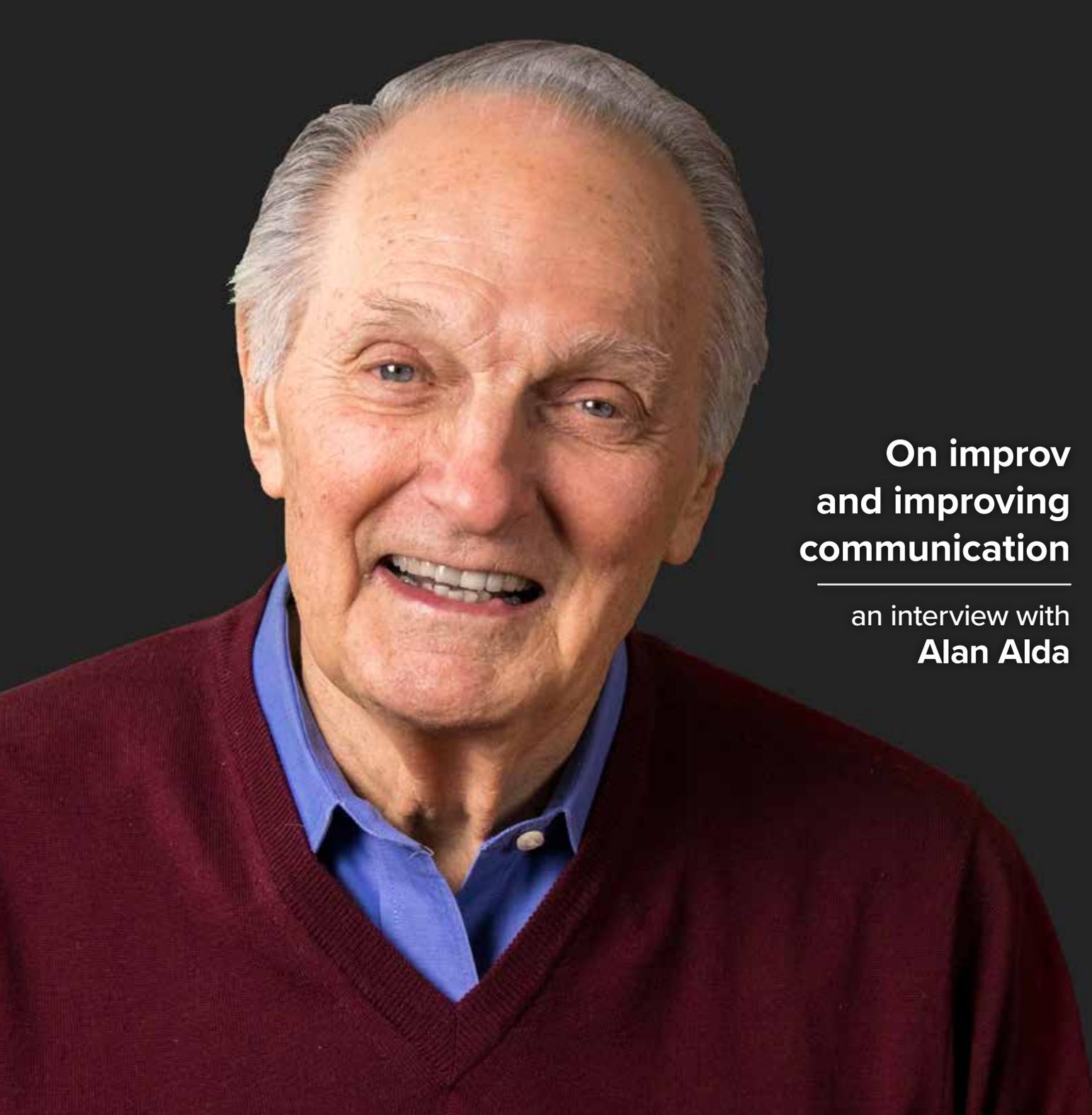




Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

MARCH 2018



**On improv
and improving
communication**

an interview with
Alan Alda



FEATURES

- 16 **Meet Alan Alda**
an interview by Adam Turteltaub
- 23 **False Claims Act 2017 report card: \$2.4 billion recovered**
by Joan W. Feldman
A look at ten settlements for the most egregious federal FCA cases in healthcare last year.
- 29 **Impact of state False Claims Acts**
by Denise Atwood
Your compliance program and training should encompass your state's regulations to protect Medicaid from fraudulent claims.
- 35 **Stacked physician compensation: Keys to compliance**
by Bartt B. Warner and Thomas A. Warrington, Jr.
To reduce the risk of enforcement action, several areas need to be explored when determining if a physician's total compensation falls within the limits of the laws and regulations.
- 42 [CEU] **Navigating Medicare Secondary Payer compliance and False Claims Act liability**
by Gary W. Herschman, Melissa L. Jampol, and Tristan A. Potter-Strait
The burden of investigating a patient's health insurance coverage is squarely on the shoulders of the provider, and knowing whom to bill for care is crucial to avoiding liability.



Compliance Today is printed with 100% soy-based, water-soluble inks on recycled paper, which includes 10% post-consumer waste. The remaining fiber comes from responsibly managed forests. The energy used to produce the paper is Green-e® certified renewable energy. Certifications for the paper include Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Programme for the Endorsement of Forest Certification (PEFC).

COLUMNS

- 3 **Letter from the Incoming CEO**
by Gerry Zack
- 5 **Letter from the CEO**
by Roy Snell
- 21 **Exhale**
by Catherine Boerner
- 27 **Managing Compliance**
by Lynda S. Hilliard
- 33 **The Compliance – Quality Connection**
by Sharon Parsley
- 40 **Security Awareness Reminder**
by Frank Ruelas
- 50 **Reflections in Research**
by Kelly M. Willenberg

DEPARTMENTS

- 8 **News**
- 15 **People on the Move**
- 76 **Newly Certified Designees**
- 78 **New Members**
- 81 **Takeaways**
- 82 **Upcoming Events**

by Joan W. Feldman

False Claims Act 2017 report card: \$2.4 billion recovered

- » Don't assume that a whistleblower complaint cannot be brought against your organization.
- » Address compliance concerns promptly, so they don't fester and result in a *qui tam* action.
- » The government will continue to rely on individuals to bring cases to their attention, motivated by sharing in a federal monetary recovery.
- » Providing medically unnecessary services to patients is typically not an isolated event.
- » The government is likely to increase the use of tools that identify outliers.

Joan W. Feldman (jfeldman@goodwin.com) is a Partner and Health Law Group Practice Chair at Shipman & Goodwin, LLP in Hartford, CT.

On December 21, 2017, the Department of Justice (DOJ) issued its yearly report card describing its most noteworthy settlements in fiscal year 2017 with healthcare providers under the False Claims Act (FCA).¹ In addition to praising the efforts of its dedicated enforcement staff, the DOJ sent a message of both acknowledgment and encouragement to the whistleblowers who bring alleged FCA violations to its attention.

It makes good sense for the DOJ to use this annual report card as a form of encouragement for those among us who believe in reporting blatant wrongdoing. Unfortunately, this message is sometimes received by bounty hunters, sometimes entirely motivated by retribution or greed, who are tempted to see wrong when there is no wrong. Nevertheless, there is plenty to learn from these significant settlements, and it never gets old reading about those in positions of power who abuse the public's trust and do the indefensible out of greed. Indeed,



Feldman

the cases that were featured were stunningly egregious and involved sophisticated healthcare companies.

Risks and consequences

One has to wonder why executives would risk so much. Perhaps this risk-taking behavior and the consequences are viewed by some as the cost of doing business, but for the rest of us who believe in complying with the law, the following cases are noteworthy.

Shire Pharmaceuticals LLC—\$350 million

As a result of a *qui tam* action brought by six whistleblowers,² Shire Pharmaceuticals LLC and other Shire subsidiaries (Shire) paid \$350 million to resolve FCA allegations that it was providing kickbacks and engaging in other unlawful methods of marketing its product Dermagraft, a bioengineered human skin substitute approved by the FDA for use in the treatment of diabetic foot ulcers. The whistleblowers alleged, among other things, that Dermagraft salespersons unlawfully induced the use of Dermagraft by incentivizing physicians with extravagant dinners, entertainment, and travel; medical equipment and supplies;

unjustified payments for speaking engagements and bogus case studies; and cash gifts, rebates, and credits. Shire was also accused of marketing Dermagraft for uses not approved by the FDA. Shire sold the assets associated with Dermagraft in early 2014. Since late 2014, Shire has been operating under a Corporate Integrity Agreement with the U.S. Department of Health and Human Services that is related to the settlement of separate FCA allegations. The Office of the Inspector General (OIG) will continue to monitor Shire's compliance with federal healthcare laws through its oversight of this agreement.

Mylan Inc.—\$465 million

Mylan Inc. and Mylan Specialty LP (collectively, Mylan) agreed to pay \$465 million to resolve claims that they violated the FCA by knowingly misclassifying EpiPen as a generic drug to avoid paying higher rebates to Medicaid.³ The rebate program was enacted by Congress to protect Medicaid programs from price gouging relating to drugs available only through a single source. Brand-name drugs are subject to a higher rebate; whereas generic drugs, available from multiple manufacturers, are subject to a lower rebate. By misclassifying the drug as generic, Mylan paid only a 13% rebate to Medicaid while increasing the price of EpiPen by 400%. Sanofi-Aventis was the whistleblower and received approximately \$38 million of the federal recovery. Mylan also entered into a five-year Corporate Integrity Agreement.

eClinicalWorks—\$155 million

eClinicalWorks paid \$155 million to resolve FCA allegations that it falsely obtained certification for its electronic health record (EHR) software when it concealed from an independent certifying entity that its software did not fully comply with all of the certification requirements.⁴ Specifically, eClinicalWorks

complied with coding requirements for only the drugs needed for certification testing, despite the requirement that all drugs be coded for certification. The eClinicalWorks software also failed to satisfy data portability requirements intended to permit healthcare providers to transfer patient data from its software to other vendors. This false certification resulted in false claims being submitted for Meaningful Use incentive payments by users of the software. A five-year Corporate Integrity Agreement was required with stiff requirements relating to customer usage of the software. The case was the result of a *qui tam* action brought by a software technician who received approximately \$30 million of the federal recovery.

Life Care Centers of America, Inc.—\$145 million

Life Care Centers of America, Inc. (Life Care) agreed to pay \$145 million to resolve FCA allegations that it knowingly caused its more than 220 skilled nursing facilities to submit false claims for rehabilitation services that were not reasonable, necessary, or skilled.⁵ Specifically, the government alleged that Life Care falsely submitted higher levels of care than its patients needed in order to receive higher reimbursement and kept patients at the facility longer than needed, so the rehabilitation services could continue to be billed. Life Care was required to enter into a five-year Corporate Integrity Agreement. The case was brought to the attention of the government by two former Life Care employees who shared \$29 million of the federal government's recovery.

Freedom Health, Inc. and former COO—\$32.5 million

Freedom Health, Inc., a Medicare Advantage plan, its related corporate entities, and former chief operating officer (COO) collectively paid \$32.5 million to resolve FCA allegations that

they submitted unsupported diagnosis codes to CMS, which resulted in a higher level of reimbursement.⁶ It was also alleged that the plan made material misrepresentations regarding the scope and content of its network of physicians, specialists, and hospitals. The case was brought to the attention of the federal government by a former employee.

Pain management physician—\$20 million

A pain management physician agreed to pay \$20 million to resolve FCA allegations that he falsely billed federal healthcare programs by billing for surgical monitoring services that he did not perform and for medically unnecessary diagnostic tests.⁷ Specifically, the federal government claimed that the physician billed for monitoring the neurological health of patients during surgery when he had a medical assistant doing the monitoring. The government further alleged that the physician billed for medically unnecessary balance tests, nerve conduction and electromyography procedures, and qualitative drug screens. The case was brought to the government's attention by three whistleblowers. In addition to the payment, the physician was sentenced to three years and two months in prison.

Medically unnecessary services—\$18 million

A physician paid more than \$18 million to resolve FCA allegations that he submitted claims for medically unnecessary biopsies and radiation therapy services, and radiation therapy services performed too frequently in contravention of medical standards. The government proved that more than 50% of the payments the physician received from Medicare were for services provided on days when he was not present in the clinic. The government also proved that the physician knew that a medical physicist had not performed the physicist services he had billed to Medicare. The case was brought

to the attention of the government by a physician whistleblower.⁸

Cardiac monitoring companies—\$13.45 million

AMI Monitoring Inc. (aka Spectacor); its owner, Joseph Bogdan Medi-Lynx Cardiac Monitoring LLC, and Medicalgorithmics, SA agreed to pay \$13.45 million to resolve FCA allegations. The government alleged that the cardiac monitoring companies marketed a pocket ECG that provided three levels of cardiac monitoring services and consistently steered physicians to the more costly monitoring service, even though it was not medically necessary. The case was brought to the attention of the federal government by a former salesperson of Spectacor, who will share approximately \$2.4 million of the federal government's recovery.⁹

MedStar Ambulance Inc.—\$12.7 million

MedStar Ambulance Inc. agreed to pay \$12.7 million to resolve FCA allegations that it routinely billed for transportation services that were not medically necessary and billed for higher levels of services than required by the patients' conditions, or services that were not actually provided. The case was brought by a former billing office employee who will share approximately \$3.5 million of the federal government's recovery.¹⁰

Urologist practicing at Gulfstream

Urology—\$3.8 million

After 21st Century Oncology LLC paid \$19.75 million to settle FCA claims in 2015,¹¹ a urologist practicing at Gulfstream Urology, which was a division of 21st Century Oncology, LLC, became the subject of FCA allegations. The urologist has agreed to pay more than \$3.8 million to resolve FCA allegations that he ordered medically unnecessary tests performed on urine to detect genetic abnormalities associated with bladder cancer.¹²

Medicare does not cover the test unless it is ordered after a full urologic workup or there is reason to suspect a recurrence of cancer in a patient previously diagnosed with cancer. The urologist was the number one ordering physician in the country for this test and received \$2 million in bonus payments for ordering the tests. The case was brought to the attention of the federal government through a *qui tam* action. The physician entered into a three-year Integrity Agreement with the OIG.

Conclusion

As evidenced by the above cases, the government will continue to rely on those entrenched in the industry to bring allegedly fraudulent conduct to their attention. Therefore, despite temptation by some to overbill, the risks are high in an environment in which your colleagues are watching. Although egregious, all of these cases are teachable moments for healthcare executives and providers alike. ☐

1. Department of Justice, Justice News, press release: "Justice Department Recovers Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017" December 21, 2017. Available at <http://bit.ly/2mcgqX2>
2. DOJ, Justice News, press release: "Shire PLC Subsidiaries to Pay \$350 Million to Settle False Claims Act Allegations" January 11, 2017. Available at <http://bit.ly/2jbbBNN>
3. DOJ, Justice News, press release: "Mylan Agrees to Pay \$465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates" August 17, 2017. Available at <http://bit.ly/2AQ04cg>
4. DOJ, Justice News, press release: "Electronic Health Records Vendor to Pay \$155 Million to Settle False Claims Allegations" May 31, 2017. Available at <http://bit.ly/2sgG3v2>
5. DOJ, Justice News, press release: "Life Care Centers of America, Inc. Agrees to Pay \$145 Million to Resolve False Claims Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services" October 24, 2016. Available at <http://bit.ly/2qUDaRe>
6. DOJ, Justice News, press release: "Medicare Advantage Organization and Former Chief Operating Officer to Pay \$32.5 Million to Settle False Claims Act Allegations" May 30, 2017. Available at <http://bit.ly/2snKh0s>
7. U.S. Attorney's Office, Eastern District of Kentucky, press release: "Pain Management Physician Pays \$20 Million to Resolve False Claims Allegations" February 1, 2017. Available at <http://bit.ly/2kVH6NK>
8. U.S. Attorney's Office, Southern District of Florida, press release: "Dr. Gary Marder and the United States Consent to a Final Judgment of Over \$18 Million to Settle False Claims Act Allegations" February 7, 2017. Available at <http://bit.ly/2lcPPvG>
9. DOJ, Justice News, press release: "Cardiac Monitoring Companies and Executive Agree to Pay \$13.45 Million to Resolve False Claims Act Allegations" June 26, 2017. Available at <http://bit.ly/2s29a1L>
10. DOJ, Justice News, press release: "Medstar Ambulance to Pay \$12.7 Million to Resolve False Claims Act Allegations Involving Medically Unnecessary Transport Services and Inflated Claims to Medicare" January 13, 2017. Available at <http://bit.ly/2k7D0lh>
11. DOJ, Justice News, press release: "21st Century Oncology to Pay \$19.75 Million to Settle Alleged False Claims for Unnecessary Laboratory Test" December 18, 2015. Available at <http://bit.ly/2Fxt9A>
12. U.S. Attorney's Office, Middle District of Florida, press release: "Fort Myers Urologist Agrees To Pay More Than \$3.8 Million For Ordering Unnecessary Medically Tests" February 1, 2017. Available at <http://bit.ly/2kSFTXl>

SCCE & HCCA 2017–2018 BOARD OF DIRECTORS

EXECUTIVE COMMITTEE

Margaret Hambleton, MBA, CHC, CHPC

SCCE & HCCA President

Vice President, Chief Compliance Officer, Dignity Health, Pasadena, CA

Lori Strauss, RN, MSA, CPC, CHC, CHPC, CCEP, CHRC

SCCE & HCCA Vice President

Assistant Vice President Hospital Affairs, Chief Compliance Officer, Stony Brook Medicine, East Setauket, NY

Art Weiss, JD, CCEP-F, CCEP-I

SCCE & HCCA Second Vice President

Chief Compliance & Ethics Officer, TAMKO Building Products, Joplin, MO

Walter Johnson, CHC, CCEP-I, CHPC, CCEP, CRCMP

SCCE & HCCA Treasurer

Director of Compliance & Ethics, Kforce Government Solutions, Fairfax, VA

David Heller, CCEP

SCCE & HCCA Secretary

Vice President Risk Management & CECO, Edison International, Rosemead, CA

Robert Bond, CCEP

SCCE & HCCA Non-Officer Board Member

Partner, Notary Public at Bristows LLP, London, UK

Urton Anderson, PhD, CCEP

SCCE & HCCA Immediate Past President

Director, Von Allmen School of Accountancy, Gatton College of Business and Economics, University of Kentucky, Lexington, KY

EX-OFFICIO EXECUTIVE COMMITTEE

Gerard Zack, CFE, CPA, CIA, CCEP, CRMA

Incoming Chief Executive Officer, SCCE & HCCA, Minneapolis, MN

Roy Snell, CHC, CCEP-F

Chief Executive Officer, SCCE & HCCA, Minneapolis, MN

Stephen Warch, JD

SCCE & HCCA General Counsel, Nilan Johnson Lewis, PA, Minneapolis, MN

BOARD MEMBERS

Shawn Y. DeGroot, CHC-F, CHRC, CHPC, CCEP

President, Compliance Vitals, Sioux Falls, SD

Odell Guyton, CCEP, CCEP-I

Managing Director, Klink & Co. Inc, Quilcena, WA

Kristy Grant-Hart, CCEP-I

Founder and Managing Director, Spark Compliance Consulting, London, UK

Gabriel L. Imperato, Esq., CHC

Managing Partner, Broad and Cassel, Fort Lauderdale, FL

Shin Jae Kim

Partner, TozziniFreire Advogados, São Paulo, Brazil

Jenny O'Brien, JD, CHC, CHPC

Chief Compliance Officer, UnitedHealthcare, Minnetonka, MN

Daniel Roach, JD

General Counsel and Chief Compliance Officer, Optum360, Eden Prairie, MN

R. Brett Short

Chief Compliance Officer, UK HealthCare/University of Kentucky, Louisville, KY

Debbie Troklus, CHC-F, CHRC, CHPC, CCEP-F, CCEP-I

Managing Director, Aegis Compliance and Ethics Center, Chicago, IL

Sheryl Vacca, CHC-F, CHRC, CHPC, CCEP-F, CCEP-I

Senior Vice President/Chief Risk Officer, Providence St Joseph Health, Renton, WA

Sara Kay Wheeler, JD, CHC

Partner, Attorney at Law, King & Spalding, Atlanta, GA