New to Compliance? Learn the Essential Components to Address in Your Program

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Why Have a Compliance Program

- The Affordable Care Act authorizes regulatory mandates for healthcare providers and suppliers to establish a compliance program as a condition of their enrollment in Medicare, Medicaid, or the Children's Health Insurance Program ("CHIP").
- Have become a necessity in today's healthcare industry
- Mitigating factor in investigations
- Improve the quality of care
- Identify and resolve potential issues

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Government Statistics (FY 2020)

https://oig.hhs.gov/reports-and-publications/archives/semiannual/2020/2020-fall-sar.pdf

- $3.14 billion in investigative recoveries
- 791 civil actions

- OIG excluded 2,148 individuals
- 624 criminal actions

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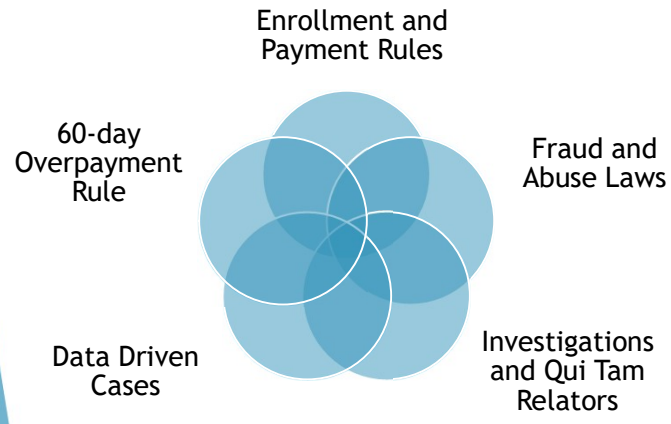
Staying out of Trouble



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Compliance Program Elements

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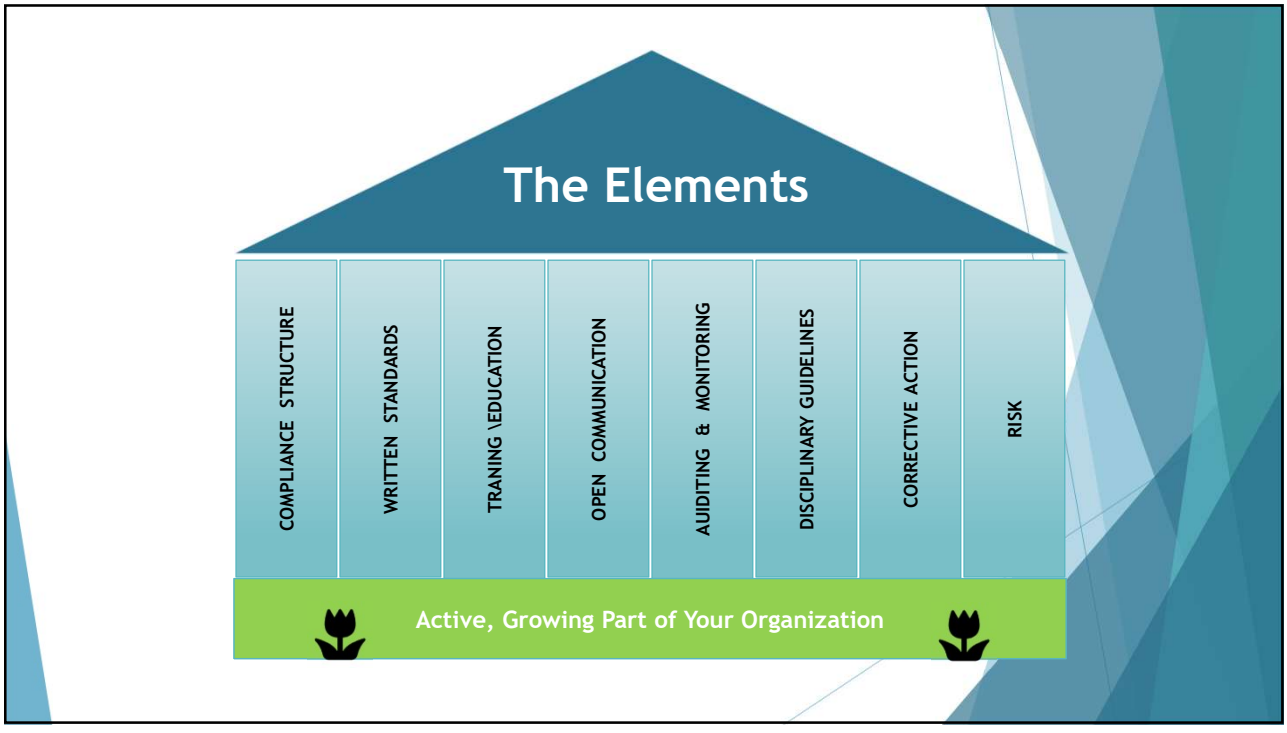

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Compliance Structure

Compliance Officer

- Implementing and maintaining the Compliance Program
- Resolving compliance issues
- Overseeing investigations and corrective action
- Helping employees understand and meet their compliance responsibilities
- Appropriate authority
  - Reporting structure

Governance

- Compliance Committee
- Board
- Culture of Compliance

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Written Standards

- Foundational documents
  - Code of Conduct
  - Compliance plans
    - Elements of the program
      - Specific to organization
      - Coding and billing compliance
      - Patient referrals/inducement
      - Patient financial assistance
      - Hiring practiced/sanctioned individuals
      - Patient rights/quality healthcare
  - Policies and procedures

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Training and Education

- Ensure employees remain knowledgeable about the Compliance Program and potential compliance risks
- Types of education
  - Employee and physician
  - Management
  - Board of Directors
  - Specialized training for high-risk areas
  - Issue based training
- Type of training
  - Frequency
  - Type

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Open Lines of Communication

- "Open Door" policy
- Reporting options
  - Direct Supervisor
  - Administration
  - Compliance Officer
  - Compliance hotline
    - Anonymous
    - Non-retaliation/non-retribu
- Procedures for processing reports

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Auditing and Monitoring

- Auditing vs. monitoring
- Ongoing evaluation process to determine whether
  - Policies and procedures are being followed
  - No regulatory concerns regarding operations
  - Individuals carrying out their responsibilities
  - Proactive approach!
- Example of types of audits and monitoring

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OIG Workplan

- The OIG work planning process is dynamic, and adjustments are made throughout the year to meet priorities and to anticipate and respond to emerging issues.
- Includes audits, reviews, and reports along a number of legal and investigative activities.
- Recently added items:
  - https://oig.hhs.gov/reports-and-publications/workplan/updates.asp
- Tips on use

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Disciplinary Guidelines

Well-publicized guidelines and consistent enforcement add credibility and integrity to a compliance program

Standards should include disciplinary measurers for failure to detect or report suspected violations

Enforcement and disciplinary procedures should be consistent, yet flexible

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Corrective Action

- Important to follow-up on reports of suspected compliance violations
- Steps should be taken to correct the problem
- Use of monitors and indicators, such as:
  - Significant changes in the number/types of claim rejections
  - Challenges to medical necessity or validity of claim
  - Unusual changes to code utilization
- Procedures for handling misconduct

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Risk Assessment

Annual risk assessment to determine areas of high risk

Based on interviews, past audit results, OIG Annual Work Plan, Advisory Opinions, CMS updates, etc.

Develop the annual compliance auditing and monitoring plan

Continuous assessment of compliance risks and identification of areas of improvement

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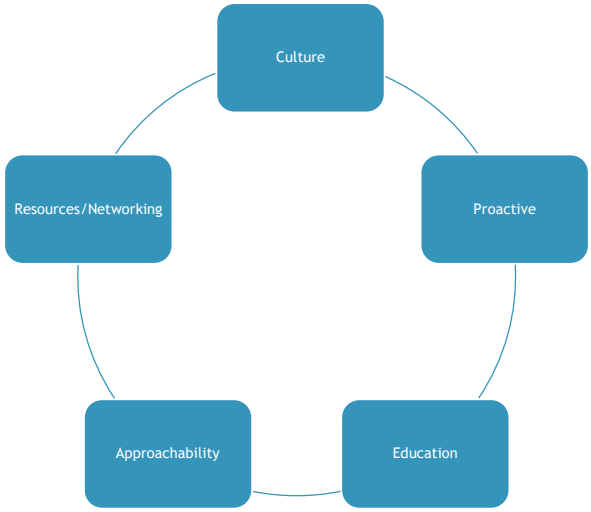
Compliance Best Practices/Tips



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CIA Core Requirements

- Appoint a Compliance Officer and Compliance Committee
  - Compliance Officer must report directly to CEO and be a part of Senior Management
- Develop and Implement Written Policies and Procedures
- Develop, Implement, and Distribute a Code of Conduct
- Develop and Implement a Risk Assessment and Internal Review Process
- Establish a Disclosure Program
- Require Board Training and Annual Training for Employees and Contractors
- Screening Requirements to prevent employment of Ineligible Persons
- Management Certifications
- Engage and Retain an Internal Review Organization for Annual Reviews
- Reporting Requirements
  - Reportable events, Overpayments, Legal Proceedings, etc.
- Submit an Implementation Report and Annual Reports to the OIG

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Compliance Effectiveness

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Compliance Program Effectiveness

- Compliance Programs should be designed, implemented, and enforced in a way that is effective
- Measuring effectiveness is recommended by numerous different agencies
- OIG Resource:
  - Measuring Compliance Program Effectiveness: A Resource Guide
    - Lists numerous compliance program metrics based on the seven elements of a compliance program
    - ”What to Measure” and “How to Measure”

https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf

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Growing Your Program

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Government Oversight

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Authorities to Know

- CMS Overpayment Rule
- False Claims Act
- Anti-Kickback Statute
- Physician Self-Referral Law
- Civil Monetary Penalties Law
- Exclusion Authorities
- HIPAA Privacy and Security

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CMS Overpayment Rule

- Provider must repay its Medicare contractor (or other applicable payor) any overpayments identified
- Consult CMS Overpayment Rule to determine whether extrapolation overpayment must be paid
  - 42 U.S.C. § 1320a-7k(d) and 42 C.F.R § 401.301-305

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False Claims Act

It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent

- Deliberate ignorance or reckless disregard
- Claims may be "tainted" (false) by violation of the anti-kickback statute or physician self-referral law
- Treble damages plus penalties on a per-claim basis

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Anti-Kickback Statute

- Prohibits cash or anything of value in exchange for Medicare or Medicaid business
- Applies to everyone, not just health care providers
- Criminal statute
- Voluntary safe harbors

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Physician Self-Referral Law

- Prohibits referrals to certain health care entities with which physicians have a financial relationship
- Mandatory exceptions

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Civil Monetary Penalties Law

- Kickbacks/ physician self-referral (Stark) violations
- False or fraudulent claims
- Billing while excluded
- Select agents
- EMTALA
- About 40 other OIG CMPs

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Exclusion Statute

- Federal health care programs will not pay for items or services furnished, ordered, prescribed, or supplied by an excluded individual or entity
- The list of excluded individuals and entities (LEIE) is updated monthly
- https://exclusions.oig.hhs.gov/

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Corporate Integrity Agreements

- OIG enters into CIAs in connection with the settlement of health care fraud cases
  - False Claims Act
  - Civil Monetary Penalties Law
- CIA in exchange for OIG's release of its permissive exclusion authority
  - 1128(b)(7) (fraud, kickbacks and other prohibited activities)
- CIA – term of 5 years / IA term of 3 years
- Purpose: improve quality of care and promote compliance

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Guidance and Resources

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OIG Compliance Resource Portal

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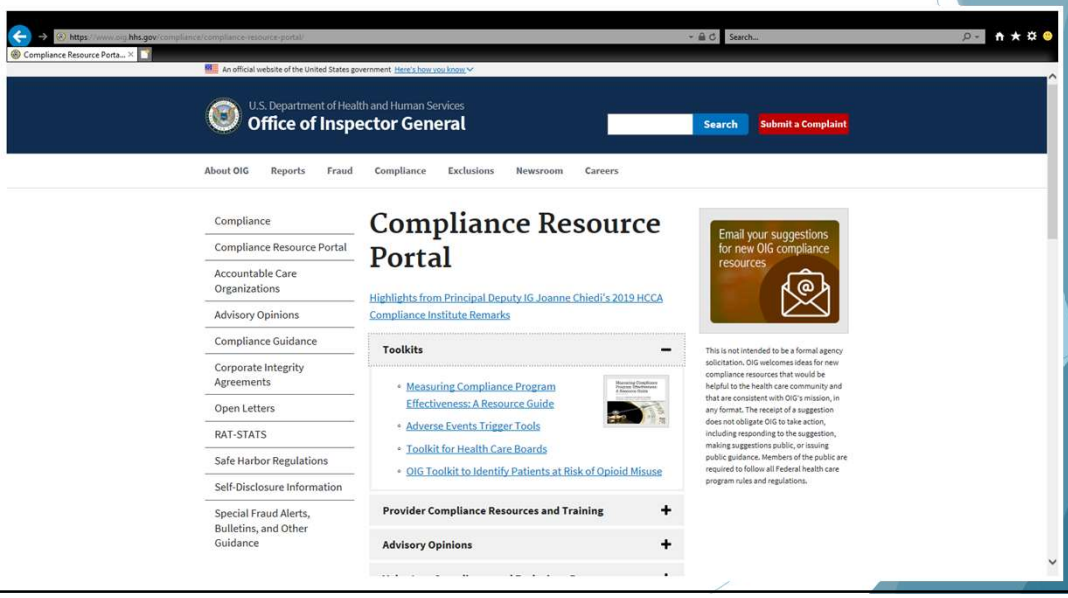
OIG Compliance Toolkits



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OIG Provider Compliance Training Videos

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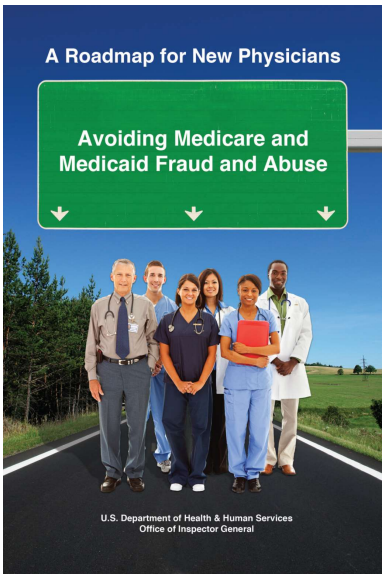

Roadmap for New Physicians

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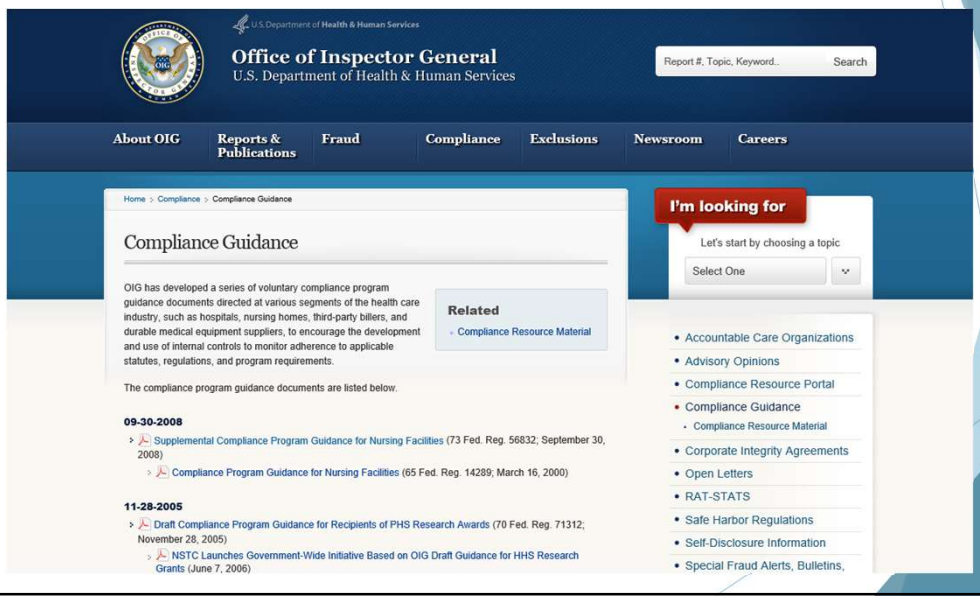
OIG Compliance Program Guidance



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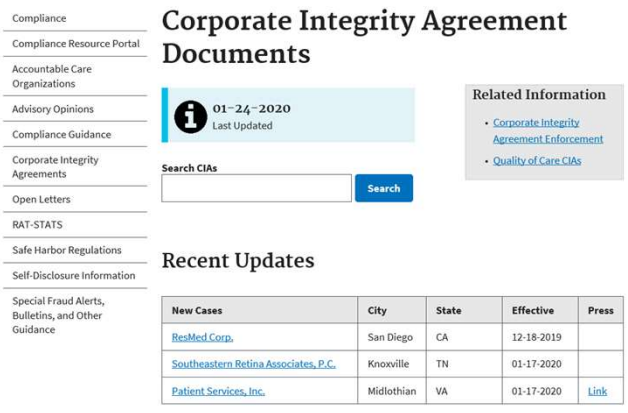

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QUESTIONS

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