

Large Hospitals and Health Systems

HCCA 22st Annual
Compliance Institute

PREAM1
APRIL 15, 2018

SL1

Session Goals

- Learn how to benchmark your program against other large hospitals and health systems through use of polling software.
- Understand challenges relevant to large hospitals and large health systems.
- Engage in dialogue with colleagues regarding operational solutions and best practices for large hospitals and health systems.

Slide 2

SL1 Shanna Luke, 3/20/2018

Discussion Facilitators

- Suzie Draper – VP, Business Ethics and Compliance
Intermountain Healthcare
- Margaret Hambleton – VP, Corporate Compliance Officer
Dignity Health
- Kimberly Otte – Chief Compliance Officer
Mayo Clinic



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Roulette Wheel

Compliance Operations

- How to Play
 1. Spin
 2. Discuss
 3. Learn
 4. Share



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Compliance Operations

1. Effectiveness Evaluation
2. Risk Assessment
3. Board Reporting / Governance Committees
4. Effective Training Strategies
5. Policy Development and Dissemination
6. Dashboards and Key Performance Indicators
7. Influencing Stakeholders
8. Work Plan Management
9. Budget Strategies
10. FTE Optimization
11. Organization Around 7 Elements
12. Relationship with Legal
13. Relationship with Internal Audit

Continue to Hot Topics

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Effectiveness Evaluation

- DOJ Evaluation of Corporate Compliance Programs
 - Analysis and Remediation
 - Oversight – Senior and Middle Management
 - Autonomy and Resources
 - Policies and Procedures
 - Risk Assessment
 - Training and Communications
 - Confidential Reporting and Investigation
 - Incentives and Disciplinary Measures
 - Continuous Improvement, Periodic Testing and Review
 - Third Party Management
 - Mergers and Acquisitions

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Effectiveness Evaluation

- Measuring Compliance Program Effectiveness – A Resource Guide
 - Based on 7 Elements
 - What to Measure
 - How to Measure
- Broad input from Operators, Compliance, Legal, etc.
- Year-over-Year trends
- Basis for Scoring
- Input for Annual Work Plan

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Risk Assessment

8th Element of an Effective Compliance Program

- Government guidance
 - Federal Sentencing Guidelines
 - “Organizations shall periodically assess the risk of criminal conduct and shall take appropriate steps...”
 - OIG Program Guidance
 - “Institutions should consider conducting risk assessments to determine where to devote audit resources...”

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Risk Assessment

Risk Identification

- Surveys
- Interviews
- Prior audit findings
- Prior compliance investigations
- Exit Interviews with separating employees
- External sources



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Risk Identification

Controls vs. Risks

- Controls:
 - Policies, procedures, audits, education, management approvals, quality reviews, automation, program structure, etc.
 - Examples:
 - Does the organization have a policy on Conflict of Interest?
 - Does the organization update the standards of conduct periodically?
 - Are Compliance Committee minutes reviewed?
 - Are procedures in place to identify and address billing misconduct?
 - Who is responsible for monitoring and enforcing adherence to these policies?

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Risk Assessment

- Impact (Severity)
 - Financial
 - Legal
 - Reputation
 - Operations
 - Strategic
- Vulnerability
 - Likelihood/Frequency/History
 - Complexity
 - Rate of Change
- Controls

Compliance Risk Assessment - FY15																
Risks		Impact						Vulnerability				Prioritization				
Risks	Category	Risk	Financial	Reputation	Legal/Regulatory	Stakeholders	Operational	Strategic	Impact Score	Likelihood / History	Complexity	Rate of Change	% Uncontrolled	Total Vulnerability	Risk Priority Score	Comments
		Risk 1	5	5	4	3	3	4	24	4	4	2	75%	7.5	180.0	
		Risk 2	5	4	5	3	4	4	25	2	2	2	25%	1.5	37.5	
		Risk 3	1	2	3	4	3	2	15	4	5	5	95%	13.3	199.5	
		Risk 4	3	3	3	4	3	3	19	4	5	4	50%	6.5	123.5	
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Board Reporting/Governance Committees

- Cadence of Reporting
- What to Report
 - Significant Matters/Investigations – ACP?
 - Government Contacts
 - Audits and Monitoring
 - Work Plan
 - Department Activities
 - Hotline Reports
 - Voluntary Refunds
 - Education
 - Other??



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Board Reporting/Governance Committees

Board Oversight

- Compliance function should be separate from, and not report directly to, legal counsel
- Boards should get regular updates on compliance efforts – can't bury head in sand
- Boards must be proactive in identifying areas of risk within particular organization/industry

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Corporate Governance Responsibilities

Duty of Care

Director shall perform his/her duties, including duties as a member of any committee of the board upon which the director may serve:

- In **good faith**;
- In a manner that director believes to be in the **best interests of the corporation**; and
- With **such care**, including reasonable inquiry, **as an ordinarily prudent person** in a like position would use under similar circumstances.

The conscientious pursuit by directors of principles of best practices is the foremost approach to the duty of care and best prophylactic against director liability.

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Corporate Governance Responsibilities

Duty of Inquiry

Cannot be passive and must actively participate in decisions.

Must **make reasonable inquiries** regarding potential decisions:

- Healthy skepticism and questioning
- Asking for clarification regarding issues and impact of decisions
- What would an ordinarily prudent person ask or want to know under similar circumstances?

Reliance on others for information and answers:

- Reliable and competent officers and employees;
- Legal counsel, accountants and others with professional or expert competence; and
- Board committees as to matters within their designated authority.

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Corporate Governance Responsibilities

Duty of Oversight

In re Caremark International Inc. Derivative Litigation

"But it is important that the board exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations, so that it may satisfy its responsibility."

"And obviously too, no rationally designed information and reporting system will remove the possibility that the corporation will violate laws or regulations, or that senior officers or directors may nevertheless **sometimes be misled or otherwise fail reasonably to detect acts** material to the corporation's compliance with the law. "

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Review and Oversight *of Compliance Program*

Based on the legal principles and resources as described, the Board:

- Has an affirmative **duty to reasonably oversee implementation and operation of** an effective program for **organizational compliance** with key federal and state laws.
- Must assure that the Compliance Program has **effective systems in place to regularly report on** the results of the **Compliance Program's work** (including internal audit) to the Board of Directors (or a committee thereof).
- Is entitled to **rely**, in good faith, **on officers and employees as well as corporate professional experts/advisors** (when board believes confidence in experts is warranted) regarding compliance, Compliance Program and effectiveness of Compliance Program.

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What are you telling your board with these measurements? *Unintended Stories*

- Hotline statistics – timeliness and adequacy of responses
- Investigation statistics
- Likelihood and severity of top risk areas
- Training completion rates
- Predictive analytics (behavior, ROI, non-official reporting channels)
- Policy dissemination
- Corrective action plans completion – from audits
- Audit findings

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Effective Training Strategies

- Recorded completion does not equal effective learning
- Measuring and operationalizing “thinking” or “reasoning” skills is far from straightforward
- Content development should reflect
 - the information needed
 - by the specific audience
- Access to “knowledgeable mentor” for questions

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Effective Training Strategies

Strategy	Pros	Cons
Computer Based Learning	<ul style="list-style-type: none">• Consistent content• Easy to track/report	Testing questions and feedback are static.
Push Down (instructor led)	Engaged at multiple levels	Revisionist content (telegraph game) FTE Intensive
Pull (just in time)	Learner engagement <ul style="list-style-type: none">• Reason to know• At time needed to know	Extensive content development (information deck for all possible needs)

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Policy Development and Dissemination

- Define “policy”
- Start with inventory and metrics
- Central door, limit administrators, templates, roles
- Mandatory field for “Required by . . .”

KEY METRICS				
Metric	Q1 2017	Q2 2017	Q3 2017	Q4 2017
Total number of policies stored in the Policy and Procedure Management System at the end of each quarter	8,102	7,552	7,176	7,051
Total number of new policy requests that have been approved by the Policy Office per quarter	37	35	55	30
Total number of policies retired from the Policy and Procedure Management System by quarter	279	396	358	518

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Dashboards and Metrics

- Use with risk assessment to earn credibility
- KPIs and KRIs
- Effort versus effectiveness measures
- Transparency and peer review
- Use a continuum

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Integrity and Compliance Office

PRIVACY OFFICE - Q1 2018 HIGHLIGHTS/TRENDS

- Proactive Monitoring will not meet plan for 2017; a new timeline has been established (see risk item below)
- No significantly large breaches this quarter

KEY RISKS

STATUS INDICATORS: On Target to Meet Plan | Moderate Risk of Not Meeting Plan | High Risk of Not Meeting Plan | Completed | Canceled | Not Started

Risk Description	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018*	Mitigation and Control Activities
Proactive Monitoring Efforts	●	●	●	●		
Plummer Project- Privacy SME	●	●	●	●		
Engagement of Key Risk Items						

KEY METRICS

Metric	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018*	2018 YTD	2017	Comments
DDOC Requests Reviewed								
For Cause Audit Requests Received								
For Cause Audits Sent to HR								
Proactive Audits Sent to HR								
Incidents Reported to Privacy (Internal)								
HHS Reportable Breaches (External)								
Number of Patients Notified								
Information Security Incident-Related								
Number of Individuals Notified as a								
Regulatory Complaints/Audits								
Terminations/Resignations/ Retirements								
Related to Reckless Behavior**								
Other Corrective Actions Related to								
Reckless Behavior								
Number of Patients Notified as a Result								
of Reckless Behavior								

* through 12/20/2017

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Influencing Stakeholders

- Role is very relationship based
- "Assume benign intent"
- Find partners, share
- Transparency and peer pressure
- Values as common denominator

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Work Plan Management

- Highest Regulatory Compliance Risks as Determined by;
 - Enterprise Risk Assessment
 - Hotline Data
 - Enforcement Activity
 - OIG Work Plan
- Integrate into Operations' Work Planning Processes
 - Catch ball
- Approved by the Audit and Compliance Committee of the Board
- Maintain Focus
 - Monthly / Quarterly updates and reports to Stakeholders
 - "Return To Green" plans documented when plan is off-track
 - Completion rate goals for all care-givers

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Budget Strategies

- Quantify the metrics that are important to your organization
 - Repayments
 - Penalties
 - Number of incidents per violation type
- FTE
 - Appropriate level of resource for activities needed
- Technology
 - Compliance standalone v piggy-backing on other enterprise systems
 - Budget and visibility
 - Tableau
 - Chronos

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FTE Optimization

- Appropriate level of resource for activities needed
- Fulltime dedicated vs available capacity within the organization
- Match resources to organizational changes

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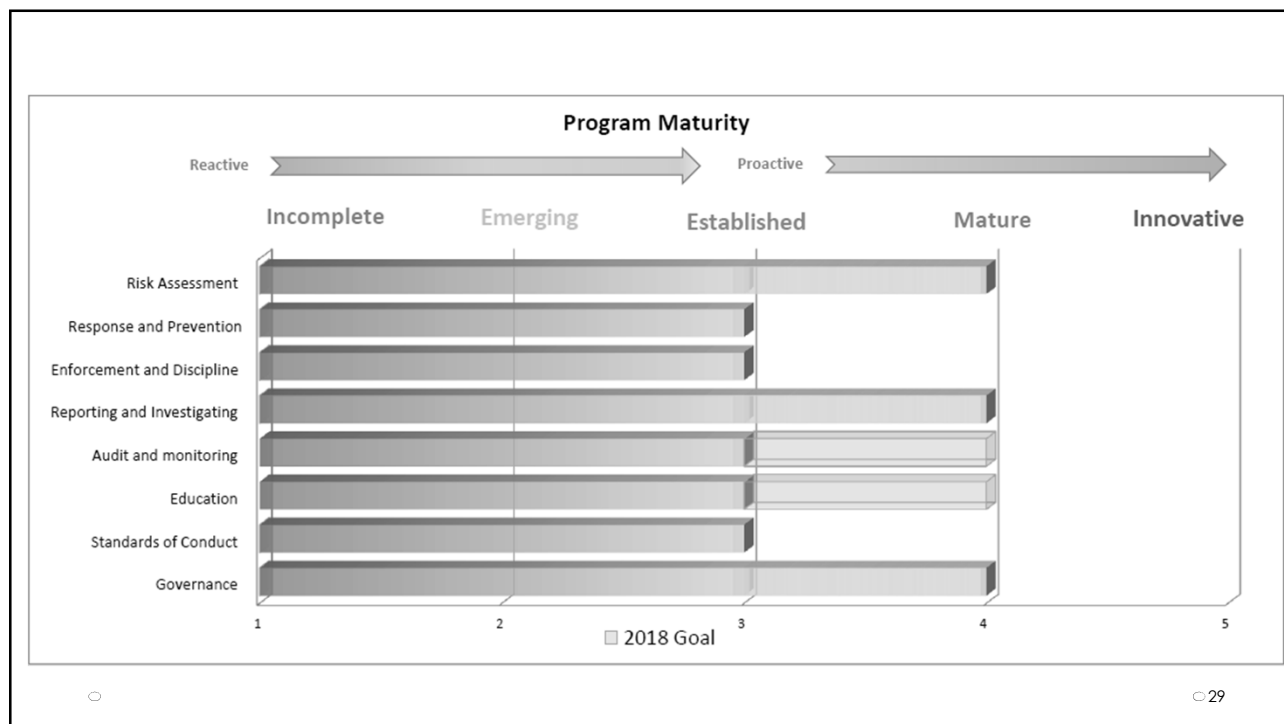
Organization Around 7 Elements

- Used to define role – first with team and then with leadership
- Tool at any level
- Not every element for every risk
- Compliance 101 book
- Self assessment tool



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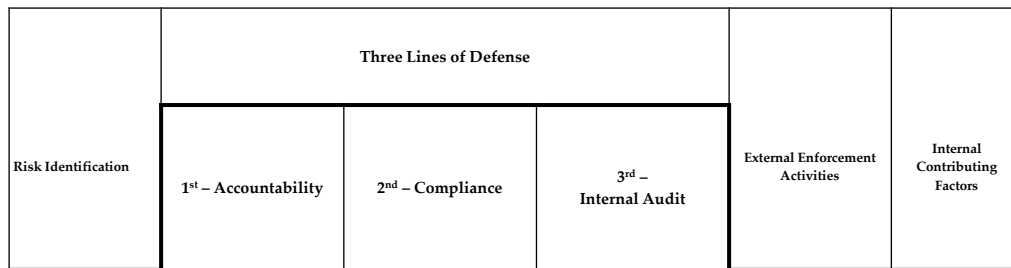
Relationship with Legal – Tips

- Essential ally
- Defense table versus going forward table
- Depends . . .
- JD needed for new interpretations
- ACP discussions
- Annual presentation of priorities



Relationship with Internal Audit – Tips

- Risk umbrella, common language, coordinated coverage
- Three lines of defense
- Routine meetings



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Compliance Hot Topics - 2021

- How to Play:
 1. Two card players – Head to Head Match
 2. Winner picks topic for discussion
 3. Discuss
 4. Share
 5. Learn



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Compliance Hot Topics

1. Large Breach Response
2. Drug Diversion / Opioid Response
3. 340B Compliance
4. Physician Integration / Population Health / Bundled Payments
5. Working with Health Plans
6. Proactive Privacy Monitoring
7. International - GDPR
8. Cybersecurity
9. Sexual Harassment
10. Joint Ventures
11. False Claims Act -- Paybacks

Continue to Future Topics ○33

Large Breach Response

- Vender for assistance with mailings and call center
- Internal communications plan ready now
- Tabletop exercises
- Consider BA breach

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Drug Diversion/Opioid Response

- Scope

- Patients vs Employees
- Setting (hospital, clinic, homecare)

Centralized Oversight

- Standardization of discipline / reporting
- Identifying risk areas
- Multidisciplinary Team

- Diversion Suspected, now what?

- Drug Screening
- Communicable disease testing
- External Reporting

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340B Compliance

- Licensed as hospital space

- "child site" compared to off-campus hospital
 - location not contiguous must be enrolled
 - off campus provider – greater than 250 yards
 - creates instances where on campus provider-based must be enrolled as child site
- Revenue and expenses – for previous calendar year – must be on the Cost Report

- Drug inventory kept separate and tracked

- Provider misunderstanding

- Makes drugs cheaper for hospitals, not patients
- Patients must still follow Patient Financial Assistance policies
- Drug savings recognized by patients other ways

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Physician Integration/Population Health

- ACO's, CIN's, Bundled Payments
 - Application
 - Operations
 - Privacy – OCHA 1 or OCHA 2?
 - Data Use Agreement
- Waivers
- Governance
- Risks and Vulnerabilities

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Working with Health Plans

- Integrated delivery systems
- Understanding state and federal government rules
- Understanding payer contract obligations
- Wild-wild west of “At Risk” arrangements – it's a mess

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Proactive Privacy Monitoring

- Great promise of data analytics
- Focus on high profile patients first
- Next use rules for neighbor and co-worker access
- Turn the light on very slowly
- Advertise capability broadly ahead of time



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International -- GDPR

General Data Protection Regulation

- Regulation passed by European Parliament, protecting data of persons in EU.
- Effective May 25, 2018

Does it apply?

- 2 ways GDPR can apply to non-EU entities
 - **“Offering goods or services”** to people in EU
 - **“Monitoring the behavior”** of people in EU

If it applies, what is required?

- Broader than HIPAA – not limited to personal health information
- Standards differ from HIPAA

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Cybersecurity

- \$\$\$\$\$\$\$\$\$\$\$\$\$\$\$\$\$\$
- Framework helps to measure and order risk
- Constant shiny objects: medical devices, pagers, disposal, mobile devices
- Requirements for Bas
- IT or risk function?
- Strong privacy link essential

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Sexual Harassment

- Change investigation techniques?
- Change Reporting
- Employee and Patient Safety
- Reputational Risk
- Education
 - State Mandated
 - Required
 - Voluntary

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Joint Ventures

- Ownership
- Management
- Compliance oversight
- Data Sharing – ACE, OCHA, OCHA 2, Other
- Leveraging resources

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False Claims Act – Paybacks

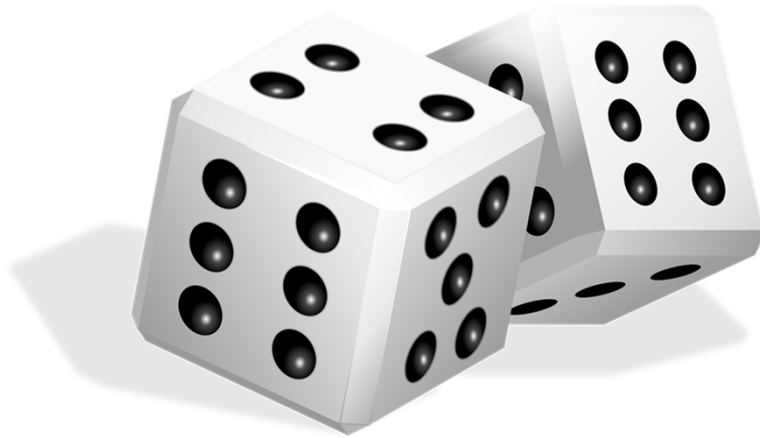
- 6 months, 60 days
- Methodology – probe, statistically valid random sample
- Whistleblower risk

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Future Topics – A Game of Dice

- How to Play
 1. Role the Dice
 2. Discuss
 3. Share
 4. Learn



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Future Topics
2. Political Environment
3. International Health Care Compliance (FCPA)
4. Care Delivery / Access Through Technology
5. Mega Mergers
6. Managing Third Parties
7. Use of Data Analytics and Artificial Intelligence
8. Manufacturing Regulations
9. Administrative Simplification
10. Risk Based Pools
11. Partnering with Technology Giants
12. MACRA

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Continue to Close

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Political Environment

- ?????????
- Brand memo
- Administrative simplification opportunity
- Use of data analytics

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International Health Care Compliance (FCPA)

- Anti Bribery (FCPA)
- GDPR
- Export Control



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Care Delivery/Access Through Technology

- Imagine the future
- Privacy and Security Assessments
- Technology Advancing Faster Than Legal Environment
- Stark/Kickback Issues
- The 5 Things

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Mega Mergers

- Here to Stay – What Does it Mean
- Effect on Philanthropy?
- Effect on U. S. Health Care?
- Combining Compliance Programs
- Development of New Standard?

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Managing Third Parties

ACO Compliance

- Ensure understanding of rules specific to the type of ACO
- Develop appropriate policies and procedures
- Ensure governance oversight of the ACO
- Coordinate with other stakeholders

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Use of Data Analytics and AI

- Compliance Opportunities
- What to Measure – Where to Look for Variance?
- New Staff Skills – Statistical Analysis
- Precision Medicine

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Manufacturing Regulations

- FDA regulations attach increasingly to innovation [find picture of big smoking factory]
- Quality processes are of a different order of magnitude
- Inventory, audit, eQMS

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Title IX Compliance

- Attach for any school accepting federal funding
- Need extensive policies, process and coordinator
- Requires “interim measures”
- Also, Clery Act and FERPA

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Administrative Simplification

- <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html>
- Trump 100 Day Plan: THIRD, a requirement that for every new federal regulation, two existing regulations must be eliminated
- Internal efforts
- Berwick article in JAMA 2017, "Breaking the Rules for Better Care"

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Risk Based Pools

- Understanding the contract obligations
- Understanding data sharing arrangements and agreements
- Disbursement of funds

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Partnering with Technology Giants

- Who will deliver Health Care in the Future?
- What will Health Care Look Like?
- Consumer versus Provider Driven Health Care
- Cost, Control, and Compliance
- Uber Medicine

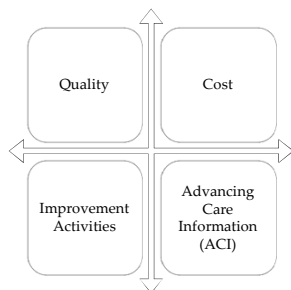
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MACRA

Merit Based Incentive Payment Systems (MIPS)

Background (what it is)

- System for physicians and other clinicians to report measures to CMS
- Payments adjusted upward or downward based on scores



Recent developments

First year

- First year of reporting completes March 31. How will first year go? Will most clinicians successfully report?

Ramp-up

- Reporting standards ramping up each year

Future

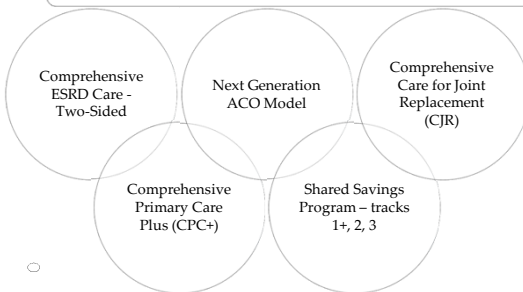
- Growing criticism / concerns about program (MedPAC, others)
- CMS initiatives to reduce burden

MACRA: Alternative Payment Models

Background (what it is)

- As alternative to MIPS, clinicians can participate in Alternative Payment Models (APMs)
- Participation qualifies clinicians for
 - lump sum bonus payments in early years,
 - higher payment rates in later years

Examples of APMs



Change in focus for future APMs?

- CMS declined to move forward on new mandatory models
- CMMI rolled out a new voluntary bundled payment model
- Possible future focus on physician-led APMs?

FWA and APMs

- Ongoing concerns about working through Stark, AKS, and related issues
- Advocacy for safe harbors, exemptions

Intermountain Healthcare

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Intermountain Healthcare

- Serves Utah and southeastern Idaho
- Not-for-profit healthcare system
- 22 hospitals
- 180 clinics
 - 24 community clinics for low-income, homeless and uninsured; 5 owned, 16 receiving financial support
- 2,200 employed doctors and advanced practice clinicians
- Health insurance - SelectHealth
 - 852,000 covered lives
- Homecare and Hospice
- Clinical Quality Board Goals
- 40,000 employees
- Total assets of \$10 billion



Dignity Health

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Dignity Health

- Founded in 1986, we've made it our goal to create environments that meet each patient's physical, mental, and spiritual needs.
- Dignity Health is made up of more than 60,000 caregivers and staff who deliver excellent care to diverse communities in 21 states.
- 39 acute care hospitals located in California, Arizona, and Nevada
- Headquartered in San Francisco, Dignity Health is the fifth largest health system in the nation and the largest hospital provider in California.
- Total assets of \$17 billion



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Mayo Clinic

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Mayo Clinic

- Founded in 1864 - primary value "The needs of the patient come first."
- Three main campuses in Minnesota, Florida, and Arizona with dozens of Mayo Clinic Health System sites.
- Over 65,000 staff
- Over 1 million people seen yearly from around the world



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