Size does not matter: How any physician practice – small or large – spots a compliance issue

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HCCA’s 23rd ANNUAL COMPLIANCE INSTITUTE
APRIL 7, 2019

OIG on Size: “use the resources available to you”

What does it mean? Lack of specifics causes angst. How do you determine what resources are available? Where has the OIG landed in the past on resource availability?
Acquisition Environment

• The current acquisition environment puts a twist on this “size matters” issue

• As the acquiring body, what are the expectations as to the newly-acquired (formerly small) division?

• If you are the acquired company, what should you expect as to culture change?

• If a few smaller companies merge, are they now deemed to have greater resources than they had?

Part one:

What can the OIG’s Seven Pillars of Compliance tell us about size & resources?
The U.S. Department of Health and Human Services, Office of Inspector General (OIG), has routinely included 7 compliance pillars that should be included in every compliance program.

The Provider must ensure these pillars are in its program.

The 7 HHS/OIG COMPLIANCE PILLARS

- Designating a Compliance Officer
- Implementing Compliance Practice Standards
- Conducting Internal Monitoring and Auditing
- Conducting Appropriate Education and Training
- Responding Appropriately to Detected Offenses and Developing Corrective Action
- Developing Open Lines of Communication
- Enforcing Disciplinary Standards Through Well-Publicized Guidelines
1. Designating A Compliance Officer or Contact

The Provider will:

• Designate a Compliance Officer in charge of overseeing the Compliance Program who will be charged with executing compliance specific activities within the organization.
• Clearly delineate Compliance Officer duties for overseeing and implementing the Compliance Program.
• Begin steps to create a Compliance Committee charged with providing general oversight responsibility for Provider’s compliance and ethics programs, policies and procedures.

2. Implementing Compliance and Practice Standards

The Provider will:

• Begin to implement compliance policies and procedures to adequately ensure compliance with state and federal laws, regulations, and sub-regulatory guidance.
• For example, Provider will implement:
  • Revised Corrective Action Plans to address non-compliant behavior.
  • Revised Self-Disclosure procedures to conform with new legal requirements.
  • Revised Screening Procedures for Excluded Providers.
3. Conducting Internal Monitoring and Auditing

The Provider will:

• Begin planning for periodic audits to be conducted for all physician employees
• Begin planning for periodic audits of all coders
• Begin planning for outside audits to be conducted by independent “outside auditors”
• Implement a procedure for follow-up audits of physicians when Corrective Action has been initiated

4. Conducting Appropriate Education and Training

The Provider will:

• Begin planning for Additional Compliance Training through:
  • Morning “line ups” filled with compliance tips
  • Dissemination of an internal newsletter and e-blast on a monthly basis
  • Implementing a plan for physicians to complete an annual training at a physician retreat; with 1:1 feedback for each physician from biennial audits conducted
  • Keeping records of all training and education completed by employees going forward to ensure records are always on hand to demonstrate that training has taken place for all personnel
5. Responding Appropriately To Detected Offenses and Developing Corrective Action

The Provider will:

- Implement or update a Corrective Action Plan that will be tailored for specific non-compliant activity
- Implement a Corrective Action Plan guideline example that can be used by all compliance personnel going forward when Corrective Action is needed
- Institute a strict schedule to accompany every Corrective Action plan that details when improvement benchmarks are to be met, follow-up audits to be completed, and further corrective action implemented if necessary

6. Developing Open Lines of Communication

The Provider will:

- Set up a reporting structure to be followed by all employees who discover non-compliant activity occurring
- Set up communication with outside compliance counsel through monthly compliance update phone calls in order to relay compliance concerns, tailor the information “feed” and help with “detection” of non-compliant activities
- Implement an employee agreement regarding reporting internally and externally.
7. Enforcing Disciplinary Standards Through Well-Publicized Guidelines

The Provider will:

- Establish policies and procedures that create a system for disciplining "repeat offenders" where it has been demonstrated that "Corrective Action Plans" have not been met by individuals who have previously engaged in non-compliant activity
- Craft a plan to widely publicize disciplinary standards to employees, so that all employees are aware of the consequences for engaging in non-compliant activity

What Civil Monetary Penalties and Corporate Integrity Agreements reveal (or don’t reveal) about whether size matters

PART TWO: ENFORCEMENT
Corporate Integrity Agreements: When Size Does NOT Matter: Common CIA Elements for **BIG** and **small** Organizations

- Establishes oversight for a defined term over the full scope of the impacted organization
- Requires the establishment and maintenance of a compliance program
- Mandates training and education
- Designates a fixed number of claims or processes to be reviewed
- Contains vendor and employee screening requirements
- Imposes detailed reporting requirements

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Corporate Integrity Agreement: **small**

*Sole practitioner, Dr. Norman Brooks, M.D., owner of The Skin Cancer Medical Center in Encino paid $2,681,400 to settle claims initially brought in a *qui tam* suit alleging that he falsely diagnosed skin cancer in some patients so that he could perform and bill for unnecessary surgeries in *United States ex rel. Burke v. Norman A. Brooks, M.D., Inc. et al.* He also entered into a CIA that included the following terms:*

- **Establish and Maintain a Compliance Program:** Within 60 Days in a prominent place post a notice that provides the HHS OIG Fraud Hotline telephone number as a confidential means by which suspected fraud or abuse may be reported.
- **Term:** Three Years
- **Scope:** Includes all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Dr. Brooks.
- **Training and Education:** Minimum of 3 hours of training during the first year and a minimum of 6 hours of training per year thereafter. Additional training may be required in year two and three.
- **Claims Review:** Independent Review Organization (IRO) to conduct a statistically valid quarterly claims review of 30 paid claims using RAT-STATS and provide the report.
- **Screening Requirements:** Screen all prospective Covered Persons against the Exclusion List prior to engaging their services and as part of hiring or contracting process and monthly thereafter.
- **Reporting Requirements:** Detailed reporting requirements including reporting overpayments, government investigations or legal proceedings, Stark Law violations, among others.
Corporate Integrity Agreement: small

*United States, et al. ex rel. Siwicki v. Arthur S. Portnow, M.D., et al.*, Dr. Arthur Portnow, P.A., d/b/a Apple Medical and Cardiovascular Group, d/b/a Apple Medical Group (collectively, Dr. Portnow) agreed to pay $1.95 million to resolve False Claims allegations related to claims for medically unnecessary services, arising from a *qui tam* claim, for ultrasound tests performed on Medicare patients from 2009-2017. Dr. Portnow entered into a CIA that included the following terms:

- **Establish and Maintain a Compliance Program:** Within 60 Days in a prominent place post a notice that provides the HHS OIG Fraud hotline. Telephone number as a confidential means by which suspected fraud or abuse may be reported.
- **Term:** Three Years
- **Scope:** Includes all owners and employees of Portnow and all contractors, agents, and other persons who furnish patient care services or services or who perform billing or coding functions on behalf of Portnow.
- **Training and Education:** Minimum of 5 hours of training during the first year on designated topics. New Covered persons to receive training within 90 days. Additional training may be required in year two and three.
- **Claims Review:** Independent Review Organization (IRO) to conduct a statistically valid quarterly claims review of 30 past claims using RITE: $1.95M and provide the report.
- **Screening Requirements:** Screen all prospective Covered Persons against the Exclusion List prior to engaging their services and as part of hiring or contracting process and monthly thereafter.
- **Reporting Requirements:** Detailed Reporting requirements including reporting overpayments, government investigations, or legal proceedings, Stark Law violations, among others.

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Corporate Integrity Agreement: BIG

*U.S. ex rel. Luke, State of California ex rel. Luke v. Gardena Hospital, L.P. d/b/a Memorial Hospital of Gardena, Avanti Hospitals, LLC* agreed to pay $8.1M to settle claims they violated the FCA by submitting or causing Avanti’s subsidiary, Memorial Hospital of Gardena (Gardena Hospital), to submit false claims to Medicare and Medicaid for referrals by a doctor who received kickbacks and other payments from Gardena and other Avanti affiliates in violation of both AKS and Stark. Specifically, they alleged that there were kickbacks to the doctor by Avanti and Gardena in engaging in the doctor as a medical director in a payment far exceeding FMV in an attempt to get him to refer to the hospital. They also entered into a CIA that included the following terms:
BIG: Overview of Avanti Gardena Hospital Corporate Integrity Agreement (continued)

Establish and maintain a compliance program to include the following elements:
1. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations
2. Develop written policies and procedures for the compliance program and update them at least annually

Term: 5 years
Scope: Defined to include Stark referral relationships

Training and Education:
Write 90 days develop a plan for at least annual training on the OIA and Compliance Program requirements including Stark and AM
Conduct Board training (2 hours minimum) addressing corporate governance responsibilities of the board members and the responsibilities of
the board members with respect to review and oversight of the Compliance Program. New board members should receive the training within
30 days of joining the Board.

Screening Requirements: Screen all prospective Covered Persons against the Exclusion List prior to engaging their services and as part of hiring
or contracting process and monthly thereafter.

Reporting Requirements: Detailed Reporting requirements including reporting overpayments, government investigations or legal proceedings,
Stark Law violations, among others.

Additional Items:
1. Compliance with AKS and Stark Law: Focus Arrangements Procedures
2. Risk Assessment and Internal Review Process (at least annually) for the term of the CIA
3. Disclosure Program (e.g., a toll-free compliance telephone line)

Corporate Integrity Agreement: BIG

Pentec Health, a specialty infusion pharmacy provider of nutritional therapies for patients suffering from chronic renal failure paid $17M to settle false claims act allegations that they billed excessive amounts of product and wasted during the compounding process and routinely waived patient copay and deductible obligations to induce prescriptions. They were also alleged to have submitted duplicate and improperly coded claims to the Federal Employee Health Benefits Program. The case, United States et al. ex rel. Jean Brasher v. Pentec Health, Inc., included a corporate integrity agreement as follows:
BIG: Overview of Pentec Health Corporate Integrity Agreement (continued)

Training and Education: Within 90 days develop a plan for 24 hours annual training on the CIA and Compliance Program requirements, to include Stark and ABA. Conduct Board training (2 hours minimum) addressing corporate governance responsibilities and the Board responsibilities for oversight of the Compliance program. New Board members to receive training within 30 days of joining the Board.

Screening Requirements: Screen all prospective Covered Persons against the Exclusion List prior to engaging them and as part of hiring or contracting process, and monthly thereafter.

Reporting Requirements: Detailed reporting requirements including reporting agreements, personal investigations or legal proceedings, Stark Law violations, and others.

Claims Review: Independent Review Organization (IRO) to conduct a claims random sample review.

Additional Items:
- Risk Assessment and Internal Review Process (at least annually) for the term of the CIA
- Disclosure program (e.g., Stark-free compliance telephone line)

Establish and maintain a compliance program to include the following elements:
1. Compliance Officer and Executive, Board of Directors, and Management Compliance Oversight.
2. Develop written policies and procedures for the compliance program and update them at least annually.

Term: 5 years
Scope: Includes all owners and employees of Pentec and all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Pentec.

Recognizing the Differences in Resources: Where Size DOES Matter in Corporate Integrity Agreements: Differences for BIG and small Organizations

A BIG organization will have more detailed requirements for establishing a compliance officer, committee and Board of Directors’ oversight of compliance

A BIG organization will have to provide detailed compliance policies and procedures under the CIA and review them annually

A BIG organization will need to conduct Board training and annual training for everyone

A BIG organization will be required to conduct an annual risk assessment

A small organization may not be required to establish it own hotline but may be able to post the HHS hotline number
A High Risk Area for Everyone: Civil Monetary Penalties and Exclusion Screening

The list goes on:

- **11-27-2018 Spurwink Services (Spurwink), Portland, Maine paid $61,461.00 to the OIG to settle claims that Spurwink employed an excluded residential treatment specialist, who provided items or services to Spurwink’s patients that were billed to MaineCare**

- **11-7-2018 University of Chicago Medical Center (UCMC), Chicago, Illinois paid $253,671.20 to the OIG to settle claims that UCMC, through a staffing agency, employed an excluded registered nurse, who provided items or services to UCMC’s patients that were billed to Federal health care programs**

- **9-27-2018 Newark Community Health Centers, Inc. paid $98,750.36 for employing an excluded QA and Risk Management physician who provided items or services that were billed to Federal health care programs**

- **8-2-2018 Gerrish Chiropractic Center, Bar Harbor, Maine paid $7,019.10 for employing an office manager and chiropractic assistant who provided items or services to Gerrish’ patients that were billed to Federal health care programs**

- **7-2-2018 William H. Newman, M.D. and Allergy & Asthma Specialists of Northern Vermont, P.C. (collectively, “Dr. Newman”) paid $61,142.96 for employing an excluded Registered Nurse who provided items or services to Dr. Newman’s patients that were billed to Federal health care programs**

- **1-4-2019 Baptist Village of Owasso (BVO) in Owasso, Oklahoma paid $96,020.92 to the OIG to settle claims that BVO employed an excluded admission specialist, who provided items or services to BVO’s patients that were billed to Federal health care programs**
Exclusion Screening and CMPs: Key Take-Aways

Exclusion screening is required regardless of company size.

Does your company engage temporary employees or employees from staffing agencies?
Does your company screen prior to hire, monthly, and require employees to notify you of any changes to their status?
All employees, clinical and non-clinical, should be screened for exclusion.
Does your company screen workers or beneficiaries enrolled in federal or state healthcare programs?

Top 10 tips in scaling your compliance program to your size and resources

PART THREE: SCALE THIS!
Tip #1: Have support for the way you structure compliance in the organization

- Is a compliance committee in charge of overseeing the compliance program in your organization?
- What are its duties, expectations and deliverables?
- What happens if deliverables aren’t delivered or duties aren’t met?
- Would you categorize their involvement as heavily detailed?
- How involved is your compliance officer in operational and compliance activities?
- Is your compliance officer responsible for performing normal job duties outside of his or her compliance role?

Tip #2: Tailor your policies to your practice’s services and structure

- Does your organization have any written policies and procedures or other standards?
- Do your policies clearly explain your adherence to all applicable federal and state statutory and regulatory legal requirements?
- Do you feel your organization’s policies successfully implement the operation of the compliance program?
- How are your compliance plan, policies, and procedures tailored to your problems at your place of work?
Do your policies and procedures provide for standards of conduct to be followed?
• How are your policies and procedures and standards of conduct disseminated to your employees?
• At what point in time do you communicate them to your employees?

Do your policies address situations when non-compliant activity is discovered by employees?
• Are there instructions on how employees are to convey non-compliant information to the compliance officer or compliance committee?

Do your policies contain protocols for exploring non-compliant activity and resolving allegations of instances of non-compliance?

Does your operational processes accurately match your policies?

Do you review your policies and operational processes annually?

Policies & Standards (continued)
Tip #3: Document why you are monitoring what you are monitoring

• Does your organization have an audit plan that addresses issues on the OIG Workplan and accounts for issues you have found at your company in the past?

• Do you have a structure in place to continuously monitor and audit to determine whether it is compliant with federal and state statutory, regulatory, and sub-regulatory requirements (including Medicare regulations)?
  • How often is each physician’s coding audited?
  • Is auditing done by a certified professional coder?
  • Is auditing done inside or outside of the hospital or physician group?
  • Is auditing done for in-office work, procedures, evaluation and management (E&M) codes, or all work?

Audits and Monitoring

Do you feel your organization devotes adequate resources to conducting routine audits to ensure compliance with Medicare regulations?

Are audit reports directly communicated to your compliance officer or compliance committee?
  • Are they performed under attorney-client privilege?
Tip #4: Use technology and free/low cost resources to educate!

- Does your organization provide any training or education on compliance matters?
- Does this education and training contain instruction on the laws and rules comprising fraud, waste, and abuse prohibitions as well as HIPAA security and privacy requirements concerning patient information?
- Can you explain how this education and training is conducted?
- Is education and training provided to all employees or just full-time employees?

Conduct Appropriate Training and Education (continued)

- At what point in time is training for employees and board members provided to them?
- How have you tried to implement training sessions?
  - What techniques have been the most effective (e.g., PowerPoint presentation, video, training exercise, handout, quiz, small group activity)?
- Do you incorporate instruction on Medicare requirements that relate to employee job functions in your education and training?
Tip #5: Have issues!
Smaller practices sometimes let things go rather than document and learn from them

Does your organization take reasonable steps to investigate all compliance issues/incidents, regardless of their perceived magnitude?

Are your investigations documented?

How quickly are your investigations initiated after learning of potential instances of non-compliant activity?

Does your organization have corrective actions in place that are tailored to correct non-compliant behavior?

Are the corrective actions tailored to address particular violations of fraud, waste, and abuse prohibitions and other federal and state statutory and regulatory requirements in your company?

How are your corrective action plans monitored after you have implemented them so that you can ensure they are working?

Issue response
Tip #6: Match lines of communication to natural reporting lines in your organization

- Does your organization use a particular method for your compliance officer or compliance committee to communicate information to employees?
- What type of information does your compliance officer communicate?
- Does this information include changes to legal requirements impacting the organization?

Foster Open Lines of Communication (continued)

- Do your written policies establish duties for your employees to report non-compliant activity, such as violations of fraud, waste, and abuse laws?
- Do you have a formal structure to receive and document compliance reports and compliance questions from employees?
- How does your organization’s reporting structure ensure confidentiality?
- Does this apply to providers as well as administrative personnel?
- Does your process ensure prompt follow-up with employees who report to ensure that they know action has been taken to further encourage future reporting?
Tip #7: Discipline without destroying culture

- Has your organization instituted disciplinary policies and procedures and ensured they are in place to address non-compliant behavior?
- How do you widely publicize disciplinary standards to your employees?
- How do you provide swift and consistent enforcement of compliance standards throughout your organization?

Tip #8: Communicating with the C-suite, Board or Practice Owner

You think you have a Compliance issue, NOW WHAT?

- When do you advise the practice owner? Compliance Committee?
- How do you present issues to your C-Suite and Board of Directors?
- When do you retain outside counsel?
- Have you reviewed your D&O Insurance Policy to determine coverage?
- Review practice policies and employment agreements and obligations to indemnity and exclusions that may apply

Report internally?
Which stakeholders?
Internal investigations may be shared with the Government

Report externally?
Regulatory agency?
Outside counsel retained to preserve privilege communications & Attorney work product Doctrine

Not ALL Compliance problems are created equal —
- Violation of internal policy, federal law, or state law?
- Violation of Payor Agreement?
• Briefing Leadership by keeping their attention
• Focus on the “high risk” compliance issues that will impact the business (don’t sweat the small stuff)
• Identify how compliance issues may impact the organization AND them personally
• Provide real numbers/demonstrate real impact
• Highlight industry trends and enforcement actions that may impact the business

• Understanding your role in the organization
• Know your scope of authority in your organization
• Remember that compliance is interdisciplinary and should be enterprise/practice wide
• Understand your organization’s appetite for risk vs. potential exposure to liability

• Provide Examples - Show examples of other organization / board members who are similarly situated
• Be selective on what documentation / handouts you provide
• Don’t forget attorney-client privilege
• Show your progress and success stories, and positive impact on the business
• Most importantly, not all doom and gloom

Tip #9 Don’t Let Your Compliance Program Get Stale

- Continuous Review and Improvement
- Risk assessment updated to reflect internal and external incidents
- Internal Audit plan updated and reviewed regularly
- Management and Board communication on patterns of activity
- Targeted and current training and education
- Disciplinary action that is consistent and responsive to past actions
- Review and update policies and procedures
Continuous Review and Improvement (continued)

• Does your organization have a process for reviewing and updating its compliance program and policies and procedures?

• Is your review and update process ongoing and does it account for issues that have arisen within the organization? Does it account for issues that the government has identified as high-risk areas?

• How do you ensure that your Board and management are continuously improving their processes and sharing these improvements with Stakeholders in an efficient manner?

Tip #10
Don’t let an acquisition throw off your compliance program!
What has been the practice’s process for implementing compliance policies and procedures at the new entity?

- Was the misconduct or the risk of misconduct identified during due diligence?
- How has the compliance function been integrated into the merger, acquisition and integration process?
- Who conducted the risk review for the acquired/merged entities and how was it done?
- What has been the practice’s process for tracking and remediating misconduct or risks identified during due diligence process?

Source: U.S. Department of Justice Evaluation of Corporate Compliance Programs

Where Did We Land?

- Physician Practice (BIG or small) is expected to establish a compliance program incorporating the OIG’s 7 pillars but scaled to their practice resources
- BIG practices expected to have a robust program with detailed policies, annual education and risk assessments, and BOD oversight.
- small practices are expected to meet the 7 elements scaled to their resources (i.e. HHS hotline poster vs. their own internal/3rd party vendor).
Thank you!

Feel free to contact us with questions or requests:

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