Compliance and Ethics Committee Meeting
Aug 21, 2019 1:30 PM EDT

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A Compliance and Ethics Committee meeting will be held on Wednesday, August 21st, 2019, immediately following the Legal Affairs and Governmental Relations Committee meeting, at the Broward Health Corporate Spectrum Location: 1700 Northwest 49 Street, Fort Lauderdale, Florida, 33309. The purpose of this committee meeting is to review and consider any matters within the committee’s jurisdiction.

Persons with disabilities requiring special accommodations in order to participate should contact the District by calling 954-473-7100 at least 48 hours in advance of the meeting to request such accommodations.

Any person who decides to appeal any decision of the District’s Board with respect to any matter considered at these meetings will need a record of the proceedings, and for such purpose, may need to ensure that a verbatim record of the proceedings is made which record includes testimony and evidence upon which the appeal is to be based.
COMPLIANCE AND ETHICS COMMITTEE
Immediately Following
Legal Affairs and Governmental Relations Committee Meeting
July 24, 2019

1. NOTICE

Notice of this meeting is attached to the official Minutes as EXHIBIT I. The official Agenda for this meeting, as presented for the consideration of the Committee, is attached to the official Minutes as EXHIBIT II.

2. CALL TO ORDER 11:05 am.

3. COMMITTEE MEMBERS

 √ Commissioner Nancy W. Gregoire, Chair
 √ Commissioner Andrew M. Klein
 √ Commissioner Christopher T. Ure
 √ Commissioner Ray T. Berry
 √ Commissioner Stacy L. Angier
 √ Commissioner Marie C. Waugh (joined WebEx @ 11:41 am)

ADDITIONALLY PRESENT Gino Santorio/President/CEO, Alan Goldsmith/CAO, Alex Fernandez/CFO, Linda Epstein/General Counsel, Jerry Del Amo/Managing Sr. Associate, General Counsel, Brian Kozik/SVP, Compliance and Privacy, Steve Forman/Compliance Consultant, Nigel Crooks/Chief Internal Auditor.

4. PUBLIC COMMENTS None.

5. APPROVAL OF MINUTES

Approval of the Compliance and Ethics Committee meeting minutes, dated June 25, 2019.

MOTION It was moved by Commissioner Klein, seconded by Commissioner Angier, to:


Motion carried unanimously.
6. **TOPIC OF DISCUSSION**

6.1. Chief Compliance Officer Report – Brian Kozik

6.1.1. Compliance Update

Mr. Kozik updated the committee on the departmental activities since his last monthly report.

- Quarterly meetings with audit department.
- Finalizing annual conflict of interest process for organization
- Ambulatory department access to ComplianceTrac disclosure log
- Regional ambulatory compliance committee meeting launch
- 3rd quarter Focused Arrangement audit.
- Tracking remuneration audits for leases, call coverage, and medical directorships
- Conclusion of hyperbaric oxygen therapy service issue
- Overpayment of outpatient claim, 48 hour rule
- Interviews and proposals for external compliance auditing firms

6.1.2. OIG/CIA Update.

- Creation of new subgroup, Annual Audit Reporting
- Status on items requested by Monitor that were not listed in CIA
- CIA training for covered persons
- Individual waivers approved by Monitor
- Status of blanket waivers requested
- Status on sleep study audit
- IRO visit and interviews
- Stipulated penalty letter request

6.3 Report from Executive Compliance Group.

* Mr. Kozik modified the reporting order of the Subgroups below

6.3.1 Training – Melanie Hatcher

Ms. Hatcher reported that year-four online training for the organization was finalized at a completion rate of 97.76% and that the manager year-four live training launched July 1, 2019. Credentialed physician’s training had a 91% completion rate. Ms. Hatcher further reported that the Procurement Steering Committee approved the Health Stream training module for compliance and HIPAA.
6.3.5 Policies – Denise Moore

Ms. Moore reported on the status of various policies for the compliance department, which included (21) policies to date.

* Mr. Kozik added item, IRO Plan of Correction, to the agenda – Beth Cherry

Ms. Cherry reported that 77% of all items that were on the plan of correction had been completed and that only 10 items remained.

6.3.3 Disclosures – Lauren Brown spoke for Dr. Calderon, who was absent

Ms. Brown reported that the open disclosures that were two-plus years old, had decreased 14 to 9. She further reported that there were approximately 160 open disclosures that were approximately a year old.

* Commissioner Waugh joined the discussion telephonically, via WebEx.

6.3.4 Risk Assessment – Zari Watkins.

Ms. Watkins reported on the progress of the risk assessment and confirmed the process had been formally memorialized, as required by the CIA. Senior Management risk assessment training took place on July 12, 2019. The IT department was in the process of retaining a data collection solution company, in which Tableau was being considered. Ms. Watkins further reported that the assessment would be scored by the Chief Financial Officer, Chief Administrative Officer and Chief Internal Auditor so that the organization could prioritize on the highest risks scored.

* Mr. Kozik confirmed that the Sanction Screening subgroup would not be reporting this month.

6.2 Policy Approval

6.2.1 GA-001-015 Conflict of Interest Policy – Brian Kozik and Lauren Brown

Policy revisions were suggested for subsections (b) and (d) to be consistent with language provided in subsection (c). The compliance department was asked to bring revisions to the following week’s board meeting for consideration.
6.2.2 GA-004-012 Gifts Gratuities and Business Courtesies Policy

* Commissioner Berry he stepped away during the GA-004-012 Gifts Gratuities and Business Courtesies policy discussion and vote, however a quorum remained present.

6.2.3 Gifts and Gratuities Matrix

**MOTION** It was *moved* by Commissioner Angier, *seconded* by Commissioner Waugh, to:

**APPROVE THE GA-004-012 GIFTS GRATUITIES AND BUSINESS COURTESIES POLICY.**

Motion *carried* unanimously, (5/0, Commissioner Berry temporarily not present).

6.3 Special Compliance Liaison – Steve Forman.

* Commissioner Berry rejoined the meeting during Mr. Forman’s presentation.

Mr. Forman presented a PowerPoint training module titled, Overview of Assessing Regulatory Risks.

7. **ADJOURNMENT** 12:07 pm.

**MOTION** It was *moved* by Commissioner Klein, *seconded* by Commissioner Ure, to:

**ADJOURN THE COMPLIANCE AND ETHICS COMMITTEE MEETING.**

Motion *carried* unanimously.

Respectfully submitted,
Commissioner Stacy L. Angier, Secretary/Treasurer
GA-004-285 Deficit Reduction Act

I. Purpose

Broward Health is committed to its role in preventing health care fraud and abuse and complying with applicable state and federal law related to health care fraud and abuse. The Deficit Reduction Act of 2005 requires state Medicaid plans to require certain types of health care providers to establish written policies and procedures that address: 1) the federal False Claims Act (“FCA”); 2) state laws pertaining to civil or criminal penalties for false claims and statements; 3) the whistleblower protections provided under both federal and state laws and the role of these laws in preventing and detecting fraud, waste, and abuse; 4) the administrative remedies found in the Program Fraud Civil Remedies Act; and 5) the provider’s policies and procedures for detecting and preventing fraud, waste, and abuse. To ensure compliance with such laws, Broward Health has policies and procedures in place to detect and prevent fraud, waste, and abuse, and also supports the efforts of federal and state authorities in identifying incidents of fraud and abuse.

The purpose of this policy is to set forth compliance with all applicable federal and state laws pertaining to fraud, waste, and abuse in federal healthcare programs including Section 6032 of the Deficit Reduction Act of 2005.

II. Key Terms

Centers for Medicare and Medicaid Services (CMS): The Federal agency responsible for administering Medicare, Medicaid, SCHIP (State Children’s Health Insurance), HIPAA (Health Insurance Portability and Accountability Act), CLIA (Clinical Laboratory Improvement Amendments), and several other health related programs.

Deficit Reduction Act of 2005 (DRA): A federal statute that requires entities that make or receive annual Medicaid payments of $5 million dollars or more to provide detailed information in written policies applicable to [KBW1] [BJ2] the entities' employees, agents, and contractors information regarding the False Claims Act and any state law that pertains to criminal penalties for making false claims and statements to the Government or its agent and the protections for whistleblowers who report violations of these provisions.

False Claims Act (FCA): A federal statute that prohibits fraud in any federally funded contract or
program, including Medicare and Medicaid.

**Fraud:** An intentional deception or misrepresentation or misrepresentation made by a person with knowledge that the deception could result in some unauthorized benefit to himself/herself or some other person. It includes any act that constitutes fraud under applicable state or federal law.

**Waste and Abuse:** Incidents or practices that are inconsistent with legal, ethical, acceptable and sound business, fiscal or medical practices that result in unnecessary cost to health care programs or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It includes Medicare and Medicaid practices that result in unnecessary cost to the program.

### III. Policy

1. It is the responsibility of all Workforce Members to comply fully with applicable federal and state laws related to healthcare fraud, waste, and abuse. This includes the Federal False Claims Act and the Deficit Reduction Act of 2005.

2. Broward Health will provide education to Workforce Members regarding:
   a. The Deficit Reduction Act;
   b. The Federal False Claims Act;
   c. Administrative remedies for false claims and statements;
   d. Applicable state laws pertaining to false claims and statements and related civil or criminal penalties;
   e. Whistleblower protections under the Federal False Claims Act and applicable state laws;
   f. The role of laws in preventing and detecting fraud, waste, and abuse in Federal healthcare programs;
   g. Broward Health’s policies and procedures for preventing, identifying, reporting, and investigating fraud, waste, and abuse within Medicaid programs.

3. Broward Health will address the following topics in the Code of Conduct and other employee handbooks if available:
   a. State and federal laws regarding false claims and fraud and abuse;
   b. Rights and protections of whistleblowers;
   c. Policies and procedures for detecting fraud, waste, and abuse.

### IV. Procedures

1. Broward Health has implemented several prevention, reporting, and detection measures in order to address potential instances of fraud, waste, and abuse. These measures are as follows:

   A. **Prevention Measures:**
      
      i. **Corporate Compliance Program:** Broward Health has established a Corporate Compliance Program which includes a Code of Conduct, policies and procedures, training
and education, auditing and monitoring, and investigations.

ii. **Training and Education**: Annual compliance training is required for all workforce members. Additionally, specific training may be developed as a result of an audit or ongoing monitoring activities to address issues of non-compliance. The Corporate Compliance Department will develop specific training sessions to address issues of non-compliance.

B. **Detection Measures**:

i. **Auditing and Monitoring**: The Corporate Compliance Department will develop an annual work plan based on risk areas identified. The work plan sets forth activities that will be undertaken in the fiscal year. All work plans are approved by the Executive Compliance Group and, the Compliance Committee of the Board of Commissioners. Audits may also be scheduled as a result of a complaint made directly to the Corporate Compliance Department.

ii. **Investigations**: The SVP/Chief Compliance Officer (CCO), or his/her designee, performs both informal and formal investigations based upon possible reports of fraud, waste, or abuse associated with federal and state health care programs. If errors of wrongdoing are found, Broward Health will report and promptly return any overpayments to the appropriate payor.

C. **Reporting Mechanisms**:

i. Broward Health Workforce Members are obligated to report suspected non-compliant activities pursuant to the Code of Conduct via the following reporting mechanisms:
   a. An immediate supervisor or department director;
   b. the SVP/Chief Compliance Officer;
   c. 

V. **Related Policies and Compliance Documents**

VI. **References**

**Attachments**: No Attachments
I. Purpose

In accordance with the mission of Broward Health, the role of the Corporate Compliance Audit and Monitoring function is to ensure compliance with applicable laws and with the organization’s compliance standards by utilizing auditing and monitoring practices to detect criminal or other improper conduct by Broward Health Workforce Members. The Corporate Compliance Audit and Monitoring function fulfills this role by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of the department’s risk management, control, and governance processes.

The purpose of this policy is to establish a policy and procedure for evaluating Broward Health’s compliance with the Corporate Compliance Program and applicable Federal and/or State rules and regulations.

II. Key Terms

Compliance Audit: Defined under this policy as a comprehensive review of an organization’s adherence to regulatory guidelines.

Compliance Monitoring: Defined under this policy as a monitoring process involving ongoing “checking” and measuring” to ensure quality control. The process of monitoring is generally less structured than auditing and is typically performed by departmental staff. Monitoring involves, daily, weekly, or other periodic spot checks to verify that essential functions are being adequately performed and that processes are working effectively and efficiently. The process of monitoring can indicate the need for a more detailed audit.

Compliance Work Plan: Each year, the Compliance Office shall develop a Compliance Work Plan utilizing the data from the Risk Assessment, Office of Inspector General’s Work Plans and other areas identified by the SVP/Chief Compliance Officer (CCO) or their designee. The Compliance Work Plan shall be finalized and issued annually on or before January.

Departmental Monitoring: Department reviews to test on an ongoing basis compliance with policies, procedures, and applicable laws. Monitoring is performed as part of the day-to-day operations.
Risk Assessments: Each year, the Corporate Compliance Office shall perform a compliance risk assessment to analyze and prioritize areas of risk.

SVP/Chief Compliance Officer (CCO): The individual responsible for overseeing, implementing, and monitoring the compliance requirements of the Broward Health Compliance and Ethics Program. In addition, this individual also holds the title of Chief Privacy Officer.

Workforce Member: Any employee, independent contractor, agent, trainee, or other person who performs work for or on behalf of Broward Health. This includes full-time, part-time, and pool employees; associates; directors; officers; managers; supervisors; members of the Board and members of standing committees; medical staff employed by or otherwise affiliated with Broward Health; medical students and all other affiliated students or others receiving training at any Broward Health facility; and others who provide goods or services to Broward Health.

III. Policy

1. The Executive Compliance Group (ECG) and the Board Compliance Committee will oversee audit and departmental monitoring. Compliance audit and departmental monitoring is designed to evaluate Broward Health’s compliance with government regulations, contractual agreements, and all applicable Federal and State laws, as well as Broward Health policies, procedures, and Code of Conduct to protect against non-compliance and potential fraud, waste and abuse. Areas of potential risk that should be considered to be part of the Broward Health Compliance Program Work Plan are to include but are not limited to:
   a. Billing process and systems (including claims accuracy, adequacy of documentation, and coding);
   b. Advance Beneficiary Notice of Non-coverage for Medicare beneficiaries;
   c. Medical necessity, quality, and written physician orders;
   d. Record retention;
   e. Waivers of deductibles, coinsurance, and patient balance write-offs;
   f. Marketing interactions and relationships with patients;
   g. Relationships with third-parties and vendors;
   h. Excluded individuals and entities;
   i. Reporting and responding to compliance concerns;
   j. Emails and other electronic communications;
   k. Privacy and confidentiality;
   l. Medical research;
   m. Conflicts of interest; and
   n. Other areas identified by the SVP/Chief Compliance Officer (CCO), Executive Management, or their designee, as compliance risk areas.

2. The CCO is responsible for overseeing Compliance audits and reporting the results of those audits to the ECG and Compliance Committee. The ECG and subordinate management staff is responsible...
for overseeing departmental monitoring and ensuring that the monitoring is properly executed.

3. General Counsel will be consulted, as necessary, with respect to audit and monitoring activities.

4. The Corporate Compliance Department will develop a Compliance Audit Plan. Generally, the Compliance Audit Plan shall consist of periodic compliance audits to assess and enhance the implementation, operation, and effectiveness of the Corporate Compliance Program.

5. The Compliance Audit Plan may be based at least in part on the results of the compliance risk assessment. The Compliance Audit Plan and subsequent revisions will be reported to the ECG and the Board of Commissioners, as necessary.

6. All audit and departmental monitoring activities are conducted in such a manner as to maintain any appropriate legal privileges, including the attorney-client, work product, quality management and self-evaluative privileges, as applicable.

7. The results of all Compliance audit and departmental monitoring functions will be provided to the CCO, who shall then report such results to the ECG, Board Compliance Committee, Chief Executive Officer, and the Board of Commissioners, as necessary.

8. The reports provided to the Board of Commissioners will include updates on completion status of individual Compliance Work Plan items and also include requests for additional resources, as needed. This will aid the Board of Commissioners in tracking and measuring the progress of the Compliance Department in meeting the Compliance Work Plan goals.

9. In the event an audit or review reveals potential violations or areas of improvement, Management will take the appropriate corrective action in accordance with Broward Health’s policies and procedures. In addition, the CCO is responsible for verifying that the a corrective action has been implemented.

10. As appropriate, the CCO is responsible for the following, in response to a potential violation: Conducting an investigation:
    a. Advising enforcement and discipline, if warranted;
    b. Development of a plan of correction with Management to ensure a plan of correction has been completed;
    c. Working with Management in modifying Broward Health’s policies and procedures, if necessary and to the extent feasible;
    d. Reporting to applicable government agencies, including submission of any overpayments made to Broward Health within sixty (60) days of being identified.

IV. Procedures

A. Oversight

1. Compliance audit and departmental monitoring processes shall be conducted by the Corporate Compliance Department and under the supervision of the CCO.

2. The CCO recommends and facilitates auditing and monitoring processes for identified risk areas related to compliance with rules and regulations, as well as Broward Health policies, procedures, and Code of Conduct.

3. The CCO and executive management will verify the completion of compliance audits and any corrective action measures arising from them.

4. The members of the Corporate Compliance Department will have unrestricted access to all system records relevant to the audit.
5. An enterprise-wide Risk Assessment will be developed and focus on identifying and evaluating risks to Broward Health including testing the existence, adequacy, and effectiveness of internal controls and lead to the development and implementation of auditing and monitoring plans of those identified areas of risk.

6. Both the Internal Audit Department and the Corporate Compliance Department will consider the results of the enterprise-wide Risk Assessment process in developing their audit plans. Similarly, management, through the ECG, will create a monitoring plan to address risks to Broward Health.

7. The CCO will develop an Audit Work Plan to include identified high-risks in operational areas, identified risks proposed on the OIG Work Plan, and potential non-compliance with the Corporate Compliance Program.

8. The Compliance Work Plan is subject to change throughout the year contingent upon additions based on the Risk Assessment, OIG Work Plan, or issues found through the Disclosure Program.

B. **Audit**

1. The Compliance Audit process will be conducted in accordance with applicable standards as set forth in the Broward Health Audit Manual and will operate under the Management and direction of the CCO.


3. For audit preparation, the Auditors will:
   i. Gather information and conduct interviews, as necessary, to gain an understanding of the operation or system under review;
   ii. Research pertinent policies, procedures, guidelines, and regulations to assess the level of compliance of the processes being reviewed; and
   iii. Provide written documentation of findings and provide sufficient evidence to support the findings.

C. **Monitoring**

1. All departmental managers throughout the organization are responsible for ongoing monitoring of compliance risks within their area of work.

2. Departmental managers are responsible for establishing and maintaining systems to ensure appropriate resolution and implementation of corrective actions, including the development and maintaining an inventory of existing internal controls, policies and procedures to address its compliance risks. These risks must be disclosed to the Corporate Compliance Department.

3. The Corporate Compliance Department may monitor risk areas when deemed necessary by conducting an informal observation, monitoring of specific data elements, or in some instances, a subsequent audit.

D. **Resolution**

1. The resolution process will include all actions required to fully correct all issues. Depending on the nature of the problems involved, each resolution will include:
a. Timely correction of management, system and program compliance issues/deficiencies;

b. Monitoring to ensure that the corrective actions on significant deficiencies were adequately implemented to resolve the problem and ensure that it does not recur; and

c. Verification that the corrective actions are operating effectively.

2. Management officials shall maintain an audit/review resolution file(s) or other appropriate records to fully document and justify all actions taken to resolve findings that include corrective action recommendations.

3. Management is responsible for monitoring implementation of corrective actions until the identified deficiencies are corrected.

4. If the follow-up review shows that unit has not completed all actions needed to fully correct the deficiencies, the manager shall notify the CCO and report on the further actions needed and completion dates. Thereafter, the manager will continue to follow-up until he/she is satisfied that deficiencies are fully and effectively corrected.

5. The CCO may independently direct a follow-up review to verify that corrective actions were successful.

6. The CCO will make regular reports to the ECG and the Board Compliance Committee on the status of all actions.

V. Related Policies and Compliance Documents

- Broward Health Compliance Department Audit Manual
- Chief Compliance Officer: Appointment, Roles, and Responsibility, Policy No. GA-004-250
- Enforcement and Discipline, Policy No. GA-004-238

VI. References


Broward Heath Corporate Integrity Agreement with the DHHS Office of Inspector General, dated August 20, 2015.

Attachments: Standard Operating Procedure for Enterprise Risk Management Risk Assessment, Review,
AGENDA

• Refresher: Statutory and Regulatory Requirements
• Refresher: Other Broward Health Requirements
  – CIA
  – Policies and Procedures
• Compliance Risk Areas
  • Signed, Written Agreement
  • Fair Market Value
  • Commercial Reasonableness
  • Volume/Value
AGENDA (cont.)

- Considerations for Special Types of Arrangements & Enforcement Actions
  - On-Call Arrangements
  - Leases and Space Use
  - Personal Services and Management Agreements
  - Employment Agreements
- Disclosure Requirements
- Individual Responsibility
REFRESHER: STATUTORY AND REGULATORY REQUIREMENTS
ANTI-KICKBACK STATUTE (AKS)
42 U.S.C. § 1320A-7B(B)

• Anti-Kickback Statute (AKS) – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal Health Care program.
AKS: ELEMENTS

- Something of value (Remuneration)
- Offered, paid, solicited, or received
- Knowingly and willfully
- To induce or in exchange for Federal program referrals
WHAT IS REMUNERATION

Remuneration is:

• Anything of value

• “In-cash or in-kind”

• Paid directly or indirectly

• Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations
OFFERED, PAID, SOLICITED, OR RECEIVED

• Different perspectives – payors and payees

• *Old focus*: Payors subject to prosecution

• *New focus*: Payors and payees (typically doctors) subject to prosecution
TO INDUCE FEDERAL PROGRAM REFERRALS

• Any federal healthcare program

• Covers any act that is intended to influence and cause referrals to a Federal healthcare program

• “One purpose test” and culpability can be established without showing a specific intent to violate the statutory prohibitions
FINES & PENALTIES

Criminal penalties:
- Felony, imprisonment up to 5 years and a fine up to $25,000 or both
- Mandatory exclusion from participating in Federal healthcare programs
- Brought by the DOJ

Civil Penalties
- A violation under the Anti-Kickback Statute constitutes a false claim under the Civil False Claims Act (FCA)
- Expanding use of the FCA

Administratively
- Monetary penalty of $50,000 per violation and assessment of up to 3x the remuneration involved
- Discretionary exclusion from participating in Federal healthcare programs
SAFE HARBORS UNDER AKS

• 26 “Safe Harbors” have been created by the OIG
• Compliance with Safe Harbors is voluntary
• In order to qualify for Safe Harbor protection, must meet all of the conditions

Examples of Safe Harbors:
• Space/equipment rentals
• Employees
• Personal Services and management contracts
• Practitioner recruitment
• Investment in group practices
• Investment interests
• Local transportation
STARK LAW’S PROHIBITIONS

• Unless an exception applies and its requirements are satisfied, a physician may not refer:
  - Medicare beneficiaries
  - For designated health services (DHS)
  - To an entity with which the physician or an immediate family member has a financial relationship

• Unless an exception applies and its requirements are satisfied, an entity may not submit a claim to the Medicare program for DHS furnished pursuant to a prohibited referral.
• Stark is an absolute prohibition of a physician referring “designated health services” to a health care provider with which the physician has a financial relationship.
  – The provider that receives the referral cannot bill Medicare for the services if there is a financial relationship.

• However, if the relationship fits into an “exception” then the referral and the billing are allowed.

• This is a strict liability law – there is only one question to consider:
  – Does the financial relationship squarely comply with all the criteria of one of the Stark exceptions?
Designated Health Services (DHS)

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services (also nuclear medicine)
- Radiation therapy services and supplies

- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
- Durable medical equipment and supplies
SANCTIONS

- **Denial** – CMS will not pay claims for improperly referred DHS.
- **Refund** – Broward Health has duty to refund
- **Civil Monetary Penalties**
  - $15,000 for improperly presenting or causing another to present an improper claim
  - $100,000 for “scheme” to circumvent
- **Potential exclusion**
- **Potential FCA liability**
COMMON ELEMENTS NECESSARY FOR COMPLIANCE WITH THE STARK LAW

• Arrangement must be in writing and signed by the parties

• Arrangements must have a 1-year duration

• Compensation must be set in advance and in fair market value

• Compensation must not be determined in a manner that varies with or takes into account the volume or value of referrals or other business generated between the parties

• Arrangements must be commercially reasonable, even in the absence of referrals
  – This is not an exhaustive list, and not all requirements exist in every exception to the Stark Law.
CERTAIN FLORIDA LAWS

• Florida Anti-Kickback Law
  – Fla. Stat. § 456.054
  – States that offering, paying soliciting, or receiving a kickback either directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients,” constitutes a violation.
  – Kickback is defined as any form of: “remuneration or payment, by or on behalf of a provider of health care services or items, to any person as an incentive or inducement to refer patients for past or future services or items, when the payment is not tax deductible as an ordinary and necessary expense.”
  – Broad applicability – “all payers” not just government health care programs
  – Although no statutory or regulatory safe harbors or exceptions, case law suggests federal safe harbors also protected under Florida law
  – Felony; 5 or 10 year maximum imprisonment
CERTAIN FLORIDA LAWS

• Florida Physician Self-Referral Law
  – Fla. Stat. § 456.053
  – Applies to all physician referrals to entities in which they have an investment interest – unless an exception is met. Certain exceptions may be more stringent than Stark Law requirements (ex: physician referral to own medical practice)
  – Restricts only physician ownership and investment interests, not compensation arrangements, and applies to all healthcare items or services regardless of the source of payment.
  – Penalties include Payment prohibition; refund obligation
  – Knowing violations subject to $15,000 civil penalty
  – $100,000 penalty for circumvention scheme
# SUMMARY: AKS v. STARK

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<thead>
<tr>
<th></th>
<th><strong>AKS</strong></th>
<th><strong>Stark</strong></th>
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<tbody>
<tr>
<td><strong>Citation</strong></td>
<td>42 U.S.C. 1320a-7b(b)</td>
<td>42 U.S.C. 1395nn</td>
</tr>
<tr>
<td><strong>General Prohibition</strong></td>
<td>Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal healthcare program business</td>
<td>Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies</td>
</tr>
<tr>
<td><strong>Referrals</strong></td>
<td>Referrals from anyone</td>
<td>Referrals from a physician</td>
</tr>
<tr>
<td><strong>Items/Services</strong></td>
<td>Any items or services</td>
<td>Designated health services</td>
</tr>
<tr>
<td><strong>Intent</strong></td>
<td>Intent must be proven (knowing and willful)</td>
<td>- Strict liability statute (no intent required) for overpayments</td>
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<td>- Knowing violation for CMPs</td>
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## SUMMARY: AKS v. STARK

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<th>AKS</th>
<th>Stark</th>
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<tr>
<td><strong>Penalties</strong></td>
<td><strong>Criminal:</strong></td>
<td><strong>Civil/Administrative:</strong></td>
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<tr>
<td></td>
<td>▪ Fines up to $100,000 per violation</td>
<td>▪ Overpayment/refund obligation</td>
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<td></td>
<td>▪ Up to a 10-year prison term per violation</td>
<td>▪ False Claims Act liability - if knowing</td>
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<td></td>
<td><strong>Civil/Administrative:</strong></td>
<td>▪ CMP and exclusion for knowing violations</td>
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<tr>
<td></td>
<td>▪ False Claims Act liability</td>
<td>▪ Potential $15,000 CMP for each service</td>
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<tr>
<td></td>
<td>▪ CMP and exclusion</td>
<td>▪ Civil assessment of up to 3x the amount claimed</td>
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<td>▪ Potential $50,000 CMP per violation</td>
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<tr>
<td></td>
<td>▪ Civil assessment of up to 3x the amount of the kickback OR 3x the</td>
<td></td>
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<td></td>
<td>amount claimed/damages</td>
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<tr>
<td><strong>Exceptions</strong></td>
<td>Voluntary safe harbors</td>
<td>Mandatory exceptions</td>
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<td>(42 CFR 1001.952); voluntary statutory exceptions*</td>
<td>(42 CFR Part 411, Subpart J)</td>
</tr>
<tr>
<td><strong>Federal Health</strong></td>
<td>All</td>
<td>Medicare (Applicability to Medicaid subject of much litigation)</td>
</tr>
<tr>
<td><strong>Care Programs</strong></td>
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FALSE CLAIMS ACT

- Violation of FCA results in civil liabilities to anyone who:
  - Knowingly presents, or is involved in presenting, soliciting, or receiving a false or fraudulent claim record or statement for payment or approval
  - Defrauds the government by getting a false or fraudulent claim allowed or paid
  - Uses a false record or statement to avoid or decrease any obligation to pay the government
FALSE CLAIMS ACT DAMAGES

• A person who violates the FCA must repay
  – Triple (3x) the amount of damages suffered by the government PLUS
  – A mandatory civil penalty of at least $11,000 and no more than $22,000 per claim

*Example*: A person who submits 50 false claims for $50 each is liable for between $557,500 and $1,115,000
CORPORATE INTEGRITY AGREEMENT (CIA) REQUIREMENTS
CIA STATUS

• Broward Health is in the 4th Year of a 5-year CIA with HHS OIG that became effective August 31, 2015:
  – Settlement leading to the CIA related to allegations that were investigated by DOJ and OIG that certain physician compensation agreements did not comply with Stark Law
  – CIA compliance requirements are much broader than settled allegations and touch all aspects of Broward Health operations
CIA REQUIREMENTS

• Reportable Events

• Compliance Disclosure Program

• Overpayments

• Disclosure of Government Investigations
CIA REQUIREMENTS

Focus Arrangements Procedures

• The CIA requires the following procedures related to all Focus Arrangements:
  – Focus Arrangements Tracking System
    • Creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements
    • Tracking remuneration to and from all parties to Focus Arrangements
    • Tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the required services
    • Monitoring lease space, supplies, and equipment
  – Internal review and approval process
    • Written review and approval process to ensure AKS/Stark Compliance, including: (i) legal review, (ii) specification of business rationale and (iii) documentation of FMV
    • Compliance Officer review
  – Implementation of effective responses to suspected violations
CIA REQUIREMENTS

Focus Arrangements Procedures (cont.)

• New or renewed Focus Arrangements
  – In writing and signed by Broward Health and parties
  – Parties that are Covered Persons must receive 1 hour of AKS/Stark training
  – Parties must receive Code of Conduct and AKS/Stark policies and procedures
  – Written certification that parties shall not violate AKS/Stark

NOTE also that auto-renewals are considered renewals
RELEVANT BROWARD HEALTH COMPLIANCE POLICIES AND PROCEDURES

• Disclosure Program

• Open Lines of Communication

• Fair Market Value and Commercial Reasonableness

• Disclosure of Physician Ownership and Financial Arrangements
RELEVANT BROWARD HEALTH COMPLIANCE POLICIES AND PROCEDURES

• Physician and Non-Physician Financial Arrangement Review, Approval, Tracking and Monitoring

• Overpayments
COMPLIANCE RISK AREAS
CLERICAL ISSUES

• Missing signatures

• Insufficient agreement in writing

• Holdovers beyond what is permitted by the Stark Law
  – Please note that the requirements of Broward Health’s CIA do not allow for holdovers in any circumstance. Any holdover identified must be reported to Corporate Compliance and General Counsel
THE WRITING REQUIREMENT

• Standard: “The relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made.” (80 FR 71315)

• Single “formal contract” is not required:
  – Collection of documents may satisfy the writing requirement
  – Collection of documents may include “contemporaneous documents evidencing the course of conduct between the parties” (80 FR 71315)
  – Note: Broward Health policy requires a single signed written agreement – this is best practice and the best way to ensure our compliance
COMMERCIAL REASONABLENESS VS. FAIR MARKET VALUE (CONT.)

• Key Distinction:
  – Fair market value assesses the reasonableness of the “range of dollars”
  – Commercial reasonableness looks to the reasonableness of the business arrangement generally

• Because of this differentiation, an arrangement may be at fair market value but not be commercially reasonable
VOLUME/VALUE OF REFERRALS

• “Referral” is used in a very broad sense in statutes, regulations, and enforcement

• Compensating based on the volume or potential volume of health care business or referrals is prohibited

• Compensating based on the value or potential value of health care business or referrals is prohibited

• All-payor because of Florida legal requirements
CONSIDERATIONS FOR SPECIAL TYPES OF ARRANGEMENTS
EMPLOYMENT

- Commencing services without written, signed agreement

- Paying for services (or promising to pay for services) without written, signed agreement

- Failure to obtain or update FMV

- Paying in excess of FMV

- Payments take into account volume/value
PERSONAL SERVICES AND MANAGEMENT AGREEMENTS

• Commencing services without written signed agreement

• Paying for services (or promising to pay for services) without written, signed agreement

• Changes to duties and responsibilities under agreement

• Failure to obtain or update FMV

• Changes to compensation

• Not commercially reasonable

• Compensation not set in advance
ON-CALL ARRANGEMENTS

• New policy addressing call arrangements finalized and approved: GA-004-500, Call Coverage Policy

• No separate panels for PPUC or consultation

• Call coverage panels for any of Broward Health’s clinical specialties shall be provided exclusively by employed physicians within a Specialty only if Broward Health determines that the inclusion of qualified non-employed physicians on such Call Coverage Panel cannot be determined to be Commercially Reasonable and consistent with FMV
ON-CALL ARRANGEMENTS

• Improved monitoring of calls and requests to come into hospitals

• Improved notification of call panels and process for requesting to be on and approved for panels

• Ability to seek internal review of determination on being approved for panels
LEASES AND SPACE USE

• Unsigned leases

• Changes to leased space

• Failure to obtain or update FMV

• Failure to confirm square footage or other factual information

• Informal space use agreements without written, signed agreements

• Failure to collect lease payments
SELF-DISCLOSURE REQUIREMENTS
OPTIONS FOR SELF-DISCLOSURE

• CMS’s Self-Referral Disclosure Protocol (SRDP)
  – Only available for violations of the Stark Law
    • Not available for routine billing noncompliance
    • Not available where violations of anti-kickback statute are present

• OIG’s Self-Disclosure Protocol (SDP)
  – Not available for Stark Law-only violations
  – Must have an Anti-Kickback Statute violation

• United States Attorney

• Medicare Administrative Contractors
  – Must refund 100% of the overpayment; no compromise authority with respect to Stark Law violations
INDIVIDUAL RESPONSIBILITY
INDIVIDUAL RESPONSIBILITY

• Yates Memorandum

• Indictment of John Holland, Former CEO of a Tenet hospital (GA)

• Settlement with Ralph J. Cox, III, Former CEO of Tuomey (SC)

• Additional Enforcement Actions

• Do’s and Don’ts
YATES MEMORANDUM

• Reiterates DOJ’s focus on bringing civil and criminal cases against individuals

• No routine releases of individuals in settlements with providers

• DOJ and OIG seeking entity cooperation as part of settlements to assess and bring cases against individuals, particularly exclusion cases

• No indications of any change with new administration

• Affirmed by DOJ prosecutor March 27 at widely-attended industry conference
INDIVIDUAL LIABILITY

- Former Tenet Healthcare executive, John Holland, is facing criminal charges for implementing a healthcare fraud scheme involving kickbacks in exchange for referrals and misleading federal authorities about the company’s billing practices.
  - Tenet Healthcare settled the allegations against the company for $514M in 2016
  - Former Tuomey Healthcare System CEO to pay $1M to settle claims arising from his involvement in the hospital’s violation of the Stark Law
    - Ralph Cox III will also be excluded from federal healthcare programs for 4 years
    - Government alleged that Cox caused the hospital to enter into arrangements with 19 physicians that violated the Stark Law.
RECENT SETTLEMENTS AND PROSECUTIONS OF STARK LAW AND/OR ANTI-KICKBACK STATUTE VIOLATIONS

- University Behavioral Health of El Paso paid $860K in a civil settlement to resolve allegations that the organization submitted false claims to Medicare that were tainted by the payment of kickbacks to a doctor under the appearance of a professional services agreement – the payments were above FMV or for services not provided.

- Tenet Healthcare Corp. and two Atlanta subsidiaries agreed to pay $513M to resolve criminal charges and civil claims relating to a scheme to defraud the United States and pay kickbacks in exchange for patient referrals:
  - The subsidiaries agreed to plead guilty to conspiracy to defraud the United States and pay healthcare kickbacks and bribes, and will forfeit $145M to the United States.
  - Tenet Healthcare Corporation paid $368M to resolve the civil claims originating in a whistleblower action.
  - The government stated this is the first case brought through the assistance of the DOJ Criminal Division’s corporate healthcare fraud strike force and is one of many active corporate investigations by the strike force.
RECENT SETTLEMENTS AND PROSECUTIONS OF STARK LAW AND/OR ANTI-KICKBACK STATUTE VIOLATIONS

- Lexington Medical Center agreed to pay $17M to resolve allegations of improper billings resulting from violations of the physician self-referral law related to its purchase of certain physician practices.
  - Whistleblower and government alleged that the purchase prices took into account the volume or value of physician referrals, were not commercially reasonable, or provided compensation in excess of FMV

- Dr. Asad Qamar and his medical practice, the Institute of Cardiovascular Excellence, agreed to pay $5.3M to resolve allegations that they improperly billed federal healthcare programs.
  - Allegations include billing and medically unnecessary and inadequately documented peripheral artery interventional services and related procedures
  - Allegations include paying kickbacks to patients by routinely and indiscriminately waiving Medicare copayments irrespective of the patient’s financial needs.
  - Dr. Qamar is excluded from participation in any federal healthcare programs for 3 years, followed by a 3-year integrity agreement with OIG.
RECENT SETTLEMENTS AND PROSECUTIONS OF STARK LAW AND/OR ANTI-KICKBACK STATUTE VIOLATIONS

- Following a self-disclosure to the United States Attorney Office, Tri-City Medical Center agreed to pay $3.2M to settle allegations that it submitted false claims to the Medicare program because it violated the physician self-referral law by entering into certain arrangements with its former chief of staff that appeared not to be fair market value for the services furnished or not commercially reasonable.
  - The hospital also identified 92 financial relationships with community-based physicians that did not satisfy the requirements of an applicable exception, primarily due to expiration of the agreements or lack of written documentation of the arrangement.
QUI TAM RELATORS

- Physicians
- Current and former employees
- Consultants
- Competitors

Nearly all FCA recoveries against healthcare entities in the last three years came from cases filed by *qui tam* relators. Of $7.3 billion recovered from healthcare entities in 2015-17, $6.9 billion of that originated from *qui tam* suits.
QUI TAM RELATORS

Source: Mintz Levin Health Care Enforcement Year in Review and 2018 Outlook: Trends In Health Care False Claims Act Cases

DO’S AND DON’TS

• Do comply with Broward policies and Code of Conduct.

• Do bring concerns to supervisor, compliance department, legal department, or hotline immediately.

• Don’t try to “figure it out” yourself.

• Don’t skip processes or fail to complete forms.

• Do give yourself enough time to follow all requirements.

• Don’t make informal commitments about compensation or compensation methodology.

• Don’t make “handshake” deals.

• Don’t overlook failure by other parties to pay amounts due.
DO’S AND DON’TS

• Don’t overlook failure by other parties to perform contracted duties.

• Don’t overlook other parties’ failure to follow policies or contractual requirements.

• Do follow business courtesies policy.

• Don’t accept gifts, payments, or anything of value in exchange for referrals or business (and don’t offer them).

• Don’t offer or accept cash or equivalents for any purpose.

• Do avoid any conflicts of interest (or the appearance of a conflict).