

COMPLIANCE PROGRAM IMPLEMENTATION WHEN YOU ARE NOT IN THE SAME FAMILY

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Donna Schneider is a progressive, visionary healthcare executive with demonstrated accomplishments in corporate compliance, privacy, internal audit, managed care contracting, physician relations, and quality improvement. She has comprehensive experience in hospital operations, involvement in inpatient, and ambulatory and physician group practice management in an integrated healthcare delivery system. Donna also has managed care and self-insured employer group health plan experience in conjunction with a messenger model physician delivery network tenure. She is a registered nurse with an MBA and certifications in quality, compliance and privacy. Donna currently works for Lifespan as the Vice President, Corporate Compliance and Internal Audit; Lifespan Compliance & Privacy Officer. Lifespan is a (4) hospital system in RI comprised of (1) Level One Trauma Center; (2) Magnet Status Community Hospitals; and (1) Pediatric/Psych Hospital. Lifespan also includes 300+ clinics, 19 residential locations and 2,700 practicing/partnering Physicians.



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Jennie Henriques holds her Master's in Business Continuity, Security & Risk Management, and certifications in Healthcare Risk Management, Compliance and Privacy. Jennie is a transformational, progressive and dynamic leader with demonstrated accomplishments in compliancy, privacy, internal audit, quality, performance improvement, risk management, accreditation and patient safety. Jennie has experience in leading a multi-hospital health system through multiple regulatory surveys and investigations. She has comprehensive experience in leading teams and critical projects with an enterprise risk management approach, including developing solutions to meet business needs. She currently works for South Shore Health as the Chief Compliance & Audit Officer. South Shore Health System which has one (1) hospital with a designated Level II Trauma Center, Level III NICU and Magnet status. South Shore Health also has a significant ambulatory presence that includes a physician practice, urgent care centers, VNA, Hospice, Home & Health Resources, Next Generation ACO and a Medicaid ACO.

OBJECTIVES

- ▶ Demonstrate how to introduce, evaluate, and maintain an effective Compliance education program when participants are from different organizations and therefore have various levels of integration and attention to the ACO.
- ▶ Lessons learned on how to implement an auditing program when participants are from multiple organizations.
- ▶ Identify best practice for implementation of a Response Line and Policies for this type of hybrid ACO organization.

ACO COMPLIANCE PROGRAM REQUIREMENTS

In addition to the US Sentencing Guidelines, OIG Compliance Program Guidelines, specific requirements are outline for ACO Compliance Programs.

- ▶ Requirements are not different but rather more specific as it relates to the reporting structure of the Compliance Officer.

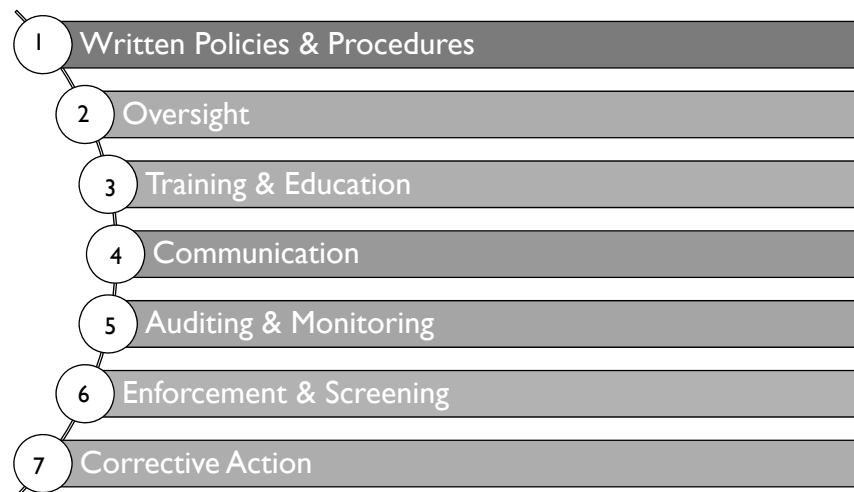
The Accountable Care Organization (“ACO”) must have a compliance plan that includes at least the following elements:

- a) Designation of a compliance officer who is **not** legal counsel to the ACO and who **reports directly to the ACO’s governing body**.
- b) Mechanisms for identifying and addressing compliance problems related to the ACO’s operations and performance.
- c) A method for employees or contractors of the ACO, Participants, Preferred Providers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems to the ACO Compliance Officer.
- d) A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.
- e) Compliance training programs for the ACO and its Next Generation Participants and preferred providers.
- f) Requirements for the ACO to report probable violations of law to an appropriate law enforcement agency.
- g) An ACO’s Compliance Plan must comply with applicable laws and regulations and be updated periodically to reflect any changes.

Reference: <https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol3/xml/CFR-2017-title42-vol3-part425.xml#seqnum425.300>
 US Sentencing Guidelines - <https://www.ussc.gov/guidelines/2015-guidelines-manual/2015-chapter-8>
 1998 OIG Guidance - <https://oig.hhs.gov/authorities/docs/cpghosp.pdf>
 2005 OIG Supplemental Guidance - <https://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>

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SEVEN ELEMENTS OF A COMPLIANCE PROGRAM



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WRITTEN POLICIES & PROCEDURES

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Written Compliance Policies: ACO shall develop and implement written compliance policies that address specific risk areas. These policies shall be made readily available to employees and agents, and be periodically reviewed and revised as necessary. In the absence of a specific written ACO compliance policy, ACO and ACO employees, contractors, providers/suppliers, professionals and participants shall follow [entity] Compliance policies.

Challenges:

- ▶ Each entity may have its own Compliance Program and accompanying policies, so which one takes priority?
- ▶ How do you align compliance program functions such as education, policies & procedures?
- ▶ How and who do you communicate the end result?

Things to review and consider:

- ▶ Develop and Implement a policy on policies
- ▶ Alignment of policies across entities and the ACO participating organizations
 - ▶ Use of attestations
- ▶ Post policies on ACO website

POLICY ON POLICIES... STARTING POINT CONCEPT TO CONSIDER

Purpose: To ensure that all ACO partner organizations have the necessary policies in place to comply with the requirements of the ACO Compliance Plan.

Policy Statement: All ACO participant partners must have policies to comply with the requirements of the ACO Compliance Plan in order to prevent violations of law and to protect patient privacy.

Application: All ACO participant organizations.

Exceptions: None.

Procedure:

All ACO participant organizations must have the policies that address the following issues:

- ▶ Notice of Privacy Practices
- ▶ Conflicts of Interest
- ▶ Marketing Materials
- ▶ Patient Incentives
- ▶ Record Retention
- ▶ Reporting of Probable Violations of Law
- ▶ Prohibited Referrals/Ensuring Freedom of Choice
- ▶ Beneficiary Data Sharing Notification
- ▶ Data Access and Use
- ▶ Beneficiary Notification
- ▶ Exclusion Screening
- ▶ Compliance and Privacy Training
- ▶ Compliance Risk Assessment and Work Plan
- ▶ Compliance Auditing and Monitoring
- ▶ Responding to Government Audits, Inquiries and Investigations
- ▶ Investigations Process (including beneficiary and provider complaints) /Hotline
- ▶ Disciplinary Policy/Guidelines



In the event that a participant organization does not have its own policy on any of the above-listed topics, the participant organization must either adopt such a policy or adopt the relevant (ORGANIZATION) policy for use in its organization.

(ORGANIZATION) has policies that cover the following topics: Marketing Materials, Patient Incentives, Prohibited Referrals/Ensuring Freedom of Choice, Beneficiary Notification and Beneficiary Data Sharing Notification. All other topics listed above are covered by (ORGANIZATION) policies.

ACO also may develop and implement formal, written policies and procedures to supplement and expand upon the ACO Compliance Plan and to otherwise underscore ACO's commitment to compliance. Where appropriate, the ACO Board of Directors may adopt and incorporate policies and procedures from (ORGANIZATION) Compliance Programs.

Responsibility:

ACO Chief Compliance Officer
ACO Participant Organizations

CMS AUDIT

CMS requested copies of the following policies:

- ▶ Code of Conduct
- ▶ Conflicts of Interest
- ▶ Patient Incentives
- ▶ Reporting of Probable Violations of Law
- ▶ Prohibited Referrals/Ensuring Freedom of Choice
- ▶ Beneficiary Data Sharing Notification
- ▶ Data Access and Use
- ▶ Beneficiary Notification
- ▶ Exclusion Screening
- ▶ Responding to Government Audits, Inquiries and Investigations
- ▶ Investigations Process (including beneficiary and provider complaints) /Hotline
- ▶ Disciplinary Policy/Guidelines
- ▶ Writing Information Security Program



Findings:

- ▶ A requirement for the ACO to report probably violation of law to an appropriate law enforcement agency.
- ▶ ACO shall notify CMS **within 15** days after becoming aware that any ACO Participant or Preferred Provider is under investigation or has been sanctioned by the government or any licensing authority.

OVERSIGHT

ACO COMPLIANCE OFFICER

ACO's Compliance Officer, who is not legal counsel to the ACO, is responsible for overseeing day-to-day compliance of the ACO. The **ACO Compliance Officer reports directly to ACO's Board (and not the General Counsel)** and will provide routine updates to the ACO Board setting forth all compliance activity. The ACO Board is responsible for ensuring that the Compliance Plan meets its stated goals and addresses the current regulatory environment and other issues affecting the health care industry.

Several other key items are highlighted and specifically required as part of the ACO Compliance Program:

1. Oversees drafting of compliance programs, including individual business unit Compliance Plans and corporate compliance policies.
2. Directs communication and implementation of compliance goals, standards and procedures throughout the ACO.
3. Directs and coordinates compliance education and training.
4. Develops and implements alternative means of communication to allow improprieties to be reported without fear of retaliation, and promotes open communication with the Compliance Office for reporting and for clarification or questions regarding policies and compliance matters. The foregoing includes the adoption of a compliance toll free (confidential and anonymous) hotline as well as good faith reporting (whistleblower) and other policies.
5. Directs compliance activities between and among ACO, Affiliates and ACO employees, contractors, providers/suppliers, professionals and participants.
6. Oversees investigation of suspected cases of illegal or improper activity within the ACO, Affiliates and ACO employees, contractors, providers/suppliers, professionals and participants. The Compliance Officer recommends corrective steps.
7. Reviews ACO policies and procedures for consistency with standards, procedures and goals of the Compliance Program.
8. Reviews Compliance Program annually, and makes revisions as necessary

OVERSIGHT....

Challenges:

- Responsibilities and reporting structure for ACO Compliance Officer
- Ensure procedures and review process is in place to evaluate potential issues and identify whether or not it is an ACO issue or a participating provider issue
 - Who takes the lead?
 - What policies apply?

Things to review and consider:

- Compliance Officer Job description is updated, especially if role is a shared resource
- Compliance Officer reporting structure
- How is the Compliance Program resourced, budget, etc.
- Maintain separate records/logs around compliance program issues/management



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TRAINING & EDUCATION

TRAINING & EDUCATION

Compliance training programs for the ACO and its Next Generation Participants and preferred providers.



Challenges:

- How do you capture all employees, participants, preferred providers and ensure that they get the required Compliance & Privacy education?
- Small provider practices don't usually have a formal compliance program, and therefore they normally do not have a training & education program.

Things to review and consider:

- Mandate education and training through medical staff credentialing and onboarding process.
- How do you deploy annual mandatory education, paper, online tool, in person...
- The role of your Code of Conduct in education and training...



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CODE OF CONDUCT

ALL employees, workforce members, leaders and medical staff are **required** to adhere to the Code of Conduct.

A valuable document that provides an overview of expectations and can be used as an educational tool that touches on many topics including but not limited to:

- ▶ Responsibility for doing the right thing, highlights standards of behavior, your role, the role of management, and the non-retaliation policy.
- ▶ Establishes a zero tolerance for fraud, waste and abuse.
- ▶ Promotes and provides guidance for all employees to take personal accountability by asking questions, seeking guidance and raising concerns.
- ▶ Information on how to report compliance and/or privacy concerns.



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COMMUNICATION

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A method for employees or contractors of the ACO, Participants, Preferred Providers, and other individuals or entities performing functions or services related to ACO activities to learn about the compliance program and anonymously report suspected problems.

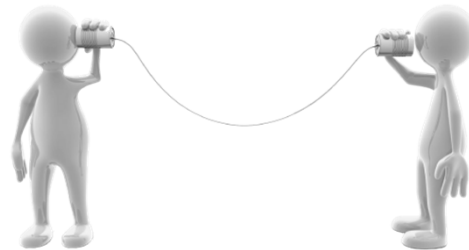
- ▶ Establish a method to report directly to the ACO compliance officer and/or compliance department
- ▶ Establish compliance hotline & email
- ▶ Ensure that you have established a working partnership with representatives from each ACO Participating provider, etc.

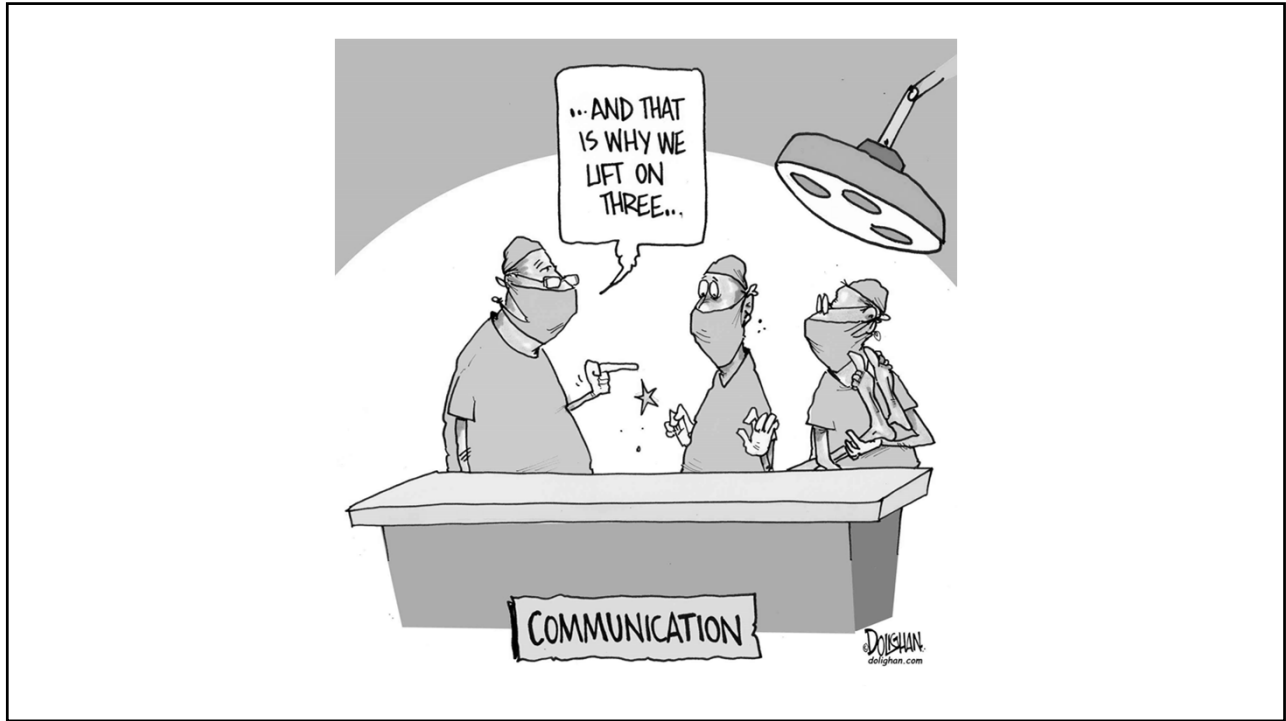
Challenges:

- Which compliance line?
- Who takes the lead?
- Which policies and procedures apply?
- What if there is a disagreement?

Things to review and consider:

- Rules of the road...
- Is it an ACO issue or participating provider issue?
- Identify compliance partners





AUDITING & MONITORING

AUDIT & MONITORING

- ▶ Annual Risk Assessments
- ▶ Audit financial and quality data to validate accuracy and completeness of data.
 - ▶ Engage outside auditor to audit financial data
 - ▶ Develop & implement audit process to validate quality data across the ACO

Challenges:

- Who will conduct audits?
- Who is going to pay for the audit?
- Access to documentation

Things to review and consider:

- What should you audit
 - Quality data
 - Financial data
- Participating provider(s) agreements



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ENFORCEMENT & SCREENING CORRECTIVE ACTION

ENFORCEMENT, SCREENING & CORRECTIVE ACTION

Program Requirements:

- Perform exclusion checks for all new ACO employees, existing employees, vendors and physicians, at minimum on a monthly basis.
- Conflict of Interest: Board members and senior management complete conflict of interest form. Additionally, Compliance office requires all ACO providers, Directors and identified members of decision making committees to complete management conflict of interest form.
- Maintain database/log of incidents reported as compliance, privacy, information security incidents, document follow-up and resolution to incidents and inquiries.
- Consistently administer corrective actions in response to compliance and privacy violations in accordance with policies and program requirements.

Challenges:

- Who is responsible for conducting exclusion checks, timely reporting of excluded individuals, and who is responsible for reporting?
- Who's policies do you follow?
- Who is not conducting exclusion checking, and how do you get them to do it?

Things to review and consider:

- Consider one unified policy
- Consider using attestations
- Notification to CMS is required within 15 days, and your policy needs to explicitly state so...
- Who will monitor who (corrective action)



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