Year One of a Compliance Journey:
A First Year Under a CIA: Tips to Prepare for and Implement Best Practices for Your CIA

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Overview

• Part 1: Introduction and Background
• Part 2: Overview of Mercy’s Corporate Integrity Agreement
  – Key Obligations
  – Key Elements
• Part 3: Case Study of Mercy’s work to comply with the CIA during year 1
  – Effectiveness Assessment conducted by Hall Render
  – Certification process
  – Education
  – Creation and re-review of policies and procedures
  – Management and process changes
  – Relationship with OIG-HHS
  – Relationship with IRO
  – Lessons Learned
• Part 4: Practical takeaways
Part 1: Introduction and Background

Introduction to Mercy

- A Catholic health system with a 190 year history in the US, formally became a health system in 1986.
- Located primarily in Arkansas, Kansas, Missouri and Oklahoma
- Includes:
  - 44 acute care and specialty (heart, children's, orthopedic and rehabilitation) hospitals.
  - More than 700 physician practices and outpatient facilities.
  - 44,000 employees (which Mercy calls “co-workers”).
  - More than 2,000 Mercy Clinic physicians.
Introduction to Hall Render

- Nation's largest health care-focused law firm
- Nearly 150 health law attorneys in 10 offices across the country
- 50 years of experience in the health law business
- Clients include:
  - Hospitals
  - Health care systems
  - Physicians and physician groups
  - Health care associations
  - Long-term care facilities
  - Ambulatory surgery centers
  - Federally Qualified Health Centers
  - Ancillary health providers
  - Other health care providers

Background

- In August 2015, Mercy agreed to pay $5.5M to the government to settle allegations brought by a whistleblower regarding a physician compensation matter.
- In May 2017, a second whistleblower lawsuit, with a different set of facts, but which also involved physician compensation, resulted in a $34M settlement and a Corporate Integrity Agreement.
Part 2: Overview of Mercy’s Corporate Integrity Agreement

Summary of Key CIA Obligations
General Timeline

- 365 Day Tasks
- 270 Day Tasks
- 180 Day Tasks
- 150 Day Tasks
- 120 Day Tasks
- 90 Day Tasks
Summary of Key CIA Obligations

90 Day Tasks (Part 1)

1. Appoint CCO, Compliance Committee (formed prior to CIA), and JCC
2. Adopt Policies/Procedures
   2.1 Management Certification
   2.2 Training Plan
   2.3 Risk Assessment
   2.4 Disclosure Program Policies
      Reporting Unethical or Illegal Conduct
      Non Retaliation
   2.5 Excluded Provider
   2.6 Overpayment

Summary of Key CIA Obligations

90 Day Tasks (Part 2)

3. Draft Certificates and Subcertificates
4. Provide Board Member Training
5. Engage IRO
6. Risk Assessment and Internal Review Process
7. Develop Disclosure Program
8. Screen all Covered Persons against Exclusion List (monthly)
9. Practice Management Certifications signed by Certifying Employees (Quarterly Cert. required by Mercy, not the CIA)
10. Quarterly Practice Certification
Summary of Key CIA Obligations

120 Day Tasks (Part 1)

11. Adopt Compliance Program Policies / Procedures
   11.1 Code of Conduct
   11.2 Compliance Program
   11.3 Conducting Internal Investigations
   11.4 Compliance Corrective Action
   11.5 Education and Training
   11.6 Federal and State False Claims
   11.7 Compliance as an Element of Performance

12. Adopt Policies / Procedures to ensure Focus Arrangement compliance with AKS / Stark
   12.1 AKS Stark
   12.2 Financial Transactions with Referral Sources
   12.3 Non-Monetary Compensation
   12.4 Compliance Document Retention
Summary of Key CIA Obligations

150 Day Tasks

13. Submit Implementation Report

14. President & CCO Certification (attached to Implementation Report)

180 Day Tasks

15. Quarterly Practice Certification
Summary of Key Obligations

16. Quarterly Practice Certification

270 Day

Summary of Key Obligations

17. IRO Transactions Review Report
18. IRO Systems Review Report

Pre-Annual Report
Summary of Key Obligations

Annual Tasks

19. Submit Annual Report
20. Obtain and Submit Annual Certification by Certifying Employees

Overview of Key Obligations

- General obligations:
  1. Strengthen compliance program.
     - policies
     - education
     - general accountability
  2. Improve Board oversight
  3. Improve Management oversight
  4. Inform OIG – through Discussions, the Implementation Report and the Annual Report each year to the OIG.

- Goal – change the organization’s culture
Focus Arrangement

• CIA applies to a “Focus Arrangement”
• FAs Include every arrangement or transaction that:
  • is between Mercy and any source of health care business or referrals to Mercy; or
  • is between Mercy and any physician (or a physician’s immediate family member) who makes a referral for Medicare/DHS services.
• Note - Scope of CIA is broader than Stark
  – All arrangements with referral sources must be in writing (e.g. NPs, CRNAs, LCSWs, Psychologists, etc.)

Key Obligations – Compliance Program

• Mercy was required to establish a Compliance Program, within 90 days, including:
  – Compliance Officer who reports directly to the President.
  – Compliance Officer responsible for developing policies, making reports to the Board, and monitoring day-to-day compliance.
  – Management Compliance Committee that meets quarterly - and must include Compliance Officers and Mercy senior management.
Key Obligations – Compliance Program (cont’d.)

- An Independent Review Organization ("IRO"), such as an accounting, auditing, law, or consulting firm, to perform 1) Arrangement Systems Review; and 2) Arrangements Transactions review.
  - The Arrangements Systems Reviews includes all systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements.
  - The Arrangements Transactions Review consists of a review by the IRO of 50 randomly selected Focus Arrangements entered into during the Reporting Period.

Key Obligations – Board Oversight

- The Board of Directors (or a committee of the Board of Directors) must be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of the CIA, including:
  - meet at least quarterly.
  - submit to OIG a report to OIG that includes a description of the documents and other materials it reviewed, and additional steps taken.
Key Obligations – Board Oversight (cont’d.)

– For each annual Reporting Period, adopt a resolution, including the following language:

  • “The Board of Directors has made a reasonable inquiry into the operations of Mercy’s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Mercy has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

Key Obligations – Management Oversight

• Certain Mercy employees (Certifying Employees) are required to monitor and oversee activities within their areas of authority.

• Certifying Employees must annually certify that the applicable department is in compliance applicable Federal health care program requirements and with obligations of the CIA.

• Certifying Employees include, at a minimum: President/CEO, CFO, COO, and CPO. Sub-certification from immediate subordinates and other staff members may be needed.
Key Obligations – Management Oversight (cont’d.)

• If the certification cannot be made, then must explain why.
• What if a Certification is False?
  – Mercy will be subject to Stipulated Penalties of $50,000 per false certification.
  – Mercy could pass some or all of these consequences through to individuals.

Key Obligations – Education

• Mercy was required to:
  – Develop a training plan for “Covered Persons” – annually – within 90 days.
  – Provide Board education – 2 hours – within 90 days.
  – Provide compliance training for new Board members - within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.
Key Obligations – Education (cont’d.)

• “Covered Persons” at Mercy includes:
  – owners, officers, directors and employees of Mercy.
  – all employees of MHM who perform services or functions for Mercy.
  – all Mercy or MHM contractors, subcontractors, agents and other persons who furnish patient care or perform billing and coding.
  – all physicians and non-physicians on the Medical Staff (integrated and non-integrated).
  – excludes part-time staff that will work < 160 hours per year.

Key Obligations – Compliance with Stark Law & Anti-Kickback Statute

• Ensure continued compliance with Stark Law and Anti-Kickback Statute:
  – The CIA applies to all “Focus Arrangements”
  – Includes every arrangement or transaction that:
    • is between Mercy and any source of health care business or referrals to Mercy; or
    • is between Mercy and any physician (or a physician’s immediate family member who makes a referral for Medicare services.
  – Certain arrangements are excluded from the definition of a Focus Arrangement, including:
    • 42 CFR 411.356 (ownership or investments interests),
    • 42 CFR 411.357(f) (isolated transactions),
    • 42 CFR 411.357(m) (medical staff incidental benefits),
    • 42 CFR 411.357(q) (referral services).
Key Obligations – Compliance with Stark Law & Anti-Kickback Statute (cont’d.)

- Ensure continued compliance with Stark Law and Anti-Kickback Statute:
  - Within 90 days after Effective Date, Mercy was required to create procedures to ensure each new or renewed “Focus Arrangement” does not violate Anti-Kickback Statute and/or Stark – including:
    - centralized tracking system for Focus Arrangements
    - system to track remuneration to physicians and others
    - maintain service and activity logs (e.g., time sheets)
    - monitoring use of space and equipment
    - create a written review and approval process for ALL Focus Arrangements
    - ensure an effective response in the event of a potential violation
  - Review all existing Focus Arrangements

Key Obligations – Compliance with Stark Law & Anti-Kickback Statute (cont’d.)

- Ensure continued compliance with Stark Law and Anti-Kickback Statute:
  - Prior to entering into new Focus Arrangements, or renewing existing, Mercy must include in the Agreement:
    - certification by the parties in the agreement that the party will not violate Anti-Kickback Statute or the Stark Law.
    - requirement that physician and other “Covered Persons” complete at least 1 hour of training.
    - provide a copy of the Mercy Anti-Kickback Statute and Stark Policies and Procedures to each physician and other “Covered Person.”
    - ensure each Focus Arrangement is in writing and signed.
Overview of Key Elements

- OIG-HHS inspection, audit, and review rights
- Successor liability
- Breach provisions

Key Elements – OIG-HHS Inspection, Audit, & Review Rights

- OIG may conduct interviews, examine and/or request copies of Mercy emails, memos, spreadsheets, and other documents for purposes of verifying:
  - compliance with CIA; and
  - compliance with requirements of Federal health care programs.
- Mercy must maintain all documents for 6 years from the Effective Date.
Key Elements - Successor Liability

• If Mercy proposes to sell business units, locations, or stock, or purchase a new business or location, then the CIA is binding on the purchaser or the new business – unless OIG waives.

• If Mercy wants the CIA requirements to be waived pursuant to a proposed acquisition, then it must notify OIG 30 days prior to the acquisition/transaction and OIG will make determination.

Key Elements – Breach Provisions

• Stipulated Penalty - $50,000 for each false certification, and $2,500 for each day Mercy fails to establish or comply with the following:
  – Section III Compliance Program and reporting requirements
    • Including: Compliance Officer, Compliance Committee, Board of Directors compliance obligation, management certifications, written policies and procedures, training requirements, Focus Arrangement procedures, risk assessment and internal review process, Disclosure program, Ineligible Persons removal, notification requirements, Overpayments policy, Reportable Events reporting.
  – Failure to engage and use IRO
  – Failure to submit required reports and certifications
  – Failure to grant access

• Mercy may submit request for extension in certain instances at least 5 days prior to the applicable due date.

• OIG will provide demand letter for any Stipulated Penalties which Mercy has 10 days to cure or request a hearing to dispute the imposition of penalties.

• If Mercy materially breaches CIA, then OIG may exclude Mercy.
Part 3: Case Study of Mercy’s Work to Comply with the Corporate Integrity Agreement During Year 1

Effectiveness Assessment Conducted by Hall Render

Goal: to conduct a high level overview of Mercy’s Compliance Program and identify what was working and what was not

<table>
<thead>
<tr>
<th>Expected Control</th>
<th>Status at Mercy</th>
<th>Recommended Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance Structure</td>
<td>Regional Compliance Officers (RCOs) were responsible for large regions that contain multiple facilities (hospitals and clinics).</td>
<td>Based on Mercy’s size and geographic coverage, it was recommended that Mercy establish more micro-compliance oversight at the facility level - adding Hospital Compliance Officers (HCOs) and Facility COs where appropriate.</td>
</tr>
<tr>
<td>Compliance Policies and Procedures</td>
<td>Policies and procedures were developed as a result of Mercy’s CIA.</td>
<td>It was recommended that policies and procedures be adopted ministry-wide.</td>
</tr>
<tr>
<td>Physician Training</td>
<td>It was often difficult to get physicians to complete mandatory training in a timely manner.</td>
<td>Recommended the CCO leverage physician leadership to stress the importance of compliance concepts and training with physician co-workers. Recommended training for physicians be conducted in person.</td>
</tr>
<tr>
<td>Compliance Risk Assessment</td>
<td>An annual compliance risk assessment was not conducted. The CCO partnered with Business Risk to gain insights on compliance risks that arose in that department’s risk assessment process.</td>
<td>Recommended that this process be strengthened.</td>
</tr>
</tbody>
</table>
Certification Process

• Certifying Employees:
  1) President
  2) Chief Financial Officer
  3) Chief Operating Office
  4) Chief Physician Officer

– For Mercy – at Hospital and Clinic, 6 individuals

Certification Process (cont’d.)

• Certification is:
  – “I have been trained on and understand the compliance requirements and responsibilities as they relate to [department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [department] with all applicable Federal health care program requirements, obligations of the CIA, and Mercy policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [department] of Mercy is in compliance with all applicable Federal health care program requirements and the obligations of the CIA. I understand this certification is being provided to and relied upon by the United States.” (emphasis added)
Certification Process (cont’d)

- Mercy created a quarterly sub-certification process with "practice" quarterly certifications and sub-certifications. The goal: Identify issues early; and avoid surprises. Create confidence that allowed each Certifier to certify.

- All sub-certification work is done under attorney-client privilege.
Certification Process (cont’d)

• An individual or committee was responsible to identify, investigate and resolve all certification issues.
• Reporting of issues was encouraged, either anonymously or with attribution. Over-reporting encouraged. Work done to cure an issue was reported back to the reporting party.
• Examples:
  – Building code – many doors had a gap at bottom of the door (between door and floor) that exceeded building code – all were fixed.
  – Billing and coding
  – Signage

Education

• 4 Key Audiences:
  – Board
  – Leadership
  – Physicians
  – Co-workers
• General education to all Co-workers:
  – For Mercy, almost all non-physician employees are MHM employees. CIA requires all employees, unless 160 hours or less at Hospital or Clinic.
  – Could not, in advance, identify the Co-Workers that will work >160 hours → Mercy educated all Co-workers to ensure compliance.
    • Example: Nurses might travel from Joplin to Springfield and work in Springfield for a month or 2 – to address a shortage. To ensure such a Co-worker received the education, all Co-workers were educated.
  – Most education was provided online – through the Mercy annual education process.
Education (cont’d)

• Physician education:
  – 1st year, provided in-person education to all physicians on Active staff.
  – Similar content to general education, but more in depth.

• Leadership and Board education:
  – CIA required 2 hours for Board – within 90 days.
  – For Mercy, 2 Boards – Hospital and Clinic.
  – In-person education was given to management and to Board.

Creation and Re-review of Policies and Procedures

Policies and procedures adopted pursuant to CIA:

1. Mercy Code of Conduct
2. Mercy Compliance Program Policy
3. Mercy Compliance Education and Training
4. Mercy Education on Federal and State False Claims Laws
5. Mercy Compliance Investigation Process – Reported Allegations
6. Mercy Compliance Corrective Action
7. Mercy Compliance as an Element of Performance Evaluation
8. Mercy Hospital Springfield and Mercy Clinic Springfield Training Plan
9. Mercy Financial Transactions with Referral Sources
10. Mercy Non-Monetary Compensation and Medical Staff Incidental Benefits to Physicians
12. Mercy Regulatory Compliance Risk Assessment
13. Mercy Reporting Unethical or Illegal Conduct Policy
14. Mercy Non-Retaliation Policy
15. Mercy Excluded Providers Policy
16. Mercy Overpayment Policy
17. Mercy Conflicts of Interest and Disclosure Policy
18. Management Certifications Policy
19. Landlord-Tenant Relationships, and Monitoring of Medical Supplies, Medical Devices, Equipment and other Patient Care Items
20. Landlord-Tenant Relationships, and Monitoring Compliance
21. Corporate Integrity Agreement and Annual Report
22. Implementation Report
Creation and Re-review of Policies and Procedures (cont’d.)

Journey of a Policy

- Financial Transaction with Referral Sources policy:
  - The Joint Compliance Committee (JCC) is the committee appointed by the Board of Mercy Hospital Springfield and the Board of Mercy Clinic Springfield Communities to oversee Financial Transactions with physicians and other referral sources.
  - Every Focus Arrangement is reviewed or approved in advance by the JCC.
    - Approximately 8 FAs per month are reviewed in person, and 8 via email.
    - Approximately 25 FAs each month approved via Guidelines
    - In addition, 750 +/- employment arrangements are approve annually
  - Detailed standards for FMV and for when JCC review and approval is required:
    - All contract initiators must complete a Financial Transactions Summary Form with supporting documentation for FMV and commercial reasonableness
Creation and Re-review of Policies and Procedures (cont’d.)

Journey of a Focus Arrangement

- **Management & Process Changes**
  - Changed controls over Focus Arrangement – primary gatekeeper became the Finance Department.
  - CCO changed to report to System and Hospital CEO.
    - Needed and got support from leadership.
  - Require root cause analysis when problems are identified with the process surrounding financial transactions.
  - Created and used an "emergency letter" to allow management to act quickly.
Creation and Re-review of Policies and Procedures (cont’d.)

• Feedback from IRO after first review efforts were too physician focused.

• Lessons learned:
  – Vendor relationships create Focus Arrangement. Improved process to identify Focus Arrangements with vendors.
  – Clinic, Hospital, vendors, supply purchasing, and finance all create Focus Arrangements and all arrangements must be properly vetted.

Management & Process Changes (cont’d.)

The following questions were added to Mercy’s new vendor setup/renewal process

[Table with questions related to vendor arrangements]
Relationship with OIG-HHS

• Focus is on maintaining the trust of the OIG-HHS
• During first year, fairly frequent communication.
• Erred on the side of caution – reported some issues that were not specifically required, but in a spirit of transparency did so.
• Open to feedback from OIG and always accepting any feedback with a focus on how Mercy can improve and strengthen compliance.
• Work to anticipate the Monitor’s needs (e.g., well-organized annual report, timely communication)

Relationship with Independent Review Organization

• Similar approach with the IRO.
• Build trust and be transparent with the IRO.
• Prior to IRO interviews, conducted mock IRO interviews to ensure that our co-workers being interviewed would be prepared.
• Mock Focus Arrangement report – to ensure we had accounted for all Focus Arrangements.
• Analyzed all areas of report where there was criticism or even observations of how we could strengthen compliance.
Lessons Learned

• Start early! Work to get a draft copy of the CIA. While the final version might change, most of the requirements are standard.
• Advocate for more resources.

Lessons Learned (cont’d.)

• Significant work effort around policies.
  – New policies will be needed, and existing policies will need to be refreshed.
• Identify Board Members who can help you to strengthen their oversight of the Compliance Program. Educate them as needed.
• Choose your IRO carefully. Make sure they have relevant experience and a good reputation.
• Engage early with your OIG Monitor. Take the initiative. Remember they are busy. Work to partner with them.
Part 4: Practical Takeaways

Planning for Year 1

• Build new processes that will meaningfully strengthen your Compliance Program
  – review and freshen up education
  – establish and validate centralized contracting process
  – review and revise policies and procedures
  – improve communication methods to the organization – frequency
  – sub-certification process
  – new Board Committee responsible solely for oversight of the compliance program
  – reintroduce your compliance hotline
Planning for Year 1 (cont’d.)

- Draft copy of the CIA
- Development of education is time consuming
- Encourage over-reporting of concerns.
- Ask for help. All leadership must be engaged to support Compliance.
- Prepare to get stronger. By design, a CIA will strengthen your compliance program.
- You already have a full-time job – advocate for other resources to assist you.
- Engage counsel with experience implementing CIAs to assist

Planning for Year 1 (cont’d.)

- Get a wall calendar – plot out all the deadlines.
- Keep a copy of the CIA on your desktop!
Preparing Governance & Leadership

• Prepare for a change in your reporting structure (e.g., to the CEO or Board) if that is not your current reporting structure.
• Board education is key (and required). Make sure you plan to allow for convenient scheduling – fairly tight timeframe to accomplish.
• Make sure that your legal counsel is available to answer questions.

Preparing Certifying Employees

• Educate your leaders, especially those who are required to be Certifying Employees, regarding their responsibilities.
• Make them aware that they will be leading change. The timelines of the CIA will cause change to happen quickly.
Changing the Culture

• Your culture will change. Embrace it. Help others to do the same.
• Implementing a CIA is hard. Celebrate the successes while you push for the changes you need to achieve long-term gains.
• Try to avoid “because the CIA makes it required” as much as possible. You will need it at times, but use that phrase sparingly.

Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

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