The Compliance Connection
Putting all the pieces together

Seven Elements + one more

Compliance programs come in all shapes and sizes
- The Seven Elements (+ one more)
  - important individually, but most effective when interdependent

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01 Written Policies and Procedures

Focused and specific centralized policies applicable across all entities
- Code of Conduct
  - System-wide policies multiple objectives
    - Unified and Standard approach ensuring System level focus
    - Consistency with compliance training, activities and processes
    - Current and responsive with changes in regulatory language
    - Confidence and consistency with external audits
    - Being alert for new policies to strengthen internal controls
    - Annual review and revisions when necessary

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02 Compliance Officer & Compliance Committee

Direct line of communication to CEO and Board
- Ensures Compliance independence and full transparency of information
- Interact directly with Board and provide timely Compliance/Privacy education
- Board’s understanding of Compliance and engagement develops naturally
- System-wide Compliance Committee / Formal Communication Tools
- Quarterly Executive Reports
- Corporate Compliance Committee Reports
- Board Audit and Compliance Committee
- Quarterly and Semiannual Board Reports

03 Compliance Education & Training

Comprehensive, relevant and on-going education
- System-wide Education
  - Mandatory
  - Board level
  - New hire, annual
  - Operations specific & special issues
  - Current/custom approach
- Continuing Education
  - Publications
  - National/Regional Conferences
  - WebEx subscriptions/free
  - Community Connections
  - Listserv
    - CMS/Noridian/Others

04 Monitoring & Auditing

System wide collaboration reinforces awareness of regulatory requirements
- Internal Processes
  - System-wide internal monitoring
  - Compliance auditing
  - Privacy auditing
  - Compliance monitored external audits
- Collaboration with Partners
  - Internal Audit
  - HIM Coding
  - Home Health
  - Laboratory
### 05 Open Lines of Communication

- Actively providing a system of constant interaction with leadership, staff and physicians
  - AlertLine / Dedicated Email
  - Engagement with Operations
  - Partnering/collaborating
  - Regular Board Education
  - Consistent/Informative Quarterly Reports
  - Internal Monitoring and Auditing
  - Privacy Activities
  - Regulatory Updates / Issues
  - Education
  - Targeted Presentations
  - Keeping It Fresh
  - On-going Messaging
  - eTips/Newsletter Articles
  - Annual Awareness Survey
  - Creating Opportunities
  - Visibility
  - Transparency

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“I found that these “extracurricular” activities were actually very helpful in processing the information from the sessions, … discussion in compare-and-contrast fashion that helped me solidify understanding and develop “next steps” for when I returned home” Compliance Today Special Edition 2017 – Marie Wagner CIC

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### 06 Response to Identified Issues

- Tracking and Closing the loop
  - Complete investigation with documentation of findings
  - Corrective actions plans within 30 days
  - Preemptive bill hold processes
  - Monitor identified corrective actions to completion
  - Monthly status report
  - Anticipate delays
  - Breach notification, 60 day overpayment protocols
07 Enforcement of Disciplinary Standards

- Consistent discipline regardless of the position
- Formal Protocols
- Specific Guidelines
- Tracking

+ 1 More: Risk Assessment

- Framework for prioritizing activities and assessing outcomes
  - Work Plan – outlines activities / color coded for risk priorities
  - Proactive quarterly assessment of new or planned ventures/processes
  - Quarterly risk analysis
  - Executive Review and Committee reports
  - Annual Program Assessment report

Work Plan

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<th>Area of Focus</th>
<th>Value Metric</th>
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<tbody>
<tr>
<td>Internal Monitoring</td>
<td>Affiliate</td>
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<tr>
<td>Compliance Auditing</td>
<td>Department</td>
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<td>Compliance Monitored External Auditing</td>
<td>Category</td>
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<td>Vulnerability</td>
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<td>Reporting Schedule</td>
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<td>Status</td>
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Putting the Pieces Together

New Requirement
Internal monitoring
Improvements
Follow-up

New Protocol
Communication
Internal monitoring
Compliance Reports

CMS National Coverage Determination
Shared Decision Making - Example

Affordable Care Act, Section 3506:
Program to Facilitate Shared Decision Making
January 5, 2010

CMS Beneficiary Engagement and Incentives (BEI) Models
Shared Decision Making (SDM) Model
December 8, 2016
- Applies to Accountable Care Organizations (ACO)
- Hospitals engaged through requirements of NCDs
Shared Decision Making

Placing the Patient at the Center of Care

- Facilitating collaborative processes and Communication
- Patient engagement in decision-making
- Preference sensitive care
- Educational tools
- Taking into account the values of the patient

NCD 210.14 Lung Cancer Screening with Low Dose Computed Tomography

B. Nationally Covered Indications
Counseling and Shared Decision Making Visit
Before the beneficiary's first lung cancer LDCT screening, the beneficiary must receive a counseling and shared decision making visit that meets all of the following criteria, and is appropriately documented in the beneficiary's medical records:

- Must include all of the following elements:

  - Shared decision making, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure

Putting the Pieces Together

- New Requirement
- Internal monitoring
- Improvements
- Follow-up
- Education
- Committee Reports
- Internal monitoring
- New Protocol
- Communication
NCD 20.34 Percutaneous Left Atrial Appendage Closure (LAAC)

The Centers for Medicare & Medicaid Services (CMS) covers percutaneous LAAC for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED) with the following conditions:

- LAAC devices are covered when the device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device’s FDA-approved indication and meet all of the conditions specified below:

The patient must have:

- A CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)

- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record.

- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program.