


HCCA Enforcement Compliance Institute
October 31, 2017


Health Care Compliance Association

The Government Enforcement Official and Chief Compliance Officer – Learned Experiences on Pro-Active Initiatives to Mitigate and Minimize Risk

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Agenda

- Speaker Introductions
- Background Information – Risk Today
- Primary Enforcement Tool – The FCA
 - *Four General Types of FCA Cases*
- Medicare Advantage Plans
- Government Enforcement Official Case Examples & Best Practices
 - *Medical Necessity and Stark-AKS Cases*
- Chief Compliance Officer Best Practices
- Closing Thoughts
- Q&A

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Goals

1. Outline Some Key Risks
2. Examine Enforcement Tools
3. Explore Real Cases and How They Were Prosecuted
4. Identify Key Components of Effective Compliance
5. Get Moving and “Do Compliance the Right Way”
6. Discuss Real-World Initiatives Which Can Prevent/Mitigate Regulatory and Law Enforcement Exposure for Providers

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Our session – Discussion Points

The negotiation activities which surround a CIA or Settlement Agreement can be stressful and potentially result in an agreement which contains flaws or inaccuracies.

What elements is the government looking for?

Who is best to negotiate for providers?

Every investigation/settlement has a history of something that could have been done differently or maybe in a more proactive manner. Hear from the speakers about applicable cases, settlements and investigations where proactive actions were missed.

Board Governance is a key element of a compliance program. Learn of proactive activities that can be taken to demonstrate that this is working as recommended by OIG-DHHS including making sure the Board is always involved and aware of their obligations.

Bret S. Bissey, MBA, FACHE, CHC, CMPE

Healthcare Compliance Executive

- 30 years of diversified healthcare management, operations and compliance experience
- Former SVP, chief of ethics and compliance officer at UMDNJ
 - Credited with re-engineering the compliance program of the nation's largest free-standing public health sciences university
 - Successfully led the compliance program to adhere to CIA with DHHS/OIG that occurred following a Deferred Prosecution Agreement
- Chief compliance and privacy officer at Deborah Heart and Lung Center
 - Three-year CIA, first settlement of Voluntary Disclosure Protocol
 - Compliance program recognized by HCCA as a "Best Practice"
- Certified in HCCA and the Medical Group Management Association
- Author of Compliance Officer's Handbook



A.G. (Alec) Alexander, III Breazeale, Sachse & Wilson, L.L.P.

- Alec Alexander is a partner in the Baton Rouge office of Breazeale, Sachse & Wilson, L.L.P. Mr. Alexander focuses his practice on healthcare-related white collar civil and criminal defense, representing corporations and senior-level corporate officials in fraud matters.
- Before joining BSW, Mr. Alexander was an attorney and healthcare executive at CHRISTUS Health Louisiana where he served as the Chief Compliance Officer.
- Before CHRISTUS, Mr. Alexander served for eight years as an Assistant United States Attorney for the Western District of Louisiana handling healthcare fraud cases.
- In 2004 and 2009, Mr. Alexander was recognized by the Inspector General of the United States Department of Health and Human Services, who twice awarded him the Inspector General's Integrity Award for prosecuting health care fraud.
- Alec currently represents hospitals, hospital systems and a wide range of other providers throughout the country in administrative, regulatory, qui tam and civil and criminal fraud matters.

Trump Administration – Where is Enforcement Headed??

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First half of 2017, OIG reported:

- Expected investigative recoveries of over \$2 Billion
- 468 criminal actions against individuals or entities that engaged in crimes against HHS programs
- 461 civil actions
- 1422 exclusions of individuals and entities from participation in Federal health care programs

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Increased Focus on Individual Actors – Yates Memo

Sept. 9, 2015 DOJ Guidance -

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

Six Steps

1. Corporations must provide all relevant facts on responsible individuals to get cooperation credit
2. Investigations should focus on individuals from the inception
3. Criminal and civil attorneys handling should be in routine contact
4. Individuals should not be released from liability when resolving a matter with a corporation absent policy or extraordinary circumstances
5. DOJ attorneys should not resolve matters with a corporation without a plan to resolve individual cases, and should memorialize any declinations as to individuals in such cases
6. Civil attorneys should focus on individuals and evaluate whether to bring suit against an individual based on considerations beyond ability to pay

• See <http://www.wirk.com/docs/IndividualAccountabilityforCorporateWrongdoing.pdf>

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June 2015 – OIG Fraud Alert Focuses on Physician Compensation Arrangements

- Targeted at physicians and directs that all compensation arrangements need to be FMV and reflect payment for bona fide services that have been provided
- If any purpose of the arrangement is to compensate a physician for past or future referrals, the potential exists AKS violation
- Could result in possible criminal, civil or administrative sanctions, including exclusion and potential draconian FCA penalties

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Compliance Risk Areas of Concern for Governance

- Federal claims for services (hospital, physician, etc.).
- Physician arrangements with hospitals.
- Contracts with ancillary services tied to referrals.
- Quality – accurate measurement and honest information.
- Regardless of federal or private payors, risk remains.

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Regulatory Sanctions

- Many times Regulatory Sanctions, such as: Fines, Penalties, Corporate Integrity Agreements, etc... have nothing to do with "Intentional" actions.
- Rather they are due to Best Practice business processes not being established to mitigate risk and to enhance efficiencies.
- You didn't know about the risk or didn't have the resources to adequately address the risk and are not advised actions to take in this high risk area.

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The False Claims Act: 31 U.S.C 3729 et seq.

- Originally enacted during the Civil War (1863)
- Prohibits false claims involving U.S. money
- Most start with relators, though not required
- Investigating Agencies (OIG, FBI, NCIS, DCIS among many others)
- Limitations Period:
 - 6 years from date of claim, record or statement OR
 - 3 years from date of discovery by an official with authority to act, *whichever is longer*,
 - but in no event more than 10 years after the submission of the claim
- Treble damages
- FCA PENALTY RANGE **RAISED** : \$10,781 - \$21,563 per proven false claim (will continue to be readjusted annually for inflation).
- Joint and several liability for defendants
- **Qui Tam Provisions**

The False Claims Act 31 U.S.C. 3729, et seq.

- “Any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval ... is liable to the United States ...for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted ... plus 3 times the amount of damages which the Government sustains because of the act of that person”
- The terms “knowing” and “knowingly” mean that a person, with respect to information --
 - Has actual knowledge of the information;
 - Acts in deliberate ignorance of the truth or falsity of the information; or
 - Acts in reckless disregard of the truth or falsity of the information.

✓ No Specific Intent to Defraud is Required

False Claims Act Recoveries

For Fiscal Year 2016:

- Total Recoveries = **\$4.7 billion**
- Total Health Care Recoveries = **\$2.5 billion** (federal only, no state Medicaid)
- Total Health Care Qui Tam Recoveries = **\$1.8 billion**
- Total New Qui Tam Filings = **702**
- Total New Qui Tam Health Care Filings = **423**
- Total relator (whistleblower) awards = \$519 million (does not include costs/fees paid separately)



Since 1986

- Total Recoveries: **\$53.6 billion**
- Total Health Care Recoveries = **\$34.3 billion**
- Total New Qui Tam Filings = **11,700**
- Total relator awards = **\$6.4 billion**
 - **DOJ intervenes in approximately 25% of the qui tam cases** in which it makes an intervention decision (some cases get dismissed pre-election)

False Claims Act

• Key Elements

- ✓ Claims
- ✓ Falsity
- ✓ Knowledge
 - ✓ Actual Knowledge
 - ✓ Deliberate Ignorance
 - ✓ Reckless Disregard
- ✓ Materiality
- ✓ Damages (actually not required but almost always present)
- ✓ Causation
 - ✓ The FCA is directed not merely at those who submit false claims but also at those who "cause" false or fraudulent claims to be submitted. ("Relator has presented evidence showing that it was foreseeable that Parke-Davis's conduct . . . would ineluctably result in false Medicaid claims"). United States ex rel. Franklin v. Parke-Davis, 2003 WL 22048255, at *5 (D. Mass. Aug. 22, 2003)

The False Claims Act Intervention Decision

- After its investigation, the United States may choose to intervene and take over the litigation. This is a critical juncture for defendants. Though Relators may proceed without the Government, 80-85% of Non-intervened cases do not go forward.
- **Key Drivers in Government's Decision:**
 - The strength of the case and the evidence
 - The magnitude of the associated damages
 - Non-monetary issues such as patient health or safety, and other quality of care concerns
 - Whether the conduct is part of a pervasive practice that the government wants to address
 - The potential for individual liability
 - The potential deterrent value of the case
- **NOT** a key driver: Relator's personal baggage.

The False Claims Act

Categories of False Claims Potentially Affecting Physicians

- Billing for Goods or Services Not Provided
 - ✓ Quality of Case Cases
- Billing for Ineligible Goods or Services
 - ✓ Medical Necessity Cases
- Inflated Billings
 - ✓ Hospitalist Cases
- False Certification Cases
 - ✓ Kickback and Stark Cases

Government Enforcement Official: Case Examples and Learned Best Practices

Example #1– Medical Necessity

Horizontal lines for notes

The False Claims Act: Billing for Ineligible Goods for Services

Medical Necessity

- Social Security Act
• "Section 1862 (42 U.S.C. §1396Y) – (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services (1)(A) which, except for items and services described in a succeeding paragraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member...."

Horizontal lines for notes

The False Claims Acts: Medical Necessity - Inpatient Surgical Case

- Part A and Part B Payments Are Inextricably Intertwined
• Transmittal 541
• If Not Medically Necessary, Related Claims Are "False"
• If Submitted With "Knowledge," FCA Implicated
• Requires Proactive, Thoughtful and Effective Compliance Efforts and Careful Management
• Occurs At The Difficult Intersection of Compliance, Risk, Quality, Legal and Med Staff

Horizontal lines for notes

Government Enforcement Official Case Examples and Learned Best Practices
 Example 2 – Physician Relationships (Stark and AKS)

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The False Claims Act:
False Certification Cases – Stark and AKS

How the FCA Intersects With Stark and the AKS

- **Stark Statute:** Civil rule that prohibits a physician from referring a Medicare patient for certain designated health care services ("DHS") to an entity with which the physician (or immediate family member) has a financial relationship, unless an applicable exception protects the referral.
- **Anti-Kickback Statute:** Criminal statute that prohibits the exchange (or offer to exchange) of anything of value if one purpose is to induce (or reward) the referral of federal health care business.
 - ✓ Under the "False Certification" theory, False Claims Act liability can attach to claims where a government payee falsely certifies compliance with a statute or regulation—like Stark or the Anti-kickback statute -- that is a prerequisite to government payment.
 - ✓ If a claim for payment grows out of a prohibited Stark relationship, or the claim is "tainted" by an intent to induce federal program business, it is false for purpose of the FCA.

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The False Claims Act:
False Certification Cases – Stark and AKS

- FCA Cases With Stark Predicates:
Adventist Health System (\$115 million), North Broward Hospital District (\$69.5 million), Columbus Regional Healthcare System and Dr. Andrew Pippas (\$35 million)
- FCA Cases With AKS Predicates:
Daichi Sankyo, Inc. (\$39 million for kickbacks to physicians), PharMerica Corp. (\$9.25 million for kickbacks to and from Abbott to promote drugs in nursing homes)
- These illustrate the need for meaningful, proactive measures to ensure appropriate physician relationships and prevent inappropriate inducements

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Medicare Advantage Plans

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Medicare Advantage Plans – Why important to Audit and Compliance Space?

- Senator Chuck Grassley (April 17, 2017) letter to CMS Administrator calls for tighter scrutiny of MA Plans – some studies suggest that \$125 Million in overcharges in at 5 MA Plans in one year....
- When Sen. Grassley speaks watch for enforcement to follow...
- MA Plans is a popular alternative to traditional Medicare
- Privately run health plans have enrolled approximately 18 million (33% of Medicare population)...

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Medicare Advantage Plan Statistics - 2017

- The average Medicare beneficiary has access to 19 Medicare Advantage plans, roughly the same since 2012
- The average Medicare beneficiary will be able to choose from many plans, but in some areas, these plans will be offered by a handful of firms
- Half of the 271 new Medicare Advantage plans in 2017 are offered by UnitedHealthcare, Aetna, and firms affiliated with BlueCross BlueShield
- UnitedHealthcare alone accounts for about one-quarter of all new Medicare Advantage plans.
- No substantial increase in patient premiums forecast
- In 2016, 7 firms and affiliates accounted for almost three-quarters of all enrollment: UnitedHealthcare, Humana, Blue Cross and Blue Shield (BCBS) affiliated companies (including Anthem BCBS plans), Kaiser Permanente, Aetna, Cigna, and Wellcare. These companies and affiliates account for 64 percent of the plans being offered in 2017.
- The Congressional Budget Office has projected that enrollment in MA plans will increase to about 21 million enrollees by 2023 and that Medicare payments to MAOs will grow from about \$154 billion in 2014 to about \$250 billion in 2023.

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How Does MA Plan Get Overpaid??

- Would you believe based upon coding???
- Does that sound familiar to hospital, practice audit and compliance professionals?
- It should...
- Grassley is concerned MA Plans are fraudulently altering their risk scores to exaggerate how sick patients are... thus increasing reimbursement from CMA..
- Multiple whistleblower suits currently in play nationwide

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How it Works... (High – Level)

- CMS implemented Hierarchical Condition Categories (HCC) to adjust capitated payments to private health plans for the health expenditure risk of their enrollees.
- HCC uses diagnosis codes... which to be accurate must reflect all diagnosis and documentation
- HCC must be captured every 12 months
- More details (time won't permit today)

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MA Plan Risk Areas

- **Coding** – inaccurate, incomplete documentation with HCC, can result in submission of claim for reimbursement that is inaccurate and potentially could be a series of false claims
- **Kickbacks to Providers**
 - Incentive to enroll patients in program in exchange for something of value
 - Anti-Kickback
 - Need to be concerned about contracting issues
 - Fair Market Value
 - Tracking Payments
 - Work actually performed
 - Time records
- **Medical Loss Ratio**
 - ACA requires insurers to pay a minimum percentage of premium dollars towards health care expenses and QI activities or.. Rebates must be made
 - Definitions and opportunity to be non-compliant creates opportunity for fraud...

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Recent MA Plan Settlement

Two Medicare Advantage Insurers Settle Whistleblower Lawsuit For \$32 Million (May 30, 2017)

- Two Florida Medicare Advantage insurers have agreed to pay nearly \$32 million to settle a whistleblower lawsuit that alleged they exaggerated how sick patients were and took other steps to overbill the government health plan for the elderly.
- The suit filed in 2009 by a physician and former medical director at the two health plans, Freedom Health and Optimum HealthCare, both based in Tampa. Alleged that Medicare overpaid the health plans after they made their patients appear sicker than they were, or claimed they had treated patients for medical conditions they either did not have or for which they had not been treated.
- Freedom's former chief operating officer, agreed to pay \$750,000 to resolve his alleged role in the scheme to expand into new counties and states without an adequate provider network.
- 5 year CIA

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Implication of Medicare Advantage Plan Risk for the future healthcare networks

- IMO – many of us soon will be working for systems which will have some sort of involvement with insuring the Medicare population
- Better to understand this risk today and get in front of it... because this is a "hot" enforcement area...
- Personally, I am looking to get involved with these insurance plans to share my compliance/audit knowledge...

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Chief Compliance Officer:
Learned Best Practices

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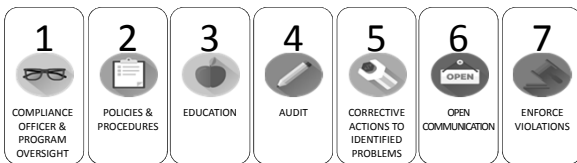
How Best to Mitigate and Minimize Risk via the Compliance Program

- Main tenets:
 - Compliance needs to be pro-active and not reactive.
 - Instill in your organizational culture that compliance is an investment and not an expense.
 - Don't lose sight of your "blocking and tackling."

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Compliance is Pretty Basic

- Seven elements of the OIG Model Compliance Program:



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Why Would You Take Sights Off of the Seven Elements?

- CCO experience of when things have the potential to "Go South" on your compliance program:
 - Pressure exerted upon doing compliance the right way.
 - Haven't sold and resold the program.
 - Haven't developed appropriate relationship with General Counsel.
 - Haven't developed appropriate compliance oversight with CEO, COO, CFO, Chair of Board, Chair of Audit Committee.
 - Don't have the necessary resources/budget.
 - Don't have authority to have healthy conflict based discussions.
 - Surrounded by leaders that display "situational compliance."

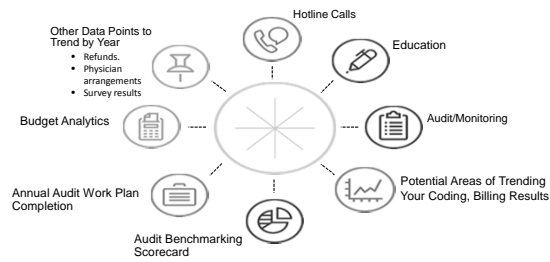
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What is Pro-Active Compliance?

1. Auditing
2. Education
3. Investment
4. Repayments
5. Preparation for Action
6. Listening Skills
7. Leadership

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Elements to Consider in Your Best Practice Efforts



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Independence

- Can you make the proper decision without fear of some sort of retaliation?
- Examples:
 - The lead admitter of patients to your hospital is in violation of the medical records completion policy – can you revoke privileges as policy states?
 - The president’s wife is asking to review sensitive and confidential information related to an upcoming community fundraiser. Can you treat her as if she were a normal citizen?
- Who validates this independence?

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Compliance and Operations

- Compliance needs to be independent from operations.
- Many CIAs state "any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA."
- This is a "big" deal that won't work in many organizations...

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Budget Analytics

- Based upon operating and FTE budgets approved by Board or Compliance/Audit Committee.
- Operating budget variance (\$\$ and %).
 - Why a variance? Consultants?
- FTE budget variance (\$\$ and %).
 - Is there turnover? Why?
 - Are there unfilled vacancies? Why?
 - What corrective action is proposed?
- Trending of budget and actual expenses over past several years.
- Good management dictates that you operate department within acceptable budget...
 - Being under budget doesn't mean you are doing a good compliance job!

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Other Data Points to Trend by Year

- Compliance presentations to senior management.
- New and renewed Focus Arrangements.
- Payments made to non-employed physicians without an agreement.
- Payments made to non-employed physicians without evidence of time and effort approval.
- Refunds.
- Survey results.

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Listening and Leadership Skills

- "An effective compliance officer must listen to the objections that are being dealt his or her way which could impede the development of good compliance..." - Bret S. Bissey
- Do you understand as a Compliance Officer all the responsibilities and pressures attached to:
 - CEO.
 - Board.
 - Medical Staff Leadership.
 - CCO.
 - CFO, etc...
- An excellent CCO needs to understand where the pushback is coming from and deal with it "head on" instead of "maybe it will go away."

If an organization is found guilty of a violation of state or federal laws, the government may offer a reduction in penalties if an effective compliance program is in place.



BREAZEALE, SACHSE & WILSON, L.L.P.
ATTORNEYS AT LAW

Our healthcare attorneys assists healthcare providers from the smallest physician practice to national hospital systems with Medicaid and Medicare reimbursement issues; Federal and state regulatory issues; negotiating acquisitions, licensing and healthcare service delivery arrangements; and litigating healthcare business disputes, antitrust issues and risk management cases.

OUR HEART IS IN THE SOUTH.
OUR REACH IS NATIONWIDE.



- | | |
|---|---|
| Accountable Care Organizations (ACOs) | Medical Staff Issues |
| Antitrust Issues | Medicare and Medicaid Participation and Compliance |
| Compliance Programs and Audits | Medicare Reimbursements |
| Credentialing and Peer Review | Mergers, Acquisitions, Divestitures and Joint Ventures |
| EMTALA | Medicaid Supplemental Payments and Upper Payment Limit Funding Programs |
| False Claims Act (FCA) and qui tam | Medical Records Law |
| Federal and state anti-kickback Statutes and Regulations | Negotiation of Physician Service Agreements |
| Fraud and Abuse Compliance | Non-Profit Hospital Conversion |
| HCQA | Privacy and Security Requirements |
| Healthcare financing through venture capital, tax- exempt bonds, private placements, credit facilities and public offerings | Regulatory |
| Healthcare Litigation | Risk Management and Professional Liability |
| HIPAA Compliance | Service Line Co-Management Arrangements |
| Hospital Operational Issues | Stark Law Issues |
| Licensure and Accreditation | State Licensing Regulations |
| Medicaid Supplemental Payments and Upper Payment Limit Funding Programs | State Self Referral Prohibitions |
| Medical Records Law | Statutory |



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PROFILE
Provides compliance expertise to hospital and healthcare organizations.

EDUCATION & HONORS

BS – Business Administration, Shippensburg University

MBA – Marketing and Healthcare Administration, Wilkes College

Health Care Compliance Association Certified

Medical Group Management Association – CMPE

Fellow of the American College of Healthcare Executives

BACKGROUND

- Bret is a nationally recognized expert and veteran in healthcare compliance.
- Bret has more than 30 years of diversified healthcare management, operations and compliance experience, and presented at more than 100 regional and national industry conferences and meetings on numerous compliance topics.
- Bret is a fellow of the American College of Healthcare Executives.
- Bret is the author of *The Compliance Officer's Handbook*, which was published in 2006.
- From 2010 to 2013, he was the Senior Vice President, Chief Ethics and Compliance Officer of the University of Medicine and Dentistry of New Jersey (UMDNJ). There he successfully re-engineered the nation's largest sector compliance and ethics program under a rigorous Corporate Integrity Agreement (CIA) with the HHS OIG.
- Bret has taught undergraduate and graduate courses as an adjunct faculty member.
- He is certified in the Health Care Compliance Association and the Medical Group Management Association.
- He is a past president (2001-2003) for Region 2 of the HCCA.

PROFESSIONAL & INDUSTRY EXPERIENCE

- Bret is a recognized thought management leader experienced in performing consulting engagements and providing compliance expertise to hospital and healthcare clients.
- At UMDNJ, the largest public sciences university in the country, Bret reported to the Chairman of the Audit Committee of the Board of Trustees and University President. There he managed 40 compliance, ethics and investigations professionals and an annual operating budget of \$3.2 million.
- Bret has extensive experience in providing Compliance Effectiveness Reviews for clients.
- Bret provides compliance education to a wide variety of healthcare clients.
- Bret was responsible for the development and ongoing management of the Corporate Compliance Program, which resulted from the nation's first Voluntary Disclosure Settlement (October, 1998) at a specialty hospital with more than 90 employed physicians. HCCA recognized the compliance program as a "Best Practice."
