the Health Law Center
Sullivan Stolier Schulze

IMPLEMENTING EFFECTIVE AND ACHIEVABLE COMPLIANCE POLICIES

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HEALTH CARE INDUSTRY

The delivery of health care services is a highly regulated industry.

Every aspect of providing care is regulated, encompassing a wide range of health care provider interactions.

MEDICARE PROGRAM INTEGRITY

CMS
Centers for Medicare and Medicaid Services

DHHS
Department of Health and Human Services

OIG
Office of Inspector General

FBI
Federal Bureau of Investigation

DOJ
Department of Justice

QIO
Quality Improvement Organizations

UPIC
Unified Program Integrity Contractor

SMRC
Supplemental Medical Review Contractor

MAC
Medicare Administrative Contractor

I-MEDIC
Investigations Medicare Drug Integrity Contractor

CRIMINAL ENFORCEMENT

Criminal False Claims Act

- 18 U.S.C. § 287

False Statements Act

- 18 U.S.C. § 1001

Illegal Patient Admittance and Retention Practices

- 42 U.S.C. § 1320a-7b(d)

Anti-Kickback Statute

- 42 U.S.C. § 1320a-7b(b)

False Statement in Connection with a Certification or Recertification

- 42 U.S.C. § 1320a-7b(c)

Assignment Violations

- 42 U.S.C. § 1320a-7b(e)

Medicare & Medicaid Fraud

- 42 U.S.C. § 1320a-7b(a)

Mail and Wire Fraud

- 18 U.S.C § 1341, 1343

CIVIL ENFORCEMENT

Physician Anti-Self Referral Statute ("Stark II")

- 42 U.S.C. § 1395

Civil Monetary Penalties

- 42 U.S.C. § 1320a-7a(a)

Civil False Claims Act

- 31 U.S.C. § 3729

FRAUD

Medicare Program Integrity Manual, § 4.2.1

"The most frequent kind of fraud arises from a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the Medicare program. The violator may be a provider/supplier, a beneficiary, an employee of a provider/supplier, or some other person or business/entity, including a billing service or a contractor employee."

- Billing for services not furnished or supplies not provided
- Soliciting, offering, or receiving a kickback, bribe or rebate
- Unbundling charges
- Billing non-covered services as covered items
- Giving false information about provider ownership
- Claiming bad debts without first attempting to collect payment
- Incorrectly apportioning costs on cost reports

ABUSE

Medicare Learning Network Booklet,

"Medicare Fraud & Abuse: Prevent, Detect, Report"

"Abuse describes practices that may directly or indirectly result in unnecessary costs to the Medicare Program. Abuse includes any practice that does not provide patients with medically necessary services or meet professionally recognized standards of care."

- Billing for unnecessary medical services
- Charging excessively for services or supplies
- Misusing codes on a claim, such as upcoding or unbundling
- Pattern of adverse MAC or QIO findings
- Providers who are subject of prepayment review for an extended period of time
- Providers whose claims must be reviewed continually and are subsequently denied because of repeated overutilization
- Exceeding the limiting charge

BENEFITS OF AN EFFECTIVE COMPLIANCE PROGRAM

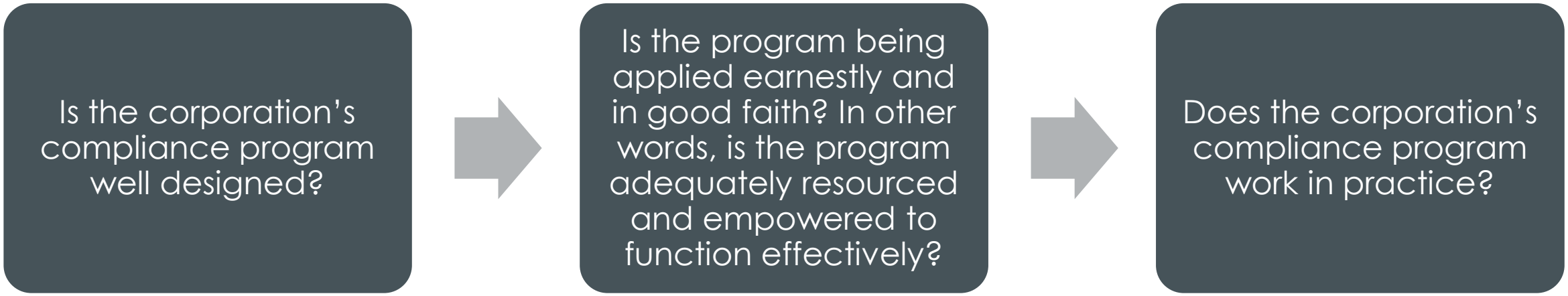
- Improve the quality of care provided to patients.
- Ensure patient care services are medially necessary and reasonable.
- Ensure claims for such services are correctly coded and timely submitted to federal health care programs and private insurance in accordance with applicable requirements.
- Achieve the Hospital's compliance goals by establishing compliance as an integral and seamless aspect of routine operations.
- Proactively avoid, detect and correct compliance issues.

AGENDA

- Getting Started – evaluating your organization's need
- 7 elements of a Compliance Plan
- Key Risk Areas and How to Evaluate Compliance

DOJ EVALUATION OF CORPORATE COMPLIANCE PROGRAMS

The DOJ updated its Evaluation of Corporate Compliance Programs guidance for prosecutors, which emphasizes there is "no one-size-fits-all" approach to compliance. Prosecutors should ask three fundamental questions to evaluate a corporate compliance program:



"We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make a reasonable, individualized determination in each case that considers various factors including, but not limited to, the company's size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company's operations, that might impact its compliance program."

STARTING / EVALUATING / UPDATING COMPLIANCE PLANS:

- Getting Started
  - What training does the compliance officer need?
  - Where do I get policies?
  - How do I know if the compliance policies are effective?
  - What needs to be in a compliance plan?
  - Does the compliance plan need to cover every operation / service?
  - What if we forget to include something?
  - Who is responsible for compliance?
- How do I start?

Perfection is the enemy of good.

THE OIG'S SEVEN RECOMMENDED COMPLIANCE PROGRAM ELEMENTS

- Implementation of Written Standards of Conduct, Policies and Procedures
- Designation of Compliance Officer and Compliance Committee
- Effective Lines of Communication
- Effective Training and Education
- Auditing and Monitoring
- Enforcement of Disciplinary Standards
- Response to and Prevention of Detected Issues

SET THE TONE AT THE TOP

While Leadership may rely on the administration/practice manager or others for day-to-day implementation of the Compliance Program, the Board should "set the tone at the top".

EDUCATE

- Leadership should be familiar with the Compliance Program and ensure the Program has been reasonably implemented.

PROMOTE

- Leadership should promote a "culture of compliance" that encourages ethical conduct and compliance with the law.
- The Board should convey this message to all staff across the provider, from senior management to clinicians to non-clinician staff.

EVALUATE

- Leadership should ensure the reporting methods in the Compliance Plan are adequate to assure Leadership receives appropriate information relating to compliance as a matter of course – a matter of the normal routine.

SETTING THE "TONE AT THE TOP"

Instill compliance as a priority and a "way of life" for the entire workforce

Regularly inquire to determine scope, adequacy and effectiveness of Compliance Program

Receive regular reports on risk mitigation and compliance efforts from variety of departments.

Stay abreast of ever-changing regulatory landscape and operating environment

Utilize regulatory experts for consulting and inquiry

Consider executive sessions with individuals responsible for compliance and risk management matters

FIDUCIARY DUTY OF CARE

Leadership has a duty to carry out its fiduciary duties in "good faith" with the level of care an ordinary person would exercise in similar circumstances, and in a manner he/she reasonably believes is in the best interest of the company.

Two Elements

Judgment

- Applying the Duty of Care to situations where Leadership is called to exercise judgment (i.e. a vote).

Oversight

- Applying the Duty of Care to Leadership's obligation to exercise meaningful oversight of the company's operations – keeping its finger on the pulse of what's happening.

What will be the level of resources necessary to implement the Compliance Program as envisioned? How has management determined the adequacy of the resources dedicated to implementing and sustaining the Compliance Program?

MISTAKES WILL HAPPEN

It's what you do that matters.

Considering the exceedingly complicated nature of health care regulations covering licensure, billing, coding, conditions of participation, financial relationships, privacy, etc., the potential for accidents and mistakes will be ever present.

An effective Compliance Program will help the Hospital reduce the number of mistakes, detect those that may occur, take corrective action and develop ways to prevent that mistake from reoccurring.

OVERSIGHT → KNOWLEDGE

When Leadership exercises its Duty of Care through effective oversight of the provider's operations, it carries the expectation of knowledge under the False Claims Act.

- Actual knowledge
- Deliberate ignorance
- Reckless disregard

WRITTEN POLICIES

STRIVE FOR CONTINUOUS IMPROVEMENT

CODE OF CONDUCT

- How has the Code of Conduct been incorporated into the provider's policies?
  - Orientation?
  - Refresher Training?
- How do we know the Code of Conduct is understood and accepted across the provider's staff and leadership?
  - Training Quizzes?
  - Staff Interviews?
- Has management taken affirmative steps to publicize the importance of the Code to all of its staff?

COMPLIANCE GOALS

- What are the provider's goals for the Compliance Program?
- What inherent limitations does the provider have and how does the provider address these limitation?
- Does the Provider have a Code of Conduct?
- Does the Provider have specific policies covering the core areas of compliance?

ASSESSING THE NEED FOR COMPLIANCE POLICIES

- What is the provider already doing and how is that documented?
- What areas need to be addressed?

Has the organization implemented policies and procedures that address compliance risk areas and established internal controls to counter those vulnerabilities?

When vulnerabilities are identified through complaint, tip, audit, observation, etc.:

- Identify if the vulnerability has resulted in any improper claims or other compliance deficiencies.
- Evaluate the potential cause of the vulnerability/deficiency.
- Determine if the remedy addressing the vulnerability should be addressed by education or policy?

POLICIES AND PROCEDURES

- The purpose of written compliance policies and procedures is to provide clear and understandable mechanisms and procedures designed to enable the provider, its staff and personnel to achieve the provider's compliance and quality goals in compliance with Federal, state and other program requirements and standards.
- Provider's policies will be tailored to and integrated into provider's personnel's day-to-day responsibilities, distributed to applicable personnel and reviewed periodically to evaluate effectiveness.

COMPLIANCE OFFICER

COMPLIANCE OFFICER JOB DESCRIPTION

- Serve as the primary source for provider's personnel for information on the Compliance Program and regulatory standards and requirements;
- Foster open communications with personnel by being available when they have a question or concern about compliance or a suggestion on improving operations;
- Monitor effectiveness of the Compliance Program;
- Receive any patient, employee or other reports, complaints or suggestions relating to compliance and other matters assigned to the Compliance Officer;
- Ensure any complaints are objectively and thoroughly reviewed and evaluated and responded to through appropriate remedial measures, including refunding overpayments, modifying policies, developing additional educational tools, etc.; and
- Ensure no one experiences retaliation for making a good faith report or asking questions related to compliance or ways to improve the provider's operations.

EMPOWERING THE COMPLIANCE OFFICER

- Has the organization empowered the Compliance Officer?
- Does the Compliance Officer participate in strategic planning process?
- If provider staff is asked, how will they explain who the Compliance Officer is?
- Is the Compliance Officer involved in orientation, training, evaluation of staff?
- Does the organizational chart show the Compliance Officer's authority and reporting lines of communication?
- Does the Compliance Officer report directly to the Board or Leadership? Is this reflected in the meeting minutes?

COMPLIANCE OFFICER INDEPENDENCE

- Is the Compliance Officer empowered to create working groups to investigate potential compliance issues?
- Can the Compliance Officer implement staff training on compliance topics?
- Can the Compliance Officer retain outside counsel?
- Does leadership listen to the Compliance Officer's recommendations and have documented reasons for not implementing them?
- What documentation is there of the provider acting on the Compliance Officer's recommendations?

COMPLIANCE COMMITTEE

COMPLIANCE COMMITTEE RESPONSIBILITIES

- Evaluating the effectiveness of the Hospital's Compliance Program;
- Ensuring policies and procedures are up-to-date;
- Developing benchmarks and goals for the Hospital and its departments;
- Reporting to the Corporate Compliance Committee.

OPEN COMMUNICATIONS

THE GOAL OF OPEN COMMUNICATIONS

- The primary goal of establishing a practice of open communications is to encourage and enable everyone to express their compliance, quality and other concerns and/or suggestions for improvement without fear of retaliation. It is the fostering of an engaged dialogue meant to improve the provider's compliance.
- Open Communication is essential to maintaining an effective Compliance Program by increasing the provider's ability to internally identify and respond to potential and/or actual compliance issues, quality issues or performance improvement suggestions.
- Open Communication is an essential element for establishing a Culture of Compliance supported throughout the provider, including all personnel as well as contractors and others.

ENCOURAGING OPEN COMMUNICATIONS

- The provider should encourage mutual and open communications with and between personnel by:
  - Training and educating personnel on applicable standards;
  - Actively encouraging personnel to identify possible ways to improve the personnel's policies and procedures and to report possible compliance issues without fear of retaliation;
  - Responding promptly and appropriately to employee reports of compliance issues and suggestions for improvement;
  - Maintaining anonymity of personnel who wish to report compliance issues; and
  - Soliciting feedback from personnel.

EDUCATION AND TRAINING

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- An effective Compliance Program is rooted in an active and adaptive education and training program for Hospital Personnel.

AUDITING AND MONITORING

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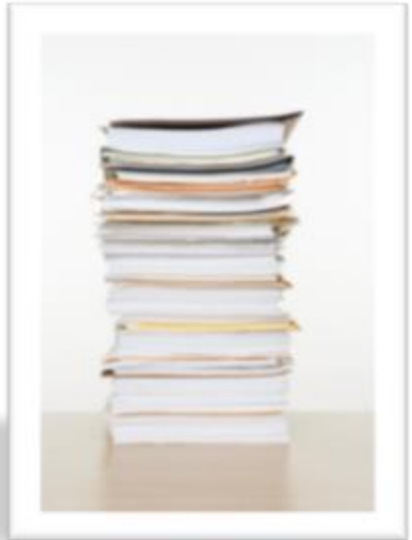
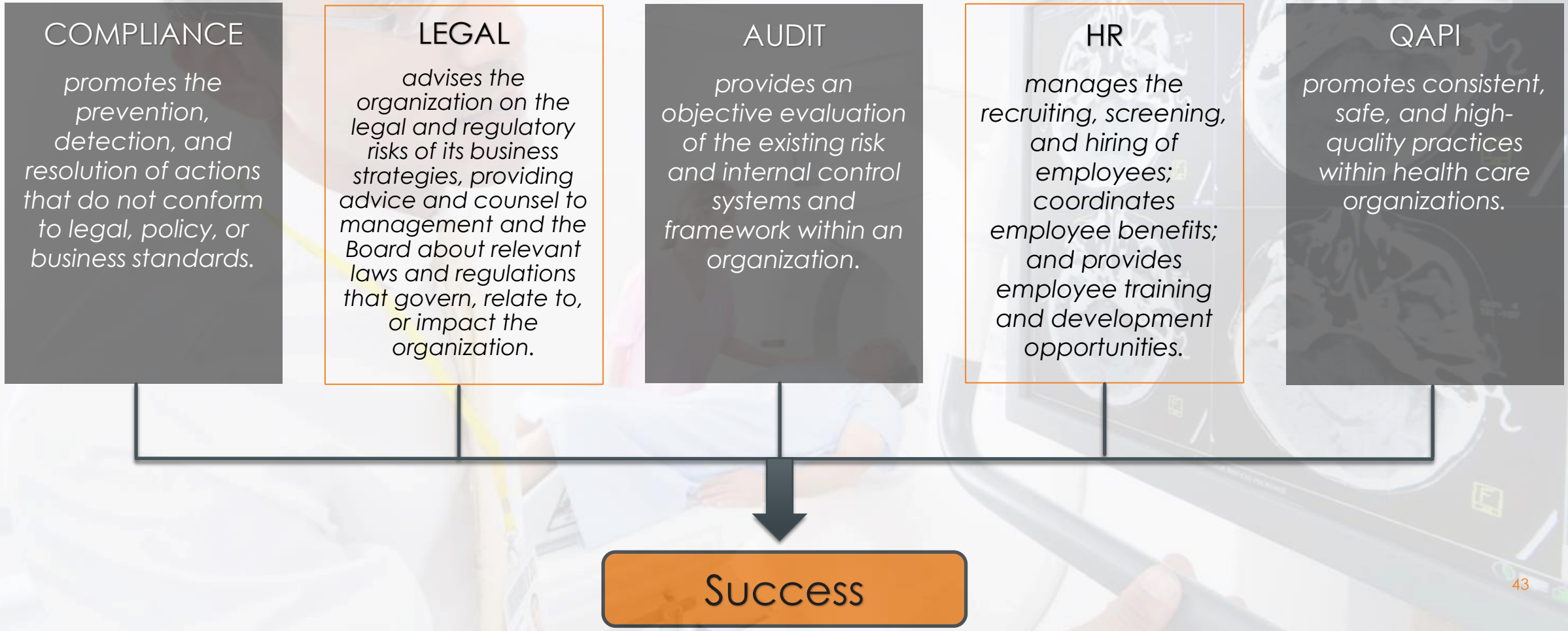
- Internal and external auditing and monitoring is an essential element of an effective Compliance Program and consists of periodic audits conducted by the Compliance Department and/or external independent legal counsel and consultants.
- Internal audits are designed to help the Hospital ensure it provides high-quality medical care to its patients in a professional, safe, effective and efficient manner that is documented in the record and is in full compliance with clinical guidelines, professional standards, contractual requirements, and regulatory requirements.
- External or Validation Audits helps ensure the accuracy of the provider's internal audits by providing an independent review.

MEDICAL RECORDS – THE MOST VALUABLE ASSET

- A Provider's most valuable physical assets are its Medical Records that are completed timely and that fully and accurately document medical necessity. An effective Compliance Program will enhance the provider's operations by enhancing clinical quality and patient outcomes, reducing audits, refunds and overpayments and avoiding government investigations.



INTERRELATIONSHIP OF THE AUDIT, COMPLIANCE AND AUDIT FUNCTIONS

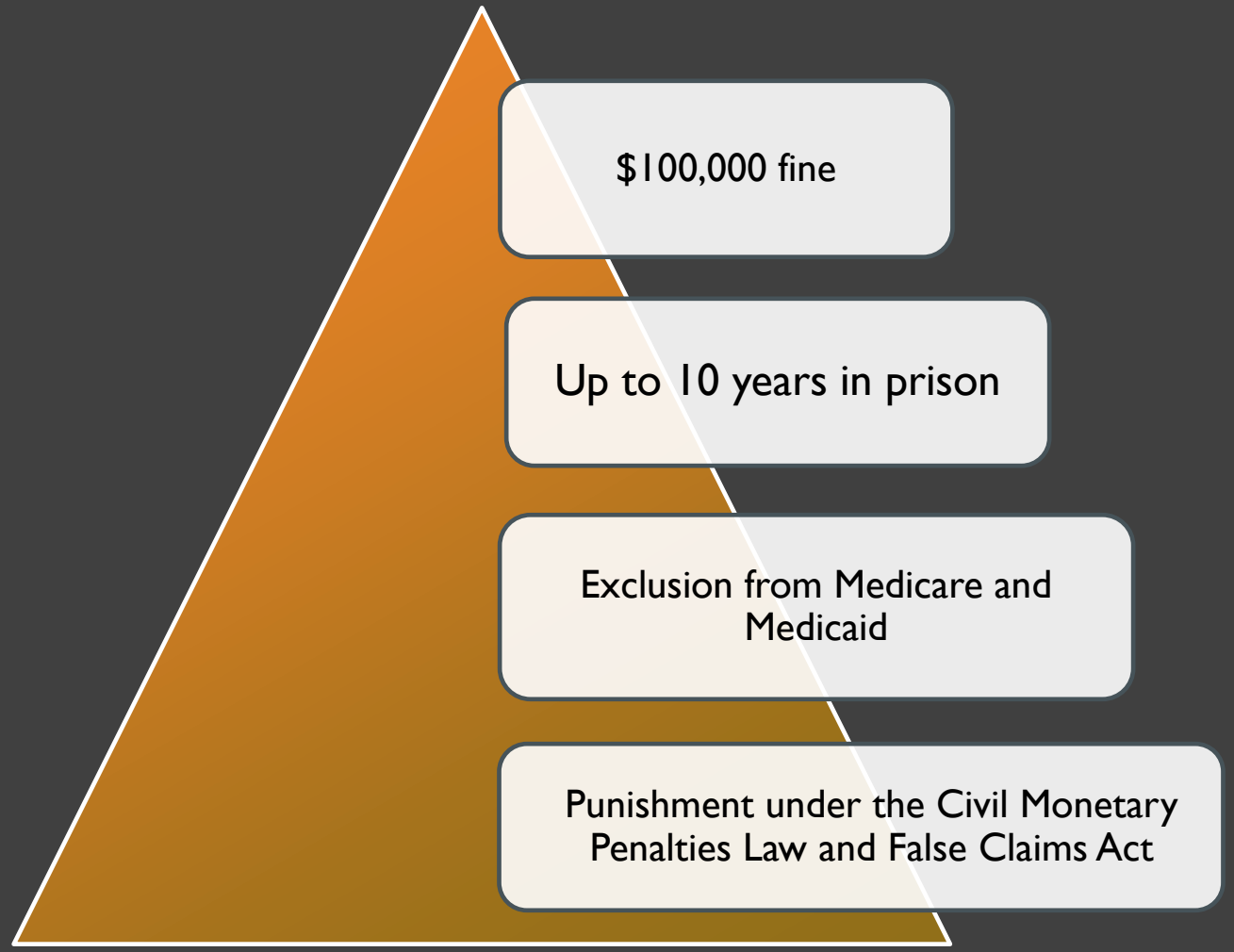


KEY RISK AREA: PHYSICIAN AGREEMENTS

ANTI-KICKBACK STATUTE: 42 U.S.C. 1320a-7b(b)

1. Knowingly paying, offering, receiving or soliciting,
2. Remuneration, directly or indirectly, overtly or covertly, in cash or in kind,
3. In return for referring an individual, or arranging for the referral of business, or for purchasing or ordering any item, good or service,
4. For which payment may be made under Medicare or Medicaid or other federal program.

ANTI-KICKBACK CRIMINAL PENALTIES



STARK II: 42 U.S.C. § 1395nn "Physician Self-Referral Statute"

There must be a financial arrangement

- Direct Ownership
- Indirect Ownership
- Compensation

Between a physician or physician's immediate family member; and

An entity that bills Medicare

For a Designated Health Service

If Stark II applies, the physician cannot make any referrals to the entity (i.e. the Hospital) payable by Medicare and the entity cannot bill Medicare for such prohibited referrals UNLESS the financial arrangement meets EVERY element of an applicable Stark II exception.

STARK "REFERRAL"

42 C.F.R. § 411.351

The Stark II regulations contain an expansive definition of "referral" – Considering almost every inpatient and outpatient hospital service is considered a Designated Health Service, virtually everything a physician does in the hospital context will be considered a "referral" under Stark II.

- Ordering a test, lab, or other service;
- Establishment of a plan of care or certifying/recertifying the need for a service; and
- Requesting a consultation with another physician and any test or procedure ordered by the other physician.
- However, the professional services the physician personally performs (not through anyone else) are NOT considered referrals. In contrast, the technical fee generated would be a "referral".

STARK II PENALTIES

NO INTENT IS REQUIRED

Stark II is a strict liability statute that will AUTOMATICALLY result in the denial of payment for ANY and ALL claims that violate the statute.

TYPES OF PHYSICIAN FINANCIAL ARRANGEMENTS

- Physician Personal Services Arrangements:
  - Employed Physicians;
  - Medical Directors;
  - On-Call Arrangements.
- Equipment or Space Leasing Arrangements:
- Non-Monetary Compensation Arrangements:
- Medical Staff Incidental Benefits:

ASSESSING PHYSICIAN ARRANGEMENT COMPLIANCE:

COMMERCIAL REASONABLENESS

- Does the provider have documentation showing the services provided by the physician are legitimately needed?
  - For Hospitals – has the MEC passed a resolution confirming the need for the service?
- If the contracted physician couldn't perform the services, would the provider contract with another physician to obtain the services?
- What documentation does the provider have that the physician has performed the contracted service?
- Time sheets?
- Meeting Minutes: MEC, Board, Committees?
- Quality Reports?

ASSESSING PHYSICIAN ARRANGEMENT COMPLIANCE:

FAIR MARKET VALUE

- What documentation does the provider have that the compensation paid is consistent with fair market value?
- Leases: what comparables did the provider have and consider when establishing the lease rate?
- Services: what information did the provider consider when establishing the compensation rates?
- Where there any negotiations? How were the negotiations documented?
- Were any other physicians considered for or offered the arrangement?

Thank you to the Louisiana Rural Health Association for organizing the Rural Health Law Summit

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