Online Compliance and Corporate Integrity Agreement Awareness Training for Vendors

Thank you for joining Regent Care Center's vendor training. This self-guided training will educate you on our Corporate Compliance Program, Compliance Policies, and Code of Conduct.

- *PLEASE DISTRIBUTE THE PDF OF THIS TRAINING FOUND AT http://www.regentcare.biz/code_of_conduct_and_compliance_policies.html TO SHARE WITH YOUR EMPLOYEES WHO SERVICE REGENT CARE BUILDINGS.*

If you have any questions regarding the material covered, please do not hesitate to contact me at: (409) 763-6000 ext. 1016 or acoaxum@regentcare.biz. Thank you for your time.

Audrey E. Coaxum, CHC, CPC, CEMC
Chief Compliance Officer

Regent Care Center

TRAINING AGENDA

1. Compliance Program Overview
2. Code of Conduct
3. Reporting and Non-Retaliation
4. CIA Requirements
5. Focus Arrangements and Contract Management Tracking (CMT)
6. Overview of Healthcare Regulatory Environment
7. Key Federal Health Care Laws

Section I:

- CORPORATE COMPLIANCE PROGRAM

Regent Care Center

COMPLIANCE PROGRAM

- **<u>Purpose</u>:** To ensure operations are

  in accordance with applicable laws and regulations

- The Corporate Compliance Program is designed to:
  - **Prevent** any accidental and intentional violations of laws
  - **Detect** violations if they occur
  - **Correct** any future noncompliance

SEVEN COMPLIANCE PROGRAM ELEMENTS

1. *Code of Conduct* is the foundation of our Corporate Compliance Program and written commitment to compliance.

2. *Chief Compliance Officer* develops, implements, operates, and monitors the program; assisted by Executive Corporate Compliance Committee.

3. *Policies and Procedures* describe operational compliance requirements and instructions.

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SEVEN COMPLIANCE PROGRAM ELEMENTS

4. *Education and Training* ensures all employees can perform job functions in compliance with rules and regulations.

5. *Hotline and Communication* provides ability to report suspected wrongdoing without fear of retaliation.

6. *Enforcement* ensures disciplinary standards imposed for noncompliance.

7. *Auditing and Monitoring* involve an ongoing review process of the Corporate Compliance Program and other risk areas.

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COMPLIANCE PROGRAM INFRASTRUCTURE

- *Corporate Compliance Committee*
  - Provides oversight
  - Advises and assists with the operation of the Corporate Compliance Program
  - Supports the Corporate Compliance Officer
- *Chief Compliance Officer*
  - Responsible for oversight of the Compliance Program
- *Corporate Compliance Department*
  - Performs daily operations of the Compliance Program

Regent Care Center

WHO IS REGENT CARE CENTERS' COMPLIANCE OFFICER?

- **Audrey E. Coaxum** is Regent Care Centers' Chief Compliance Officer
- Her contact information is:
  - Phone Number: (409) 763-6000 ext. 1016
  - Email: acoaxum@regentcare.biz

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COMPLIANCE IS EVERYONE'S RESPONSIBILITY

- ***Responsibility of Our Vendors' Employees***
  - Understand how the Corporate Compliance Program applies to your job and ask questions when necessary
  - Report any suspected violations
  - Actively participate in compliance activities (e.g., training)

- ***Responsibility of Our Vendors' Supervisors and Managers***
  - Build and maintain a culture of compliance
  - Prevent, detect, and respond to compliance problems
  - Prevent retaliation or reprisals against employees who report violations

Section II:
CODE OF CONDUCT

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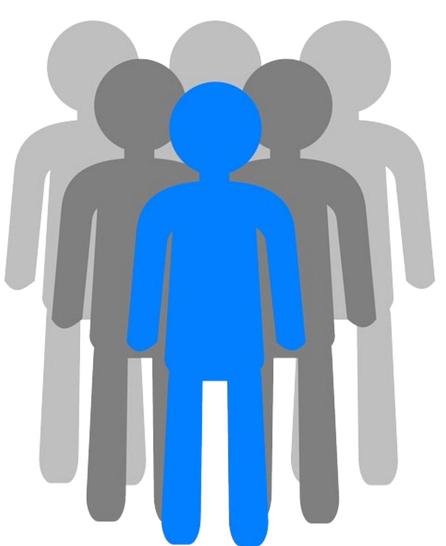
CODE OF CONDUCT (CODE)

- The Code provides the principal guidelines to conduct daily business activities ethically and legally.
- The Code is the "Constitution" of Regent Care Centers' Corporate Compliance Program and ensures that Regent Cares Centers' compliance goals are met.
- As always, if you have any questions please contact the Compliance Office.

Regent Care Center

CODE OF CONDUCT

- Must be observed by everyone, including:
  - Employees
  - Executives/Managers
  - Contractors/Vendors
  - Board of Directors
  - Medical Staff
  - Affiliated Medical School Personnel
  - Volunteers



CODE OF CONDUCT - STANDARDS

The Code includes eight Standards of Behavior:

1. Quality of Care
2. Compliance with Laws and Regulations
3. Human Resources
4. Billing and Coding
5. Federal and State False Claims Act
6. Protection/Use of Information, Property, and Assets
7. Conflicts of Interest
8. Health and Safety

Regent Care Center

QUALITY OF CARE

1. Standard of Conduct:

We are committed to providing outstanding care and services. Our first responsibility is to our residents, their families, and the physicians we serve.

QUALITY OF CARE

- All employees have the responsibility to provide appropriate, respectful, and professional treatment to all customers.

- Regent Care Centers' customers include:
  - Residents
  - Families
  - Physicians and Medical Staff
  - Co-workers
  - Vendors
  - Any outside contacts

COMPLIANCE WITH LAWS & REGULATIONS

2. Standard of Conduct:

We are committed to high standards of business and professional ethics and integrity. We will provide resident care and conduct business while following applicable Federal, state, and local laws, regulations, and internal policies.

COMPLIANCE WITH LAWS & REGULATIONS

- All business and operations will be conducted in compliance with applicable Federal and state laws and regulations, as well as, internal policies.
- Any violations should be promptly reported to management, the Corporate Compliance Officer, or the Compliance Hotline.

HUMAN RESOURCES

3. Standard of Conduct:

We are committed to creating a work place where employees are treated with respect and fairness while being empowered to get the job done at or above expectations. We strive to attract and retain employees who share a personal commitment to our Mission.

HUMAN RESOURCES

- We recognize that our employees are our most valuable assets.
- All employees are entitled to a work environment that is fair, consistent, equitable, free from violence, hostility, and harassment, and in which everyone is treated with respect.
- Any behavior that violates this standard and any related policies and procedures will <u>not</u> be tolerated.

BILLING AND CODING

4. Standard of Conduct:

We are committed to fair and accurate billing that is in accordance with all Federal and state laws, regulations, related administrative remedies, and similar state statutes, as well as, internal policies and procedures.

BILLING AND CODING

- Employees should only bill for services or items actually provided and documented in the medical record.
- All billing activities will be in compliance with applicable laws and regulations.
- Violations could result in serious fraud charges not only for the organization, but for individuals as well.

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FALSE CLAIMS ACT

5. Standard of Conduct:

We are committed to maintaining fair and accurate billing procedures in accordance with the Federal False Claims Act and State False Claims Act.

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FALSE CLAIMS ACT

- It is a violation of Federal and state laws to submit claims for payment with false and untrue information.
- Penalties for Federal FCA violations include civil penalties between $5,500 and $11,000 per violation *plus* three times the amount of damages.
- *Qui Tam* provisions (whistleblower rights) protect anyone who reports violations.

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PROTECTIONS/USE OF INFORMATION, PROPERTY, AND ASSETS

6. Standard of Conduct:

We are committed to protecting Regent Care's property and information against loss, theft, destruction, and misuse.

PROTECTIONS/USE OF INFORMATION, PROPERTY, AND ASSETS

- All employees should take steps to protect resident privacy and use property of any type only as authorized.
- We will maintain all protected health information and residents' records in accordance with laws and our record retention policies.

CONFLICTS OF INTEREST

7. Standard of Conduct:

We are committed to acting in good faith in all aspects of our work. We will avoid conflicts of interest or the appearance of conflicts between the private interests of any employee and his or her work duties.

CONFLICTS OF INTEREST

- All employees should avoid situations where their actions or activities may result in an improper personal gain or have an adverse impact on our interests.
  - No one should offer, accept, or provide gifts or favors, such as meals, transportation, or entertainment that might be interpreted as a conflict of interest.

HEALTH AND SAFETY

8. Standard of Conduct:

We are committed to maintaining a work place that protects the health and safety of our residents and employees.

HEALTH AND SAFETY

- We must comply with environmental, health, and safety laws and regulations.
- There may be severe penalties for any violations of the laws, including the costs of any clean up.
- All drugs must be safely stored, and spills and accidents should be promptly reported.
- To maintain an environment free from violence, unauthorized weapons are strictly prohibited.

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Quiz 1: *Code of Conduct*

- The following *Quiz Questions* will let you self-test your knowledge on the Compliance Program and the Code of Conduct.

- All questions are either in True/False or Single Choice format. Only one option is the correct one. You will get feedback for each question.

Question 1

How can we ensure that our billing and coding practices comply with all laws, regulations, guidelines, and policies?

A. Code and bill only for services actually provided

B. Analyze payments systematically and reconcile any overpayments

C. Ensure claims are accurate, and document the services rendered

D. All of the above

Answer to Question 1

D. All of the above

To ensure compliance with all applicable laws, regulations, and our policies, we will only bill for services and items provided and documented in the residents' medical records. All claims will be accurate and correctly document the services ordered and performed. We will periodically review our billing and coding practices and policies, including software edits.

Regent Care Center

Question 2

Which of the following situations would most likely constitute a conflict of interest?

A. Reporting an eligibility discrepancy to your supervisor

B. Participating in a government audit

C. Making a decision required as part of your duties that could be influenced by a financial or other gain to you or a family member

Answer to Question 2

C. Making a decision required as part of your duties that could be influenced by a financial or other gain to you or a family member

A conflict of interest may arise when your own private interests conflict with your work duties. It is important to avoid any activities that may influence or appear to influence your ability to render objective decisions in the course of your job responsibilities. All decisions should be based on the needs of our residents, community, and the organization.

Question 3

Which of the following is not a potential false claims violation?

A. Knowingly charging for a service not covered by Medicare

B. Unintentionally billing for services at a higher rate level than necessary once

C. Furnishing medically unnecessary services

Answer to Question 3

B. Unintentionally billing for services at a higher rate level than necessary once

Knowledge or intent is required before a potential false claims violation can be alleged. Here, a bill was submitted unintentionally, so it would not be a potential false claims violation. However, willfully neglecting known billing errors gives rise to potential false claims.

Question 4

Who is responsible for compliance with all laws, regulations, and policies?

A. Board of Directors
B. Corporate Compliance Officer
C. Employees and Medical Staff
D. All of the above

Answer to Question 4

D. All of the above

Responsibility for compliance resides with everyone, including Regent Care Centers' Board of Directors, employees, officers, medical staff, volunteers, contractors, vendors, and agents. All of our activities will be conducted in compliance with all applicable laws, regulations, and internal policies and procedures.

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Our Code of Conduct and CIA Policies

- Please view our Code of Conduct and CIA Policies at the following:

http://www.regentcare.biz/code_of_conduct_and_compliance_policies.html

Please read through the 2 PDF files – *Compliance Policies* and *Code of Conduct and Ethics*

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Section III:
REPORTING AND NON-RETALIATION

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REPORTING POTENTIAL PROBLEMS

- We are committed to providing everyone a means to raise questions and report violations or misconduct.
- Employees have an affirmative duty to report any violations of the law or the Code of Conduct.

NON-RETALIATION POLICY

Regent Care Centers' is committed to protecting employees and others who report problems and concerns in good faith from retaliation and retribution.

- No disciplinary action or retaliation will be taken against you when you report a perceived issue, problem, concern, or violation "in good faith."
- "In good faith" means an employee actually believes the information reported is true.

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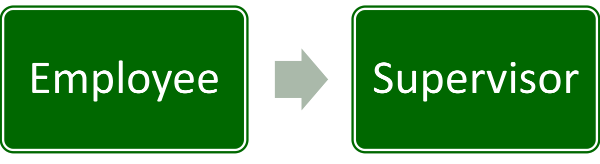
REPORTING PROCESS

Your immediate supervisor is your primary reporting option



OR you may report to one of these resources:

Administrator

Human Resources

If you are uncomfortable reporting locally, you may report to:

Chief Compliance Officer
(409) 763-600 ext. 1016

Anonymous Compliance Hotline
1-877-245-6675
reportlineweb.com/regent

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WHEN IN DOUBT

- The following words and phrases are warning signs about potential problems:
  - “Well, maybe just this once.”
  - “Everyone does it.”
  - “No one will ever know.”
  - “Shred that document – no problem.”
  - “No one will get hurt.”

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WHEN IN DOUBT

- The following "quick quiz" will help you determine what to do next:
  - "Does this break a law, regulation, policy, or our Code of Conduct?"
  - "How will I feel about myself afterwards?"
  - "What would my family, friends, our physicians, or residents think?"
  - "How would this look if it were in the newspaper tomorrow?"
  - "Am I being fair and honest?"

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WHEN IN DOUBT

- If you have any doubts, recognize similar warning signs, or are not comfortable with your answers to the “quick quiz,” follow the reporting process to report the activity.

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Quiz 2: *Reporting & Non-Retaliation*

- The following *Quiz Questions* will help you self-test your knowledge on the Compliance Program and Reporting Violations.

- All questions are either in True/False or Single Choice format. Only one option is the correct one. You will get feedback for each question.

Question 1

We have a policy that protects individuals who report suspected violations of the Code of Conduct, policies and procedures, or law.

A. True

B. False

Answer to Question 1

A. True

Regent Care Centers has a non-retaliation policy and will not tolerate any retaliation against an employee or Medical Staff member who in good faith reports a suspected violation. "In good faith" means an employee actually believes that the information reported is true.

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Question 2

How could one promptly report a potential violation of a law, regulation, or policy?

A. Contact the direct supervisor
B. Contact the Compliance Officer
C. Call the Compliance Hotline
D. All of the above

Answer to Question 2

D. All of the above

In accordance with Regent Care Centers' Code of Conduct and reporting process, we encourage reporting up the chain of command. Employees should promptly report any violations or concerns to their supervisor or management, the Compliance Officer, or the Compliance Hotline.

Question 3

The *Qui Tam* provisions for whistleblower rights only apply to the Federal False Claims Act (FCA).

A. True

B. False

Answer to Question 3

B. False

The Qui Tam provisions protect whistleblowers under both the Federal and State False Claims Acts. It allows individuals to file lawsuits under the FCA on behalf of the Federal Government. Accordingly, we will not engage in retaliatory conduct against any employees who exercise their rights under the Qui Tam provisions.

Section IV:
CIA Requirements

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What is a CIA?

- A Corporate Integrity Agreement (CIA) is a document that outlines the obligations an entity agrees to as part of a civil settlement.
- An entity agrees to the CIA obligations in exchange for the Office of Inspector General's agreement that it won't seek to exclude an entity from participation in Medicare, Medicaid, or other Federal health care programs. CIAs have common elements, but each one is tailored to address the specific facts of the case.

CIA Details for Regent Management Services, LP

- Covers management company and all 11 facilities
- Lasts for 5 years
- Focuses on Anti-Kickback Statute (AKS) and Stark Law

CIA Requirements

1. Compliance Officer and Committee
2. Board of Directors
   - To meet quarterly, oversee the compliance program, submit documents/materials reviewed, and adopt resolution summarizing its review and oversight of Regent Care Centers' compliance with federal health care program requirements and CIA obligations
3. Management Certifications
   - Certain Regent Care Centers' employees will certify their applicable department's compliance
4. Written Standards
   - Distribution of Code of Conduct and CIA related policies to employees and vendors who meet a set criteria

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CIA Requirements

5. Training and Education
   - Training Plan to cover education of:
     - Board members
     - Employees and vendors that meet a set criteria, referred to as “Covered Persons”
6. Compliance with AKS and Stark
   - Contracts with vendors that meet a set criteria, or “Focus Arrangements,” will need to be tracked with monitoring of remuneration, service/activity logs
   - Written review and approval process
7. Review Procedures/Arrangements Review
   - Performed by an Independent Review Organization (IRO)

CIA Requirements

8. Risk Assessment for Arrangements by Chief Compliance Officer
9. Compliance Hotline
10. Ineligible Persons: Exclusion List Screening for Covered Persons
11. Notification of Government Investigations or Legal Proceedings to OIG
12. Overpayment Procedures

Policy

CIA Requirements

13. Reportable Events to OIG
    - Substantial Overpayment
    - Probable violation of criminal, civil, or administrative laws applicable to any Federal health care program
    - Employment or contracting of a covered person who is excluded from participation in federal health care programs
    - Filing of bankruptcy
14. Implementation and Annual Reports to OIG

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Section V:

Overview of Focus Arrangements & Contract Management Tracking

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WHAT ARE FOCUS ARRANGEMENTS?

- "Focus Arrangements" means every Arrangement that:
  - Is between Regent Care Centers and any <u>actual source of health care business or referrals</u> to or from Regent Care Centers and involves, directly or indirectly, the offer, payment, or provision of anything of value; or
  - Is between Regent Care Centers and <u>any physician or physician's family member who makes a referral</u> to Regent Care for designated health services.

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FOCUS ARRANGEMENT EXAMPLES

- Examples include, but are not limited to, contracts with:
  - Ambulance Companies
  - Hospice Companies
  - Imaging Companies
  - Labs
  - Medical Directors
  - Pharmacies
  - Podiatrists

REVEIWING FOCUS ARRANGEMENTS

- All Focus Arrangements are reviewed internally by the following:
  - President/CEO
  - Chief Compliance Officer
  - Legal Counsel, as appropriate
- The President/CEO is the only person allowed to sign a Focus Arrangement.
- The finance department reviews Focus Arrangements to ensure proper compensation.
- A written contract, signed by the parties, must be in place before Focus Arrangement services may be provided.

FOCUS ARRANGEMENTS

- Contracting shall be negotiated by the President/CEO or his or her designee.
- Health care businesses that contract with Regent Care Centers shall bill or be billed as per the contract.
- Regent Care Centers' personnel shall not pressure another health care business to accept a contract, shall not threaten to move their residents, and shall not pressure a facility to pay a greater than Fair Market Value (FMV) fee.

FAIR MARKET VALUE

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FOCUS ARRANGEMENTS

- Regent Care Centers will monitor the use of leased space, medical supplies, medical devices, equipment, or other resident care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) if applicable.
- The Compliance Officer is responsible for:
  - Investigating reports of suspected violations of the Anti-Kickback Statute and Stark Law, (according to Regent Care's Policy #018 Consequences of Non-Compliance to Code of Conduct and Ethics and RMS Policies and Procedures).
  - As applicable, disclosing reportable events, and quantifying and repaying overpayments when appropriate (according to Regent Care's Policy #015 titled Claims Submission and Overpayment Procedures).

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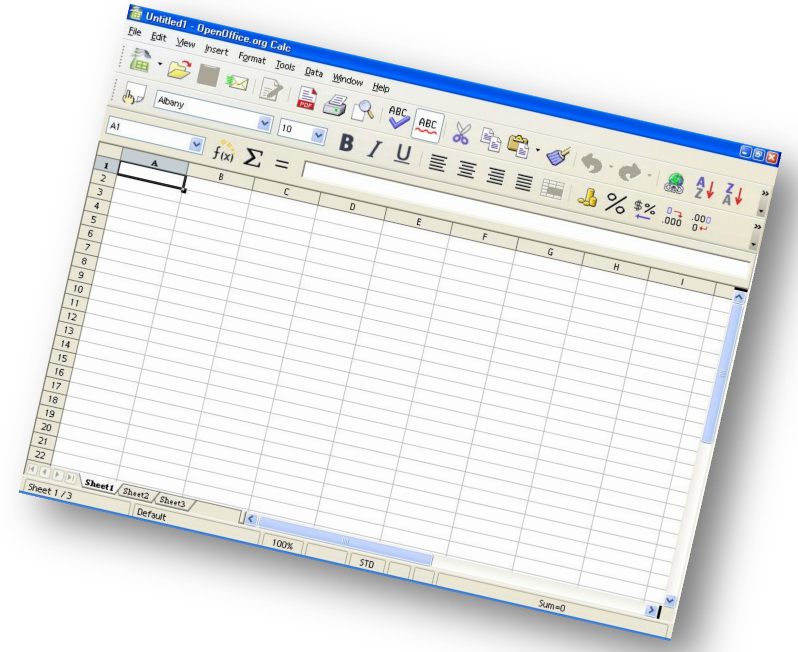
TRACKING FOCUS ARRANGEMENTS

- Regent Care has designed and implemented a Contract Manager Tracker (CMT) to track Focus Arrangements as it pertains to:
  - Internal Review
  - Approval Process
  - Remuneration/Compensation



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Quiz 3: Focus Arrangements and the Contract Management Tracker

- The following *Quiz Questions* will help you self-test your knowledge on the Compliance Program and Reporting Violations.

- All questions are either in True/False or Single Choice format. Only one option is the correct one. You will get feedback for each question.

Question 1

Focus Arrangements are reviewed by which of the following?

A. President/CEO

B. Chief Compliance Officer

C. Legal Department, as needed

D. All of the above

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Answer to Question 1

D. All of the above

To ensure compliance with all applicable laws, regulations, and our policies, Focus Arrangements are reviewed by Regent Care Centers' President/CEO, Chief Compliance Officer, and Legal Counsel.

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Question 2

Regent Care has designed and implemented a Contract Manager Tracker (CMT) to track Focus Arrangements as it pertains to which of the following?

A. Internal Review
B. Approval Process
C. Remuneration/Compensation
D. All of the above

Answer to Question 2

D. All of the above

To ensure compliance with all applicable laws, regulations, and Regent Care Centers' policies concerning Focus Arrangements, the Contract Management Tracker was designed and implemented.

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Question 3

What does CMT stand for?

A. Country Music Television
B. Cubic Metric Ton
C. Contract Management Tracker
D. None of the above

Answer to Question 3

C. Contract Management Tracker (CMT)

The Contract Management Tracker was designed and implemented in order to manage all Focus Arrangements.

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Section VI:

Overview of Healthcare Regulatory Environment

HEALTHCARE FRAUD IS A TOP ENFORCEMENT PRIORITY

- Deficit Reduction Act of 2005
- Federal and State False Claims Act
- Anti-Kickback Statute (AKS)
- Stark Law
- Elder Justice Act
- Health Insurance Portability & Accountability Act (HIPAA)

FRAUD & ABUSE

- **Fraud**: Making material false statements or representations of facts that an individual knows to be false or does not believe to be true in order to obtain payment or other benefits to which we would otherwise not be entitled

- **Abuse:** Practices that directly or indirectly result in unnecessary costs or improper payments for services which fail to meet recognized professional standards of care

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ENFORCEMENT AUTHORITIES

- Department of Justice (DOJ)
- Department of Health and Human Services (HHS)
- Centers for Medicare & Medicaid Services (CMS)
- Office of Inspector General (OIG) of HHS
- Federal Bureau of Investigation (FBI)
- Internal Revenue Services (IRS)
- Intermediaries, Carriers, DMERCs under CMS contract
- State Medicaid Fraud Control Units (SMFCUs)
- Federal Drug Administration (FDA)
- Drug Enforcement Agency (DEA)
- HHS Office of Civil Rights (OCR)

CENTER FOR MEDICARE AND MEDICAID SERVICES

- CMS administers the federal Medicare Program under which people over 65 years or those with certain disabilities may obtain healthcare coverage.
  - Part A – Hospitals/Inpatient
  - Part B – Physician services/Outpatient
  - Part C – Medicare Advantage
  - Part D – Prescription Drugs

- Medicaid is a partnership between the federal government and states that have administered the program to provide coverage to low income people.

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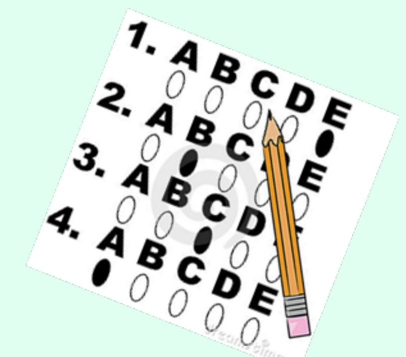
QUIZ 4: *Healthcare Regulatory Environment*



- The following *quiz* will let you self-test your knowledge on the Compliance Program and Healthcare Regulations.

- All questions are either in True/False or Single Choice format. Only one option is the correct one. You will get feedback for each question.

Question 1

Which of the following best describes the major goal of our Corporate Compliance Program?

A. Enhance development of healthcare services

B. Prevent, detect, and correct potential problems

C. Promote enhancement of healthcare services

Answer to Question 1

B. Prevent, detect, and correct potential problems

Regent Care Centers' Corporate Compliance Program was designed to prevent accidental and intentional violations of laws, regulations, and policies, to detect violations if they occur, and to prevent future noncompliance.

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Question 2

Which of the following is NOT an element of our Corporate Compliance Program?

A. Education and training

B. American Medical Association reporting

C. Hotline and employee communication system

D. Policies and procedures

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Answer to Question 2

B. American Medical Association reporting

Reports to the AMA are not a basic element. Although compliance programs may have various characteristics, they all typically contain seven basic elements, including education and training, a hotline and communication system, auditing and monitoring, enforcement, policies and procedures, and a Compliance Officer.

Question 3

What is the responsibility of every employee?

A. Willing to stay beyond the normal shift

B. Report suspected compliance violations

C. Report annually to the Compliance Office

D. None of the above

Answer to Question 3

B. Report suspected compliance violations

We expect all employees to be familiar with Regent Care Centers' Corporate Compliance Program and will not tolerate violations of laws, regulations, or organizational standards, policies, or procedures. Furthermore, it is the duty of every employee to report suspected violations.

Question 4

Which one of the following government entities enforces laws in healthcare?

A. Office of Inspector General (OIG)

B. The Joint Commission (TJC)

C. Government Accountability Office (GAO)

D. Central Intelligence Agency (CIA)

Answer to Question 4

A. Office of Inspector General (OIG)

The OIG of the Department of Health and Human Services (HHS) is a leading federal enforcement agency for healthcare. They protect the integrity of government healthcare programs (e.g., Medicaid and Medicare), as well as the health and welfare of the patients.

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Question 5

Purposely billing for services that were not provided is considered which of the following?

A. Abuse
B. Neglect
C. Fraud
D. None of the above

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Answer to Question 5

C. Fraud

Fraud is an intentional misrepresentation of the truth that results in some unauthorized benefit; therefore, deliberately billing for services or items not provided is fraud.

Section VII:
KEY FEDERAL HEALTH CARE LAWS

- Anti-Kickback Statute (AKS)
- False Claims Act
- Physician Self-Referral Law (Stark Law)
- Civil Monetary Penalties Law
- Elder Justice Act
- HIPAA
- Emergency Preparedness

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ANTI-KICKBACK STATUTE (AKS)

- Criminal statute (42 U.S.C. § 1320a-7b(b))
- Prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program (e.g., Medicare, Medicaid)
- Imprisonment for up to 5 years and fines up to $50,000
- "One purpose" rule: If one purpose of remuneration (e.g., payments or gifts) is to induce referrals, the statute is violated, even if the payment or gift was also intended to compensate for professional services.

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ANTI-KICKBACK STATUTE LEGAL ELEMENTS

- Anyone, individual or entity, who knowingly and willfully offers, pays, solicits, or receives remuneration – directly or indirectly, overtly or covertly, in cash or in kind – in return for referring, furnishing, or arranging for any item or service for which payment may be made under a Federal health care program (e.g., Medicare or Medicaid).

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ANTI-KICKBACK STATUTE (AKS)

Generally prohibits the asking or receiving of remuneration in exchange for:

- The referral of residents or business that will be reimbursed under the federal healthcare programs
- The arranging for the referral of residents or business that will be reimbursed under the federal healthcare programs
- The purchasing, leasing, ordering, or arranging for or recommending any good, facility, service, or item paid for by federal healthcare programs

WHAT IS REMUNERATION?

- Includes the transfer of anything of value, whether in cash or in kind and whether made directly or indirectly, covertly or overtly.
- Examples include:
  - Gifts/Free Goods
  - Cash
  - Bribes
  - Kickbacks
  - Discounts
  - Rebates
  - Above or below fair market value rent

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SAFE HARBOR ARRANGEMENTS

- Arrangement must meet all elements of the safe harbor to be protected.
- Compliance with a safe harbor is <u>not mandatory</u>.
- Failure to satisfy a safe harbor does not make the arrangement automatically illegal.
- Government will analyze the intent, facts, and circumstances of the arrangement before determining if the Anti-Kickback Statute (AKS) has been violated.

ARRANGEMENTS THAT DON'T MEET A SAFE HARBOR

- If the arrangement does not meet a safe harbor, it is not protected from Anti-Kickback Statute (AKS) liability.
- It may violate the Anti-Kickback Statute.
- Must analyze intent, facts, and circumstances of the arrangement.

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QUESTIONABLE ARRANGEMENTS

Be on the look out for these prevalent and questionable arrangements:

- Contracts that are above or below Fair Market Value (e.g., a Medical Director being compensated higher or lower than the usual and customary salary for the geographic region where the services are being rendered)
- Soliciting gifts from referral sources or vendors
- Employment Agreements/Independent Contractor Agreements/Recruitment Agreements
  - Excessive payment
  - No required duties (no show position)

For more information about AKS visit:

https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Anti-Kickback%20Statute.aspx

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STARK LAW

- Also called the Physician Self-Referral Law.
- Prohibits physicians from referring Medicare residents to entities for "designated health services" if the physician (or immediate family member) has a financial arrangement with the entity, *unless* an exception applies.

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STARK LAW LIABILITY

- The Stark Law is separate and distinct from the Federal anti-kickback law and other Federal fraud and abuse authorities, which can also be implicated by physician financial arrangements with entities in which they refer Medicare and Medicaid residents.

- Compliance with the Stark Law does not guarantee compliance with other fraud and abuse provisions, and compliance with those other fraud and abuse provisions does not guarantee compliance with the Stark Law.

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What's the difference between the Anti-Kickback Statute (AKS) and Stark?

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	**THE STARK LAW** (42 USC §139Snn)
Prohibition	Prohibits offering, paying, soliciting, or receiving anything of value to induce or reward referrals or generate Federal health care program business	• Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies • Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items/Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	• No intent standard for overpayment (strict liability) • Intent required for civil monetary penalties (CMP) for *knowing* violations
Penalties	Criminal: • Fines up to $25,000 per violation • Up to a 5 year prison term per violation Civil/Administrative: • False Claims Act liability • Civil monetary penalties (CMP) and program exclusion • Potential $50,000 CMP per violation • Civil assessment of up to three times amount of kickback	Civil: • Overpayment/refund obligation • False Claims Act liability • Civil monetary penalties and program exclusion for *knowing* violations • Potential $15,000 CMP for each service • Civil assessment of up to three times the amount claimed
Exceptions	*Voluntary* safe harbors	*Mandatory* exceptions
Federal Health Care Programs	All	Medicare/Medicaid

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WHY SELF-REFERRALS SHOULD BE AVOIDED

1. Helps maintain the integrity of and confidence in the physician's professional judgment
2. Eliminates the corruptive influence of benefiting from self-referrals with severe penalties for violations
3. Prevents overutilization, fraud, and waste of services

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KEY STARK PROVISIONS

- Bars self-referrals for laboratory services under the Medicare program.
- Physicians are prohibited from making a referral for the furnishing of a Designated Health Service (DHS) if they or an immediate family member has a financial relationship with that entity.
- Entities are prohibited from presenting or causing the presentation of a bill or claim to anyone for a DHS furnished as a result of a prohibited referral.

WHAT IS A REFERRAL?

Includes any of the following that are not for personally performed Designated Health Service (DHS):

- Requests by a physician for any DHS for which payment may be made under Medicare or Medicaid
- Establishment of a plan of care by a physician that includes a DHS
- Certifying or recertifying the need for a DHS

WHAT HAPPENS IF STARK IS VIOLATED?

Significant civil sanctions, but not criminal sanctions

- Proof of intent to violate the law is not required – “strict liability” statute
- Denial of payment/refund of amounts collected in violation
- Civil money penalties (CMP) of up to $15,000 for each bill or claim for a service a person knows (or should have known) is a service for which payment may not be made
- Penalty of up to three times amount of each item or service wrongfully claimed
- Potential exclusion from Federal health care programs
- CMP of up to $100,000 for each arrangement or scheme that the physician or entity knows (or should know) has a principal purpose of assuring referrals which, if directly made, would be in violation of the proscription
- Potential liability under the False Claims Act
- For more information, visit: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html

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FEDERAL FALSE CLAIMS ACT (FCA)

- Government's primary civil anti-fraud enforcement tool
- Treble damages plus penalty of $10,957 to $21,916 per false or fraudulent claim presented to federal Government after February 3, 2017.
- Whistleblower provisions and protections
- Applies to false claims to Medicare and Medicaid, including claims for items or services that are not medically reasonable and necessary

FALSE CLAIMS ACT LIABILITY FOR:

- Knowingly submitting a false or fraudulent claim seeking payment for a Federal program
- Knowingly making or using a false record or statement to get a false or fraudulent claim paid for or approved by the Government
- Knowingly concealing, improperly avoiding, or decreasing an obligation to pay or transmit money or property back to the Government (relates to return of Medicare "overpayments")

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FERA EXPANDED FCA LIABILITY

- FERA - Fraud Enforcement and Recovery Act of 2009
- Amended and expanded the False Claims Act (FCA) to apply to "reverse false claims"
  - False records and statements made to grantees and contractors
  - Improper retention of overpayments, e.g., a health care provider retaining identified Medicare/Medicaid overpayments

QUI TAM (Whistleblower) LAWSUITS

- Private person ("relator") can bring an FCA lawsuit on behalf of the United States.
- Filed under seal while the DOJ investigates.
- After investigation, the DOJ can intervene (take over lawsuit), allow the relator to proceed with the lawsuit alone, or seek to dismiss the action.
- If case is successful, the relator can claim attorney fees plus a share of the recovery (between 15 and 30 percent of the amount recovered by the government).

CIVIL MONETARY PENALTIES LAW (CMPL)

- Administered by the HHS OIG
- OIG imposes penalties, assessments, and program exclusion for various types of improper activities:
  - False or fraudulent claims
  - Violations of the AKS
  - Violations of the Stark Law
  - Arrangements with excluded persons to provide items and services billed to Medicare/Medicaid
  - Providing unnecessary items or services

ELDER JUSTICE ACT

- The **Elder Justice Act** (EJA) is a comprehensive elder abuse prevention law which was enacted as part of the Patient Protection and Affordable Care Act on March 23, 2010.

- The **Elder Justice Act** is designed to provide federal resources to prevent, detect, treat, understand, intervene in and, where appropriate, prosecute elder abuse, neglect and exploitation.

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KEY ELDER JUSTIC ACT PROVISIONS

- Requires the immediate reporting to law enforcement of crimes in a long-term care facility and establishes civil monetary penalties for failure to report.

- Provides for penalties for long-term care facilities that retaliate against an employee for filing a complaint against or reporting a long-term care facility that violates reporting requirements.

- Requires covered individuals to annually be notified of their reporting obligations.

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WHAT IS ABUSE

- Abuse may be:
  - **Physical Abuse**—inflicting physical pain or injury on a senior, e.g. slapping, bruising, or restraining by physical or chemical means.
  - **Sexual Abuse**—non-consensual sexual contact of any kind.
  - **Neglect**—the failure by those responsible to provide food, shelter, health care, or protection for a vulnerable elder.
  - **Exploitation**—the illegal taking, misuse, or concealment of funds, property, or assets of a senior for someone else's benefit.
  - **Emotional Abuse**—inflicting mental pain, anguish, or distress on an elder person through verbal or nonverbal acts, e.g. humiliating, intimidating, or threatening.
  - **Abandonment**—desertion of a vulnerable elder by anyone who has assumed the responsibility for care or custody of that person.
  - **Self-neglect**—characterized as the failure of a person to perform essential, self-care tasks and that such failure threatens his/her own health or safety.

REPORTING REQUIREMENTS

- Every individual employed by or associated with a long-term care facility as an owner, operator, employee, manager, agency, or contractor is required to report any reasonable suspicion of a crime against facility residents to the Secretary of HHS and to law enforcement officials.
- If the event that caused the suspicion results in serious bodily injury, the individual is required to report the suspicion immediately, but not later than 2 hours after forming the suspicion.
- If the event does not result in bodily injury, the individual is required to report no later than 24 hours after forming the suspicion.

PENALTIES/REPERCUSSIONS

- Monetary penalties for failing to report.
  - Failure to report, within the specified timeframe, a reasonable suspicion of a crime committed against an elderly resident may be subject to a maximum civil penalty of $200,000.
  - If the failure to report the suspicion exacerbates the harm to the elderly resident or to another person, the maximum civil penalty is $300,000.
  - Possible exclusion from the federal programs.
  - During any period for which a covered individual is classified as an excluded individual, a facility that employs such individual shall be ineligible to receive Federal funds under this Act.

EXCLUSION

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HIPAA RULES

- **HIPAA Privacy Rule** sets forth regulations addressing:
  - Authorized uses and disclosures of protected health information (PHI)
  - Rights of residents with regards to their health information
- **HIPAA Security Rule** sets forth regulations addressing:
  - Protecting confidentiality, integrity, and availability of electronic PHI (ePHI) when it is stored, maintained, or transmitted
  - Encompasses administrative, physical, and technical safeguards
- **HIPAA Breach Notification Rule** sets forth regulations addressing:
  - Notifications following a breach of unsecured PHI

PENALTIES/REPERCUSSIONS

- HHS Office for Civil Rights (OCR) enforces HIPAA and conducts investigations of possible violations of HIPAA.
- Potentially significant civil monetary and criminal penalties for violating HIPAA, including:
  - $100 to $50,000 per violation
  - $25,000 to $1.5 million per violation if several similar violations occur in a calendar year
  - Exclusion from federal health care programs
  - Imprisonment for up to 10 years
- Additional negatives include:
  - Negative publicity
  - Loss of clients and business partners
  - Legal liability

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Simple Ways to Promote HIPAA Privacy

- Privacy Rule covers PHI in all forms (written, verbal, or electronic).
- Store resident medical records containing PHI in a secured location (file cabinets, closed charts, charts turned over on your desk) that can only be accessed by employees with an appropriate need to know.
- Ensure that reasonable efforts are made to limit use, disclosure of, and requests of PHI to the minimum necessary to accomplish the intended purpose.
- Use reasonable precautions when communicating with residents through the mail or by phone to avoid disclosure of PHI.

Simple Ways to Promote HIPAA Security

- Do not share your computer username or password for **any** reason.
- Use password-protected screen savers on workstations if you are in a public area.
- Log off or lock workstations (Ctrl-Alt-Del) if you leave them unattended.
- Do not send ePHI over the Internet via e-mail **unless** it is encrypted. Verify the proper address **first.**
- Do not open attachments from people you do not know.
- Do not try to apply a virus fix described in an email.

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EMERGENCY PREPAREDNESS

- An emergency is an unforeseen combination of circumstances or the resulting state that calls for immediate action.
- Disasters are defined as events that cause severe damage, injury or loss of life and/or property.
- Disasters can occur naturally (i.e. hurricanes, tornados, wildfires, floods, draughts, etc.). They can be caused by people (i.e. chemical exposures, terrorism, bomb threats, active shooter, etc.) or from technological events (i.e. power outages, epidemics, computer viruses, communication failures, etc.).

EMERGENCY PREPAREDNESS

- On September 16, 2016, the Centers for Medicare and Medicaid Services (CMS) published new federal regulations that included updated emergency preparedness requirements for providers and suppliers participating in Medicare and Medicaid, including skilled nursing facilities.
- These regulations require providers to develop and maintain comprehensive emergency preparedness plans that include completing risk assessments, having written emergency policies and procedures, developing a communication plan and providing their employees with annual emergency preparedness training.
- An emergency/disaster response plan is a “living” document.
- It needs to be updated on a regular basis and put to the test at least annually.
- The plan should be developed and written in a manner that is easy to use for any level of staff.

DISASTER PROGRAM ELEMENTS

- Best practices have demonstrated that the minimum critical elements of an effective disaster program should include:
  - Identifying hazards specific to the facility
  - Risk assessment specific to the facility
  - Developing a robust emergency/disaster plan that addresses how to mitigate, prepare, respond and recover from hazards and risks specific to the facility
  - An employee-wide training program on the disaster response plan
  - Drills and exercises to test the disaster plan
  - Schedule of regular updates to the disaster plan

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EMERGENCY RESPONSE PROGRAMS CRITICAL AREAS

- The CMS published an emergency preparedness checklist as a "recommended tool" for health care facilities that suggests that the following critical areas be included within emergency response programs:
  - Emergency Response Plan should be developed with an all-hazards approach
  - Evacuation and Shelter-in-Place plans
  - Collaboration with local emergency management agencies
  - Collaboration with suppliers and vendors that have been identified as part of a community emergency response plan
  - Communication contingencies
  - Transportation resources
  - Resident identification
  - Family member notification
  - Necessary provisions
  - Tracking of residents
  - Relocation assistance
  - Resident medical concerns (physical and psychological)
  - Resident-specific needs (i.e., feeding tubes, oxygen, wheelchair)
  - Prescriptions
  - Medical records
  - Impact of event on residents

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SHELTERING IN PLACE

- When developing the disaster response plan, keep in mind that one of the first decisions, to be made at the time of the event, will be to either evacuate the facility or shelter-in-place.
- If the decision is to shelter-in-place, some additional needs will include:
  - Securing the facility
  - Power supply
  - Sufficient food/water supplies for 3-10 days
  - Vulnerable populations
  - Prescription supplies
  - Medical supplies and equipment
  - Staffing capabilities
  - Communication with families
  - Medical emergencies

DISASTER RECOVERY

- Restoring Business Operations Involves

Facility	Operations	Financial	Emotional
• Assess Damage • Office Space Needs • Equipment Needs • Business & Medical Record Access • Computer Data Recovery	• Employee Status • Patient Tracking • Contact Patients & Suppliers • Information Processing • Debriefing	• Assess Loss • Inventory & Document Loss • Contact Insurance Carrier • Review of Financial Resources & Assistance	• Assess Mental Health Needs • Promote Psychological First Aid • Monitor Mental Health Needs

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Quiz 5: *Key Healthcare Laws*

- The following *Quiz Questions* will help you self-test your knowledge on the Compliance Program and Key Federal Healthcare Laws.

- All questions are either in True/False or Single Choice format. Only one option is the correct one. You will get feedback for each question.

Question 1

Abuse of the Medicare and Medicaid programs is knowingly providing false information in order to obtain payment or other benefit to which we would otherwise not be entitled.

A. True

B. False

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Answer to Question 1

A. True

Abuse practices are those that directly or indirectly result in unnecessary costs or improper payments for services which fail to meet recognized professional standards; fraud is making willful false statements in order to obtain payment or other benefits to which we would otherwise not be entitled.

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Question 2

Paying for referrals can be subject to enforcement actions under both the Anti-Kickback Statute and Stark Law.

A. True

B. False

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Answer to Question 2

A. True

In many respects, the Anti-Kickback Statute (AKS) and Stark Law are similar in that they reflect concern about the corrupting influence of money in medical decision-making. AKS is primarily a criminal statute where intent is key; Stark is strict liability and a regulatory statute.

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Question 3

"Whistleblowers" may receive a financial reward for reporting individuals engaged in fraud against Medicare and Medicaid.

A. True

B. False

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Answer to Question 3

A. True

Under the Qui Tam provision of the False Claims Act, whistleblowers, referred to as "relators," are entitled to receive between 15 and 25 percent of the amount recovered by the government.

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Question 4

Under the Anti-Kickback Statute, “remunerations” are improper payments that are made in cash in return for making referrals of business paid for by Medicare and Medicaid.

A. True

B. False

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Answer to Question 4

A. True

Remuneration is any flow of benefit in return for making a referral of business under Medicare and Medicaid; may be cash or anything of value, including gifts, below market rent or lease payments, discounts, waiver of payments due, etc.

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Question 5

Under the Stark Law, physicians cannot make a referral to an entity where they have a financial interest when paid under Medicare or Medicaid.

A. True

B. False

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Answer to Question 5

A. True

The Stark Law prohibits referrals to an entity where a physician has a financial interest when payment is made by Medicare and Medicaid.

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Question 6

Under the Elder Justice Act, a long-term care employee is required to report a reasonable suspicion of a crime against a facility resident that results in bodily injury to the Secretary of HHS and to law enforcement officials within 24 hours.

A. True

B. False

Answer to Question 6

A. False

Under the Elder Justice Act, if the event that caused the suspicion results in serious bodily injury, the individual is required to report the suspicion immediately, but not later than 2 hours after forming the suspicion.

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Question 7

HIPAA Privacy Rule protects a resident's right to privacy and confidentiality of resident information:

A. In only paper and electronic formats
B. In only electronic format
C. In paper and electronic formats, as well as resident information orally communicated
D. In only paper format

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Answer to Question 7

C. In paper and electronic formats, as well as resident information orally communicated

The HIPAA Privacy Rule covers PHI in all forms (written, verbal or electronic). Resident medical records containing PHI should be stored in a secured location that can only be accessed by authorized employees. Reasonable precautions should be used when communicating with residents through the mail or by phone to avoid disclosure of PHI.

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Question 8

A type of disaster is:

A. A flood
B. A power outage
C. An active shooter
D. All of the above

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Answer to Question 8

D. All of the above

Disasters can occur naturally (i.e. hurricanes, tornados, wildfires, floods, draughts, etc.). They can be caused by people (i.e. chemical exposures, terrorism, bomb threats, active shooter, etc.) or from technological events (i.e. power outages, epidemics, computer viruses, communication failures, etc.).

Thank you for taking Regent Care Centers' Compliance and CIA Training!

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