Massachusetts Health Data Consortium

18-Mar-2015

Healthcare Compliance in 2015

"Achieving seamless compliance with healthcare mandates."

Agenda

I Introduction

II Legal – Issues in Compliance

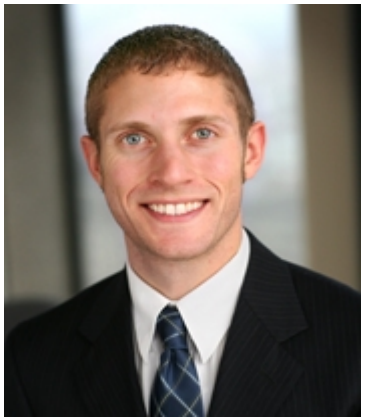
III Provider(s) Challenges

IV Engagement Scenario

V Technology as a Tool

VI Summary / Q&A

I. Introductions



Matthew Fisher

Matt Fisher is the co-chair of Mirick O'Connell's Health Law Group and a member of the firm's Business Group. Matt focuses his health law practice on regulatory compliance, including HIPAA and fraud and abuse.

Paresh K. Shah

Paresh Shah is a founder and president of MindLeaf, with over 20 years of experience in healthcare. He is a Specialist in Healthcare Regulatory Compliance

* HIMSS – ICD10 Task Force member
* ICD10 Playbook: Co-Chair.

Achieved INC 500/5000 from 2007 - 2012 as a fastest growing company in the US. Achieved Boston Business Journal Pacesetters Award from 2009-2011.

Don Gleason

Don Gleason is recognized for driving cross-organizational efforts that advance delivery excellence with a vision directly tied to customer satisfaction and compliance. Throughout his career he oversaw strategic client programs and operational improvements and provided strategic portfolio leadership and direction to over commercial payer, provider, and government healthcare / health information initiatives.

II. Achieving Compliance in 2015

12 Months

2015

Jan	Feb	March	April	May	June	July	Aug	Sep	Oct	Nov	Dec

HIPAA Privacy & Security

Meaningful Use – Stage 2

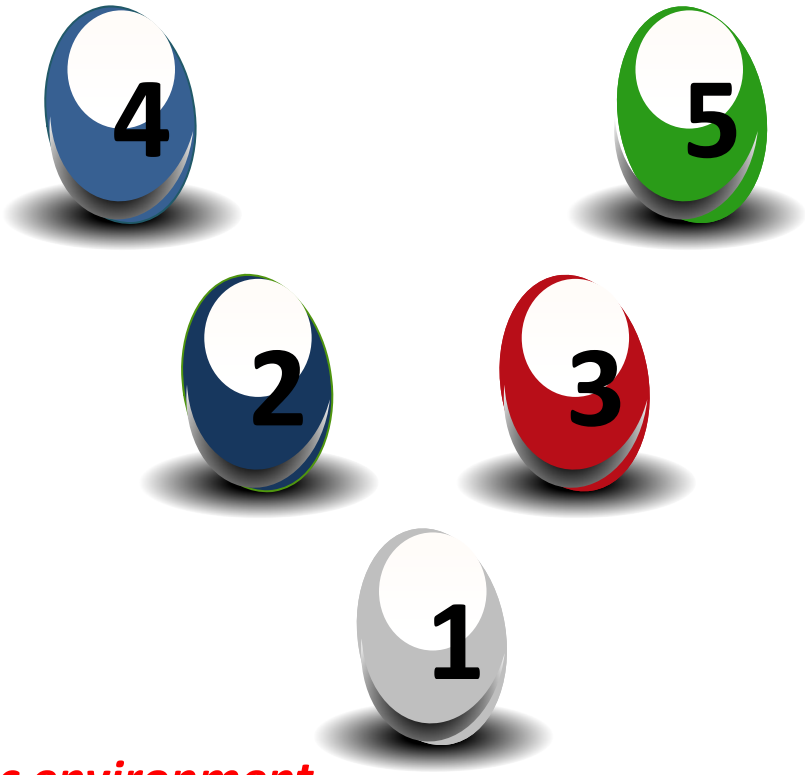
ICD-10 (Meet compliance)

ICD-10 Post compliance

Goal – Fear of not being compliant and the penalties associated.

Challenges

1. Establishing enterprise-wide understanding of the new compliance programs (MU-2, ICD-10, HIPAA Privacy/Security
2. Assessing current vs. desired state for the enterprise. Developing a plan to close the gap
3. Reworking affected systems while not disturbing production during transition
4. Training
5. Attestation/ Audit



Budgeting the costs in a difficult economic environment

Will you be able to achieve?

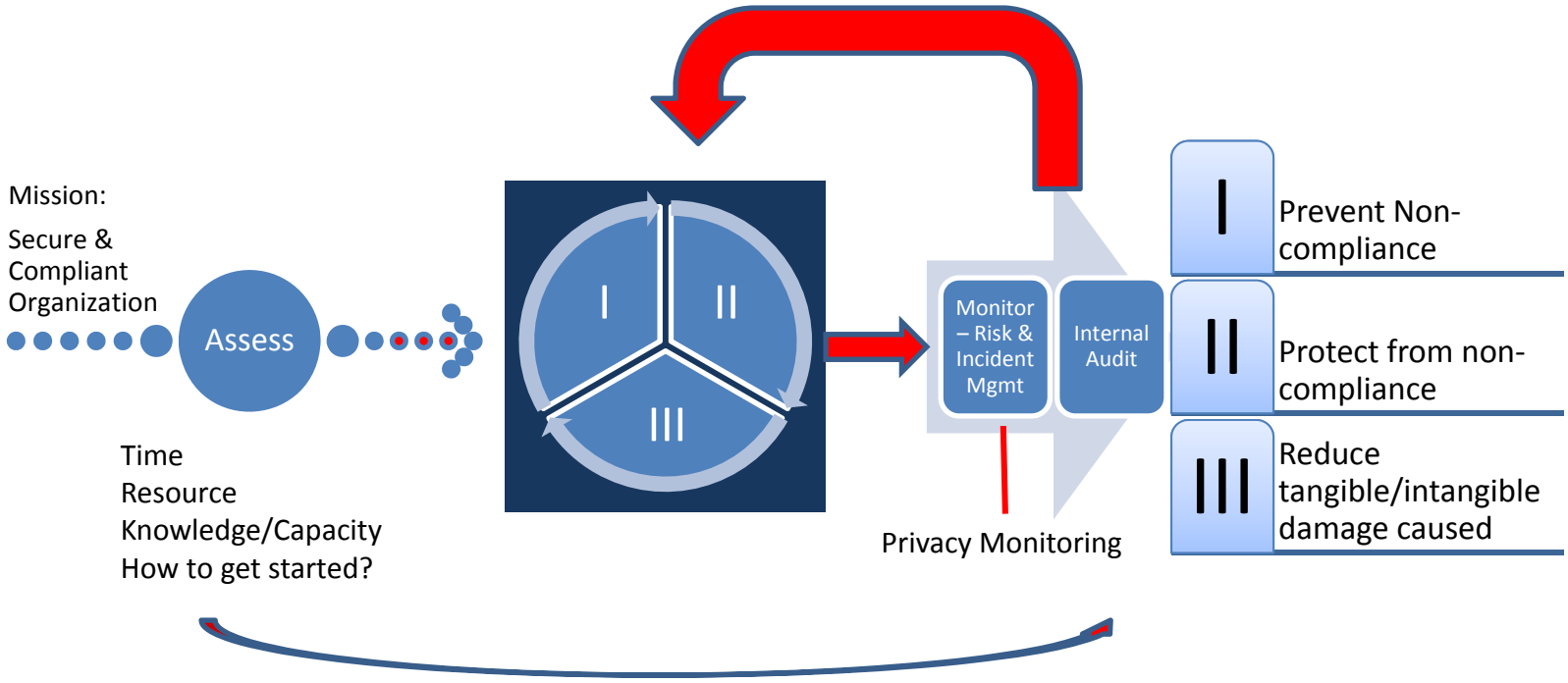
This presentation will offer a look into establishing a Compliance Program and potential areas of focus for you to consider, as your organization determines its approach to become a secure and compliant organization.

At the end of the presentation you will be able to discuss:

- How to prevent non-compliance
- How to protect from non-compliance
- Reduce tangible/non-tangible damage caused

MindLeaf model

I	Assess/ Define to become a secure organization
II	Develop documentation
III	Train people and attest



SAAS based platform

- Compliance Mgmt Platform
- (Documentation library)

II. Legal – Issues in Compliance

Start with an end in mind

The opportunity to secure ourselves against defeat lies in our own hands, but the opportunity of defeating the enemy is provided by the enemy himself.
- Sun Tzu

Your company might get hacked, but 'you can't make it easy for them'
- Homeland Security Official Mar 11, 2015, 2:35pm EDT

Meaningful Use: Assignment of Incentives

Assignment a contractual issue

- CMS explicitly stated it does not want to play a role
- Who gets the incentive?
  - Eligible Professionals (EP) and Eligible Hospitals
- How can incentive be assigned?
- What happens if EP leaves or retires?

Meaningful Use: Attestation

- Attestations and incentive payments being audited
- Essential to maintain documentation to support attestation
- What are biggest risks?
  - Risk assessment (similar to HIPAA)
- What are risks associated with attesting through proxy?

HIPAA:
Lessons to Learn from Recent Breaches/Settlements

New York Presbyterian Hospital and Columbia University

- Settlement announced May 7, 2014
- Breach result of physician hooking personal computer server to system network
- System not secure, connecting server resulted in ePHI being accessible through internet search
- No prior efforts made to assess security of server
- No assessment of software protections available for server
- OCR found lack of adequate risk analysis
- Fined $4,800,000

HIPAA:
Lessons to Learn from Recent Breaches/Settlements

Parkview Health System

- Retired physician filed complaint
- Parkview supposed to retain custody of medical records on behalf of physician
- Instead, Parkview employees delivered boxes of records to retired physician's home
- Employees knew physician not at home
- Boxes of records left on driveway
- Fined $800,000

HIPAA:
Lessons to Learn from Recent Breaches/Settlements

Concentra Health Services

- Laptop stolen from facility
- Laptop not encrypted
- Numerous prior risk analyses identified lack of encryption was a critical risk
- Some steps taken to encrypt, but efforts incomplete and inconsistent
- Fined $1,725,220

HIPAA:
Lessons to Learn from Recent Breaches/Settlements

Anchorage Community Mental Health Services

- Self-notification of breach resulting from malware
- Malware compromised security of whole IT system
- ACMHS adopted Security Policies, but took form policies
- Policies, once adopted, not followed
- Software not updated with available patches and used outdated software
- Basic risks not identified nor addressed
- Fined $150,000

HIPAA:
Lessons to Learn from Recent Breaches/Settlements

Nebraska Medical Center

- Treated first Ebola patient in the country
- 2 employees asked patient's medical record
- Employees did not have purpose for access
- Employees terminated
- No fines, yet

HIPAA:
Lessons to Learn from Recent Breaches/Settlements

Community Health System

- Data breached as a result of being hacked
- Not apparent whether controls and systems adequate or insufficient
- Offered warning to all other healthcare entities
- Demonstrates high value placed upon healthcare information
- No fines yet Lawsuits filed

Anthem

- Hackers broke into system
- Up to 80 Million individuals impacted
- Result of cyber attack
- Need to analyze unusual activity
- Highlighted weaknesses in healthcare IT
- Lawsuits coming

HIPAA:
How to Reduce Exposure?

HIPAA Security Risk Analysis (SRA)

- Common Findings of a HIPAA Security Risk Analysis
  - Lack of system activity review
  - Lack of encrypted offsite data backup
  - Lack of an implemented and tested disaster recovery plan
  - Lack of email encryption
  - Lack of laptop encryption
  - Lack of mobile encryption (smartphones / tablets / USB drives, etc.)
  - Lack of anti-virus on all endpoints and servers
  - Lack of security patching of servers and desktops
  - Lack of security penetration and vulnerability testing
  - Lack of security incident response procedures

Inventory, Access Risk, Recommend Additional Security

HIPAA:
How to Reduce Exposure?

Training

- Training must create a culture of compliance (highlight sanctions)
- Consider different types of training for different categories of employees (e.g., special training for people with remote access or BYOD training)
- Training must extend to physicians
- Don’t forget about Security Reminders! (and Privacy Reminders!)

HIPAA:

How to protect patient information

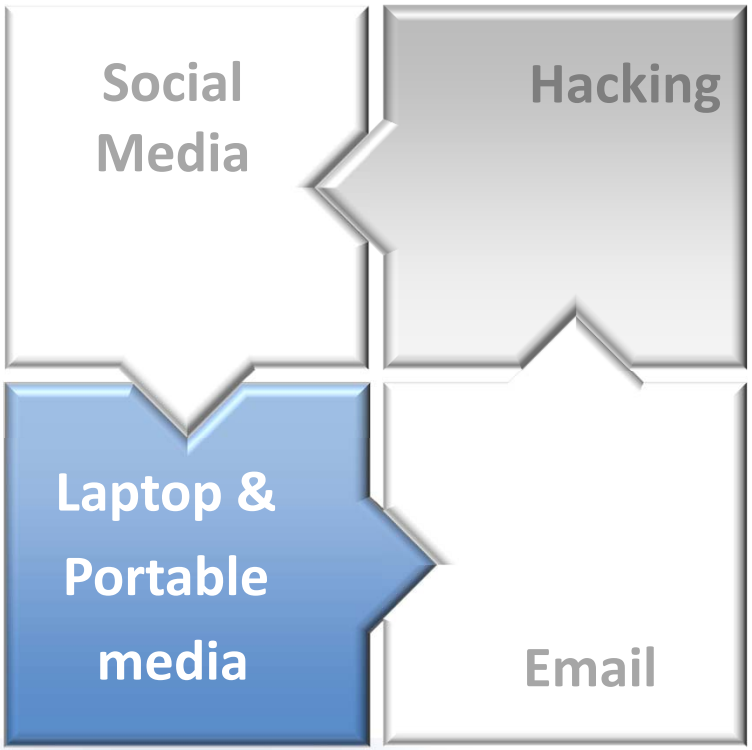
- Inappropriate access to patient information
- What is inappropriate access?
  - Snooping (movie star/ex-girlfriend)
  - Stealing (gang member's girlfriend)
  - Modifying/deleting (disgruntled employee)
- Ways to detect:
  - Auditing of Access
  - Employee education

HIPAA:

How to reduce exposure?

- **Have a policy**
  - People, it's just Facebook. Not reality. Hello? Again ... it's just a name out of millions and millions of names. If some people can't appreciate my humor then tough. And if you don't like it, too bad, because it's my wall and I'll post what I want

- **Use of Encryption**
  - Safe harbor/get out of jail free card?
  - Inexpensive
  - Easy to implement



- Increasing concern
- Protecting against hackers:
  - Passwords – easy, but causes debate
  - Need to be complex, change often
- Anti-Virus – install & run
- System Patching
- Penetration & vulnerability scans

- **Do Not Send Unencrypted PHI**
- Constitutes 10% of breaches
- Considerations for encrypting:
  - Relatively inexpensive
  - Easy to implement
  - Patients wants/expect to communicate by email
  - Omnibus Rule opens door

III. Providers Challenges

What is a bigger challenge for hospital CIOs and CISOs – selection of hardware and software for compliance or implementation of policies and procedures for security?

Policies & Procedures make you compliant, and ***Tools*** only assist in making your organization compliant.

Health Care Industry Oversight

Congress

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Supreme Court

Federal Circuit Courts

RAC / Program Integrity

Departmental Appeals

Office Inspector General

PRRB Reviews

State-Level
- Licensure
- Surveys & Certifications
- Courts
- Attorneys General
- Medicaid
- Health Boards
- Medical Boards
- Oversight Departments

CMS Regional Offices

Intermediaries

Carriers

Quality Improvement Organizations

DME Regional Contractors

NHIC, Corp. A CMS Contractor — Regional Home Health Intermediary

Drug Enforce

Fed Aviation

Security Exchange

GSA

IRS

Enviro. Protection Agency

Federal Trade Commission

Federal Emergency Mgmt. Agency

Federal Comm. Commission

Other Accreditation Agencies

HRSA

NIOSH

The Joint Commission

Nuclear Regulatory Commission

Labor

FDA Food & Drug

Trans

OSHA Occup. Safety

Justice

Treasury

FBI

A comprehensive Compliance Program

- Health care organizations face an increasingly complex regulatory environment with federal and state agencies enforcing laws and statutes and imposing significant penalties for non-compliance.
- Mitigating non-compliance requires a number of steps:
  - Assess compliance risks
  - Implement corrective-action plans and unify compliance activities
  - Monitor compliance risks and improve traceability for rapid response to audit inquiries
  - Manage incidents and complaints and third-party vendors
- Overall goal is to:
  - Establish a **culture of ethical behavior and commitment** to compliance with the applicable regulations, statutes and laws
  - Provide a safe **mechanism for reporting** and seeking help
  - Help **raise awareness**
  - Assist in **creating a positive impact** on our corporate reputation and public image

Compliance Factors

A recent report sponsored by the Association of Healthcare Internal Auditors revealed top compliance priorities. These include, but are not limited to:

- Health Information Exchanges (HIEs)
- Value-based Purchasing
- ICD-10 implementation, impact and readiness
- Payment Bundling
- Accountable Care Organizations (ACOs)
- Clinical Documentation
- Pay-for-Performance quality standards (CMS core measures and HCAHPS)
- HIPAA | ARRA (HITECH) | PPACA
- Meaningful Use
- Federal Information Security Management Act (FISMA)
- State-specific Privacy/Security laws
- CMS ACO Quality Measures
- CAHPS Survey for ACOs
- RAC / PI

There is **no silver bullet to compliance**; however, best practice suggests create a strong compliance program to:

- establish strong standards;
- communicate those standards to all levels of the organization; and,
- enforce those standards.

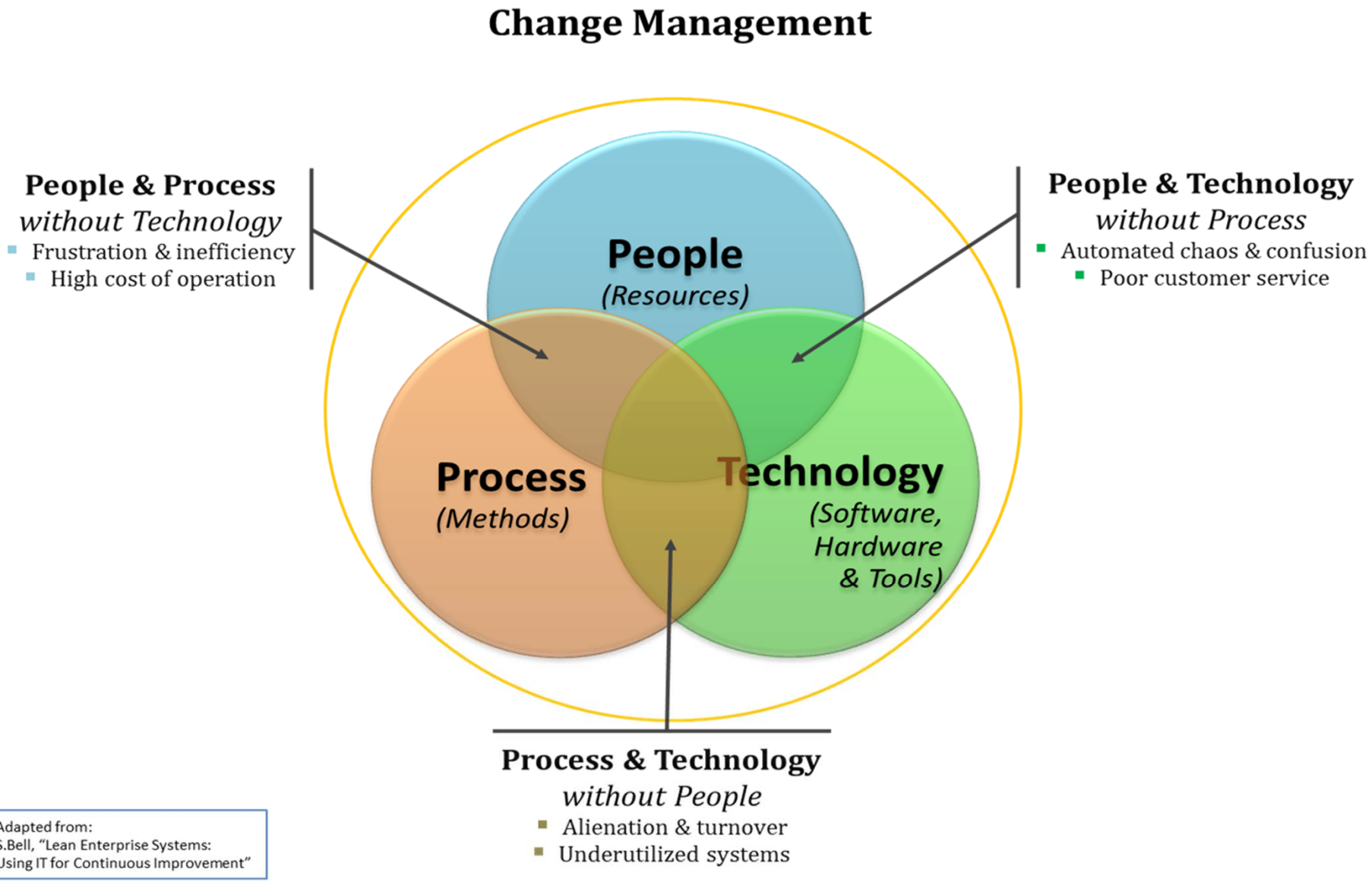
According to US Sentencing Commission Compliance guidelines state that if your organization is found in violation of the law but has a strong compliance program in place, the penalties incurred will be significantly reduced.

Compliance Strategic Planning

An effective Compliance Program is developed in the context of your organization's mission. Some purposes of the program could be:

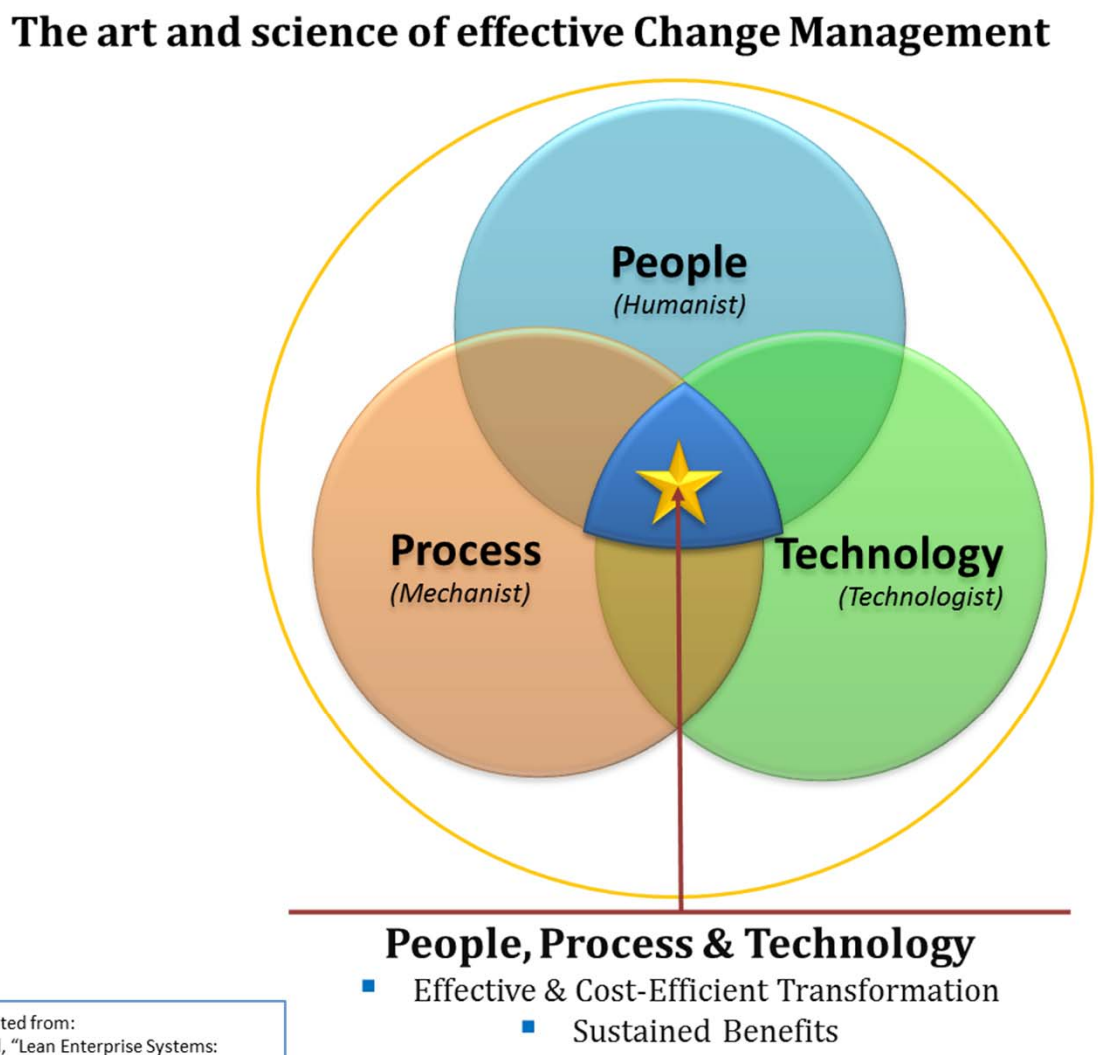
- Maintain and enhance quality of care
- Demonstrate sincere, ongoing efforts to comply with all applicable laws
- Revise and clarify current policies and procedures to enhance compliance
- Enhance communications internally and/or with BOD and governmental entities with respect to compliance activities
- Empower all responsible parties to prevent, detect, and resolve non-conformance with applicable laws, regulations and the program; and
- Establish mechanisms for employees to raise concerns about compliance and ensure concerns are appropriately addressed.

Approach



Adapted from:
S.Bell, "Lean Enterprise Systems: Using IT for Continuous Improvement"

Compliance – Right Approach



Adapted from:
S.Bell, "Lean Enterprise Systems: Using IT for Continuous Improvement"

The "PEOPLE" aspect of successful business change or transformation is the most critical component of sustainable change and effective Organizational Change Management (successful business transformation.)

Technology and/or process changes are easier to prescribe and manage than are the effects on the people – sustainable solutions are *people-inclusive*.

Assuring this enables the transformation by allowing people to part of the evolution, rather than revolutionaries opposing change.

IV. Engagement Scenario - Assessment

Representative Assessment / Discovery Life Cycle

Planning
- Management Synchronization
- Tailor Pre-Survey Materials
- Adjust Interview Q's
- Project Kick-off
- Distribute Questionnaires

Data Gathering
- Prepare Site Reviews
- Collect Data from Support Team
- Conduct Reviews
- Conduct Response Reviews
- Prepare Clarifications

Analysis
- Conduct Analyses
- Document Findings
- Review Results & Findings
- Draft Corrective Action Plan / Implementation Roadmap

Reporting
- Prepare Report
- Finalize Corrective Action Plan / Implementation Roadmap
- Present Report
- Synchronize all stakeholders

Actions
- Set Priorities
- Perform Corrective Actions, including OCM, training, etc.
- Measure, Manage, Monitor & Maintain Transformations
- Plan Transitions

Strategic Business Planning

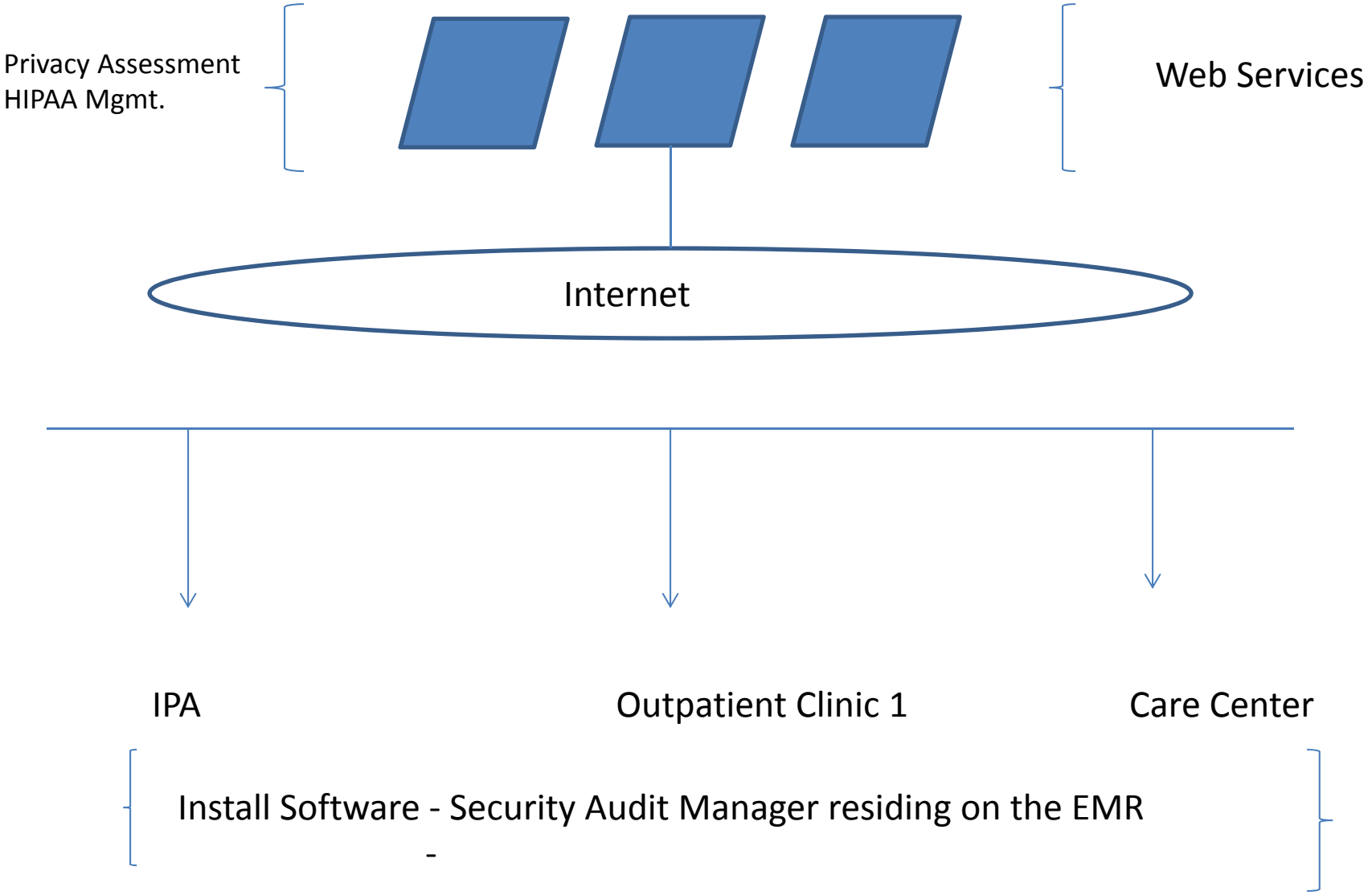
Solutions Implementation Planning

Improved Operations Management

Discovery ♦ *Analyses* ♦ *Reporting* → *Out-of-Scope*

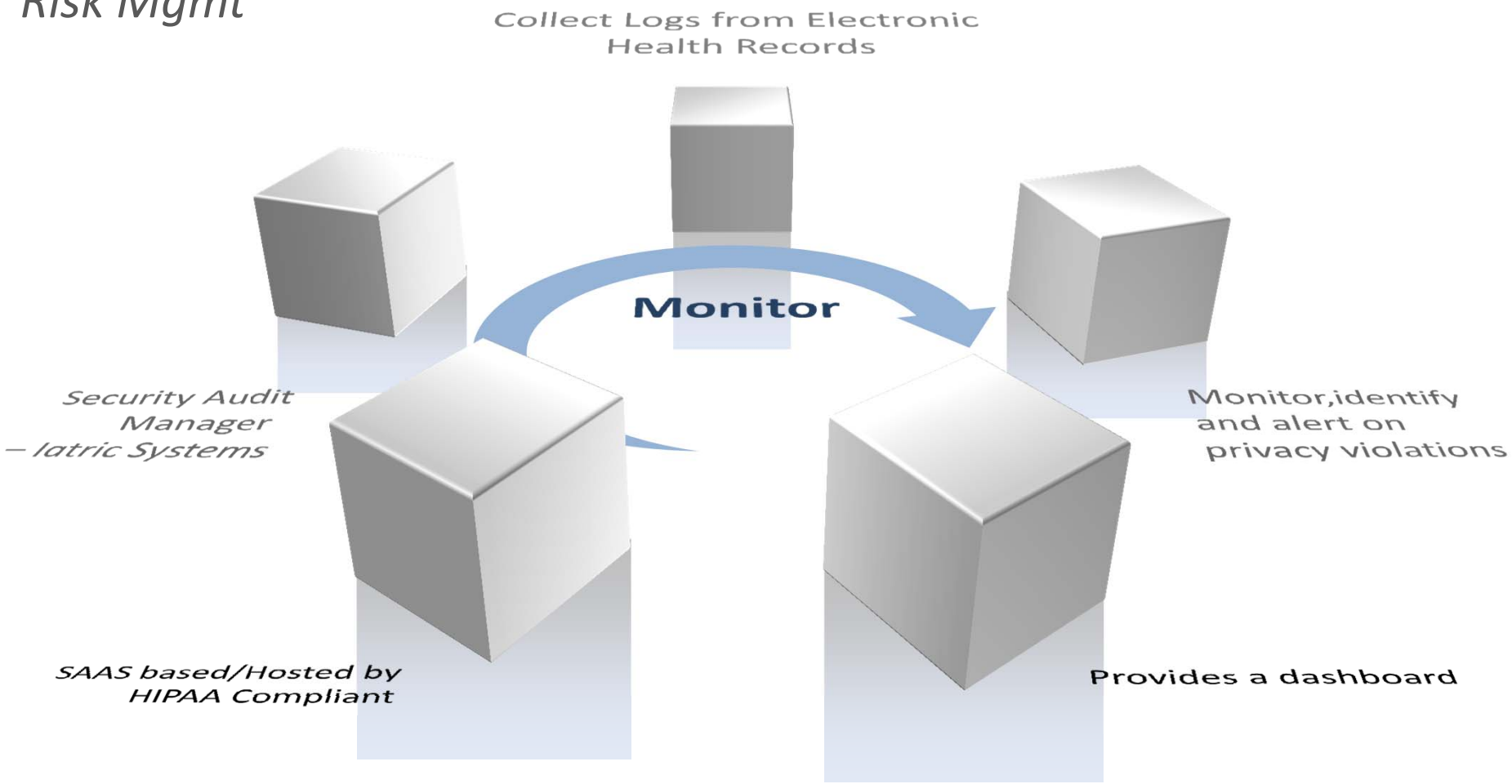
Estimated duration: 8-16 weeks

V. Technology as a tool – for compliance



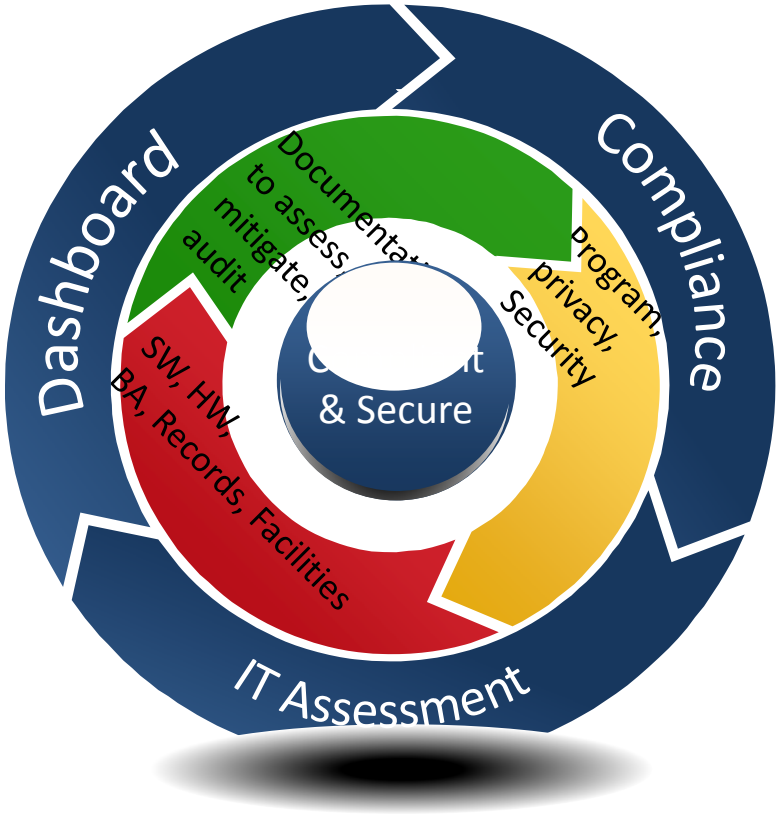
Privacy Monitoring of PHI

Provide Iatric/Security Audit Manager – Patient Privacy & Incident Risk Mgmt

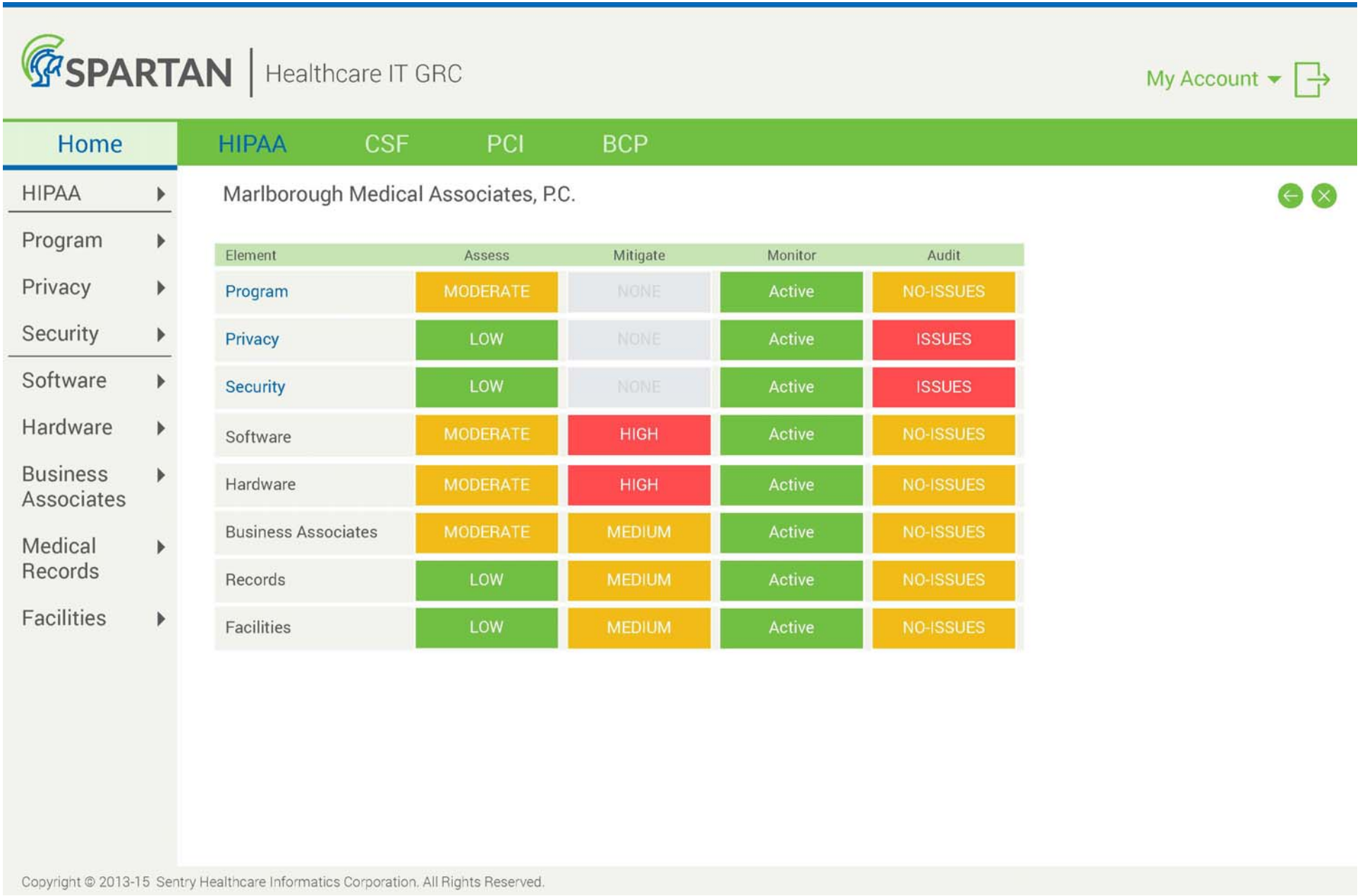


Tools –

SAAS-based Platform to Assess, Mitigate, Monitor, Audit - HIPAA compliance



- Develops, initiates, maintains, and revises policies and procedures for Compliance Program and its related activities to prevent illegal, unethical, or improper conduct.
- Manages day-to-day operation of the Compliance program


SPARTAN | Healthcare IT GRC
My Account
Home
HIPAA
CSF
PCI
BCP
HIPAA
Program
Privacy
Security
Software
Hardware
Business Associates
Medical Records
Facilities
Marlborough Medical Associates, P.C.
Element | Assess | Mitigate | Monitor | Audit
Program | MODERATE | NONE | Active | NO-ISSUES
Privacy | LOW | NONE | Active | ISSUES
Security | LOW | NONE | Active | ISSUES
Software | MODERATE | HIGH | Active | NO-ISSUES
Hardware | MODERATE | HIGH | Active | NO-ISSUES
Business Associates | MODERATE | MEDIUM | Active | NO-ISSUES
Records | LOW | MEDIUM | Active | NO-ISSUES
Facilities | LOW | MEDIUM | Active | NO-ISSUES
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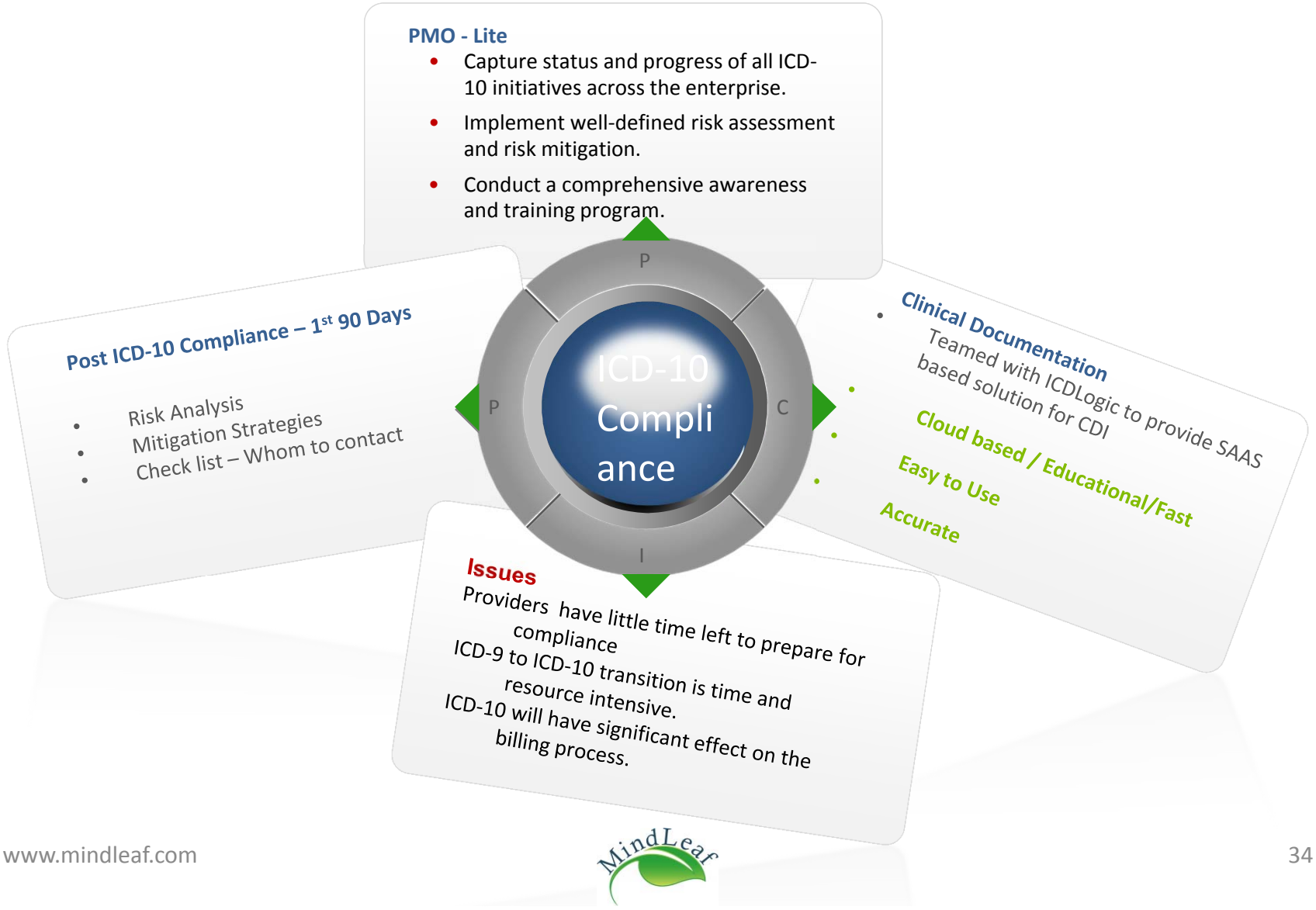
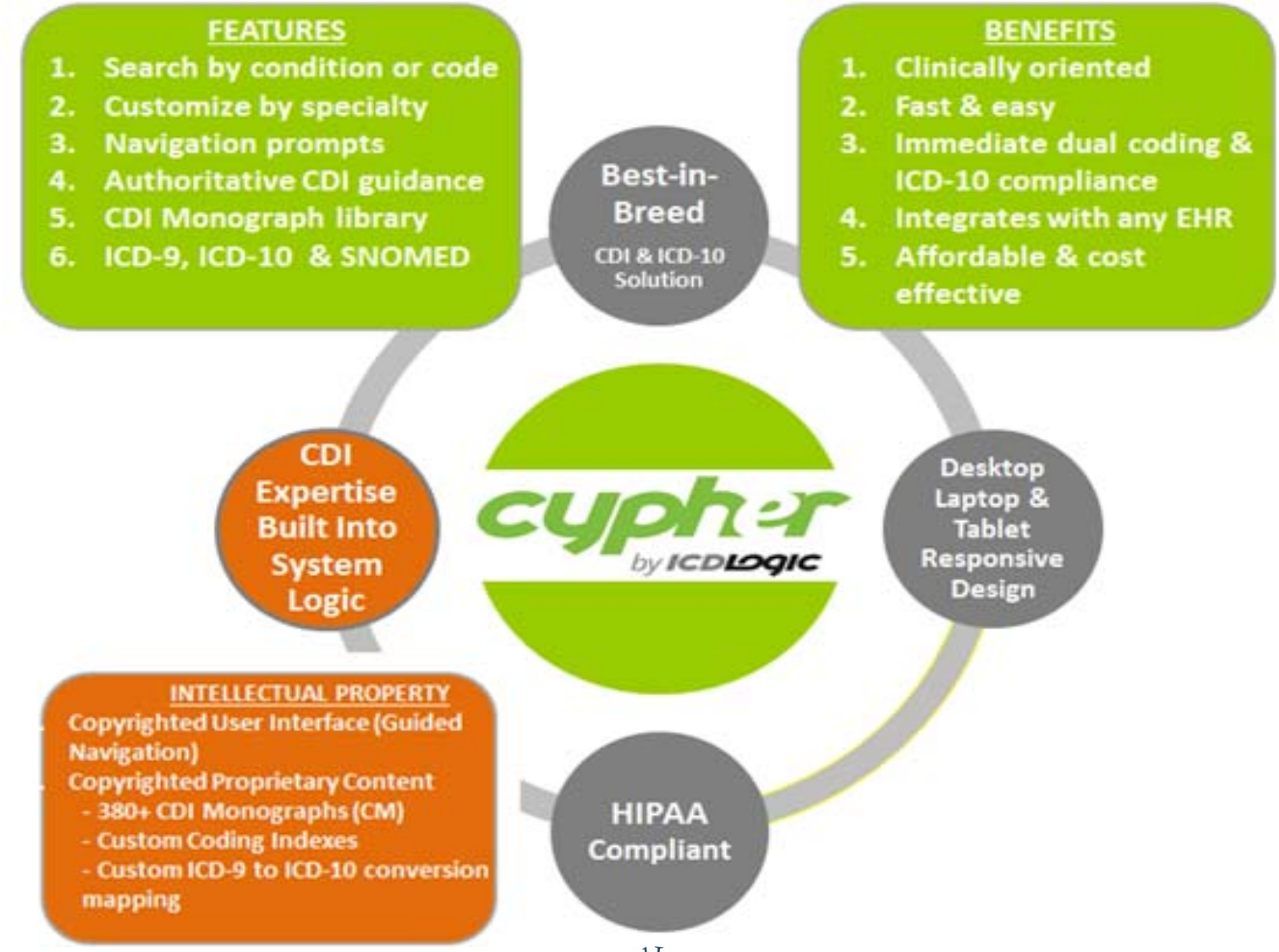
HIPAA Privacy & Security Compliance
Since 2009 40M Patient Data Breach
2015 – Anthem - Healthcare Data Breach – 80M patients
Patient record breach exceeds 20+ % year over year
2014 – Healthcare Data Breach 8M patients
2015
Enforcement heats up
OCR – Audit Program
Security and Privacy must be addressed, but it is a constraint.
ISSUES
Resources
Time
Software tools & IT support
Assess
Define & develop documentation to become a secure org.
Train people, Attest, Monitor and Audit
Our goal – To make your organization secure & compliant
www.mindleaf.com.

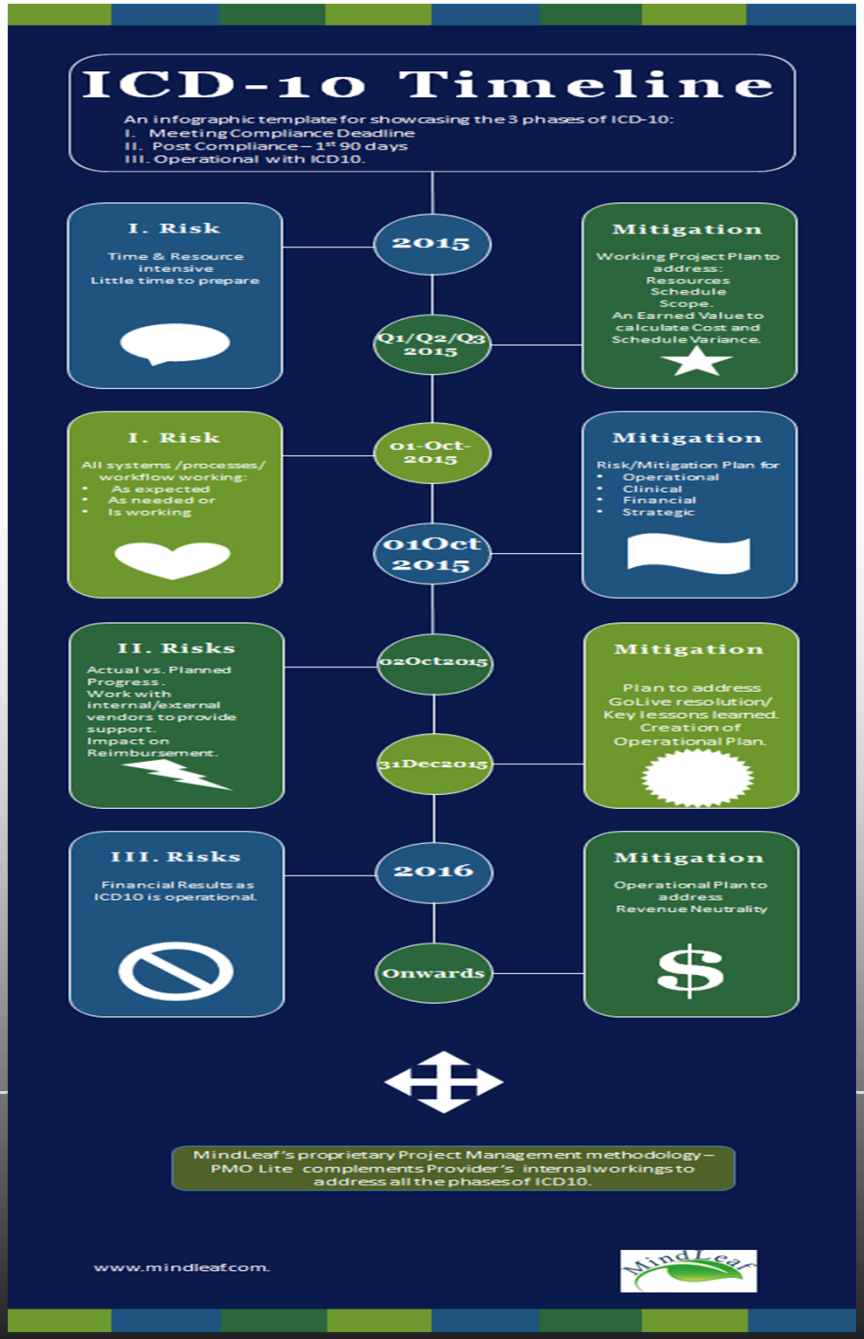
TRIGGER EVENT:

ICD-10 implementation deadline (01-OCT-2015)



Cypher is like having a Clinical Documentation expert at your fingertips.

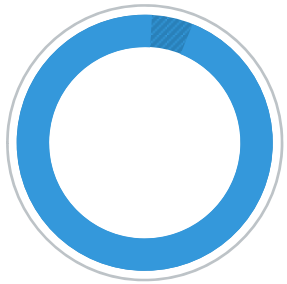



ICD-10 Timeline
An infographic template for showcasing the 3 phases of ICD-10:
I. Meeting Compliance Deadline
II. Post Compliance – 1st 90 days
III. Operational with ICD10.
I. Risk
Time & Resource intensive
Little time to prepare
2015
Mitigation
Working Project Plan to address:
Resources
Schedule
Scope.
An Earned Value to calculate Cost and Schedule Variance.
Q1/Q2/Q3 2015
I. Risk
All systems /processes/ workflow working:
As expected
As needed or
Is working
01-Oct-2015
Mitigation
Risk/Mitigation Plan for
Operational
Clinical
Financial
Strategic
01Oct 2015
II. Risks
Actual vs. Planned Progress
Work with internal/external vendors to provide support.
Impact on Reimbursement.
02Oct2015
Mitigation
Plan to address GoLive resolution/ Key lessons learned.
Creation of Operational Plan.
31Dec2015
III. Risks
Financial Results as ICD10 is operational.
2016
Mitigation
Operational Plan to address
Revenue Neutrality
Onwards
MindLeaf's proprietary Project Management methodology – PMO Lite complements Provider's internal workings to address all the phases of ICD10.
www.mindleaf.com.

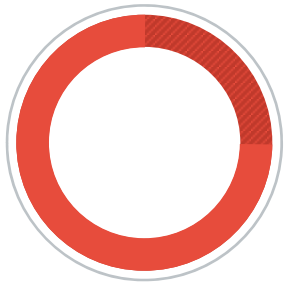
VI. Compliance Program(s) Status

- PREVENT NON-COMPLIANCE
- PROTECT FROM NON-COMPLIANCE
- REDUCE TANGIBLE / NON-TANGIBLE DAMAGE CAUSED

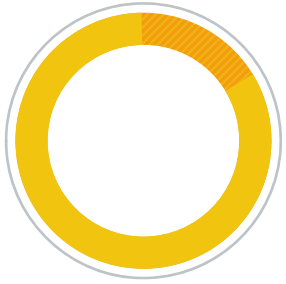
HOW DOES YOUR ORGANIZATION LOOK?



Use compliance to
Get Best Practices



Failure to meet
Compliance

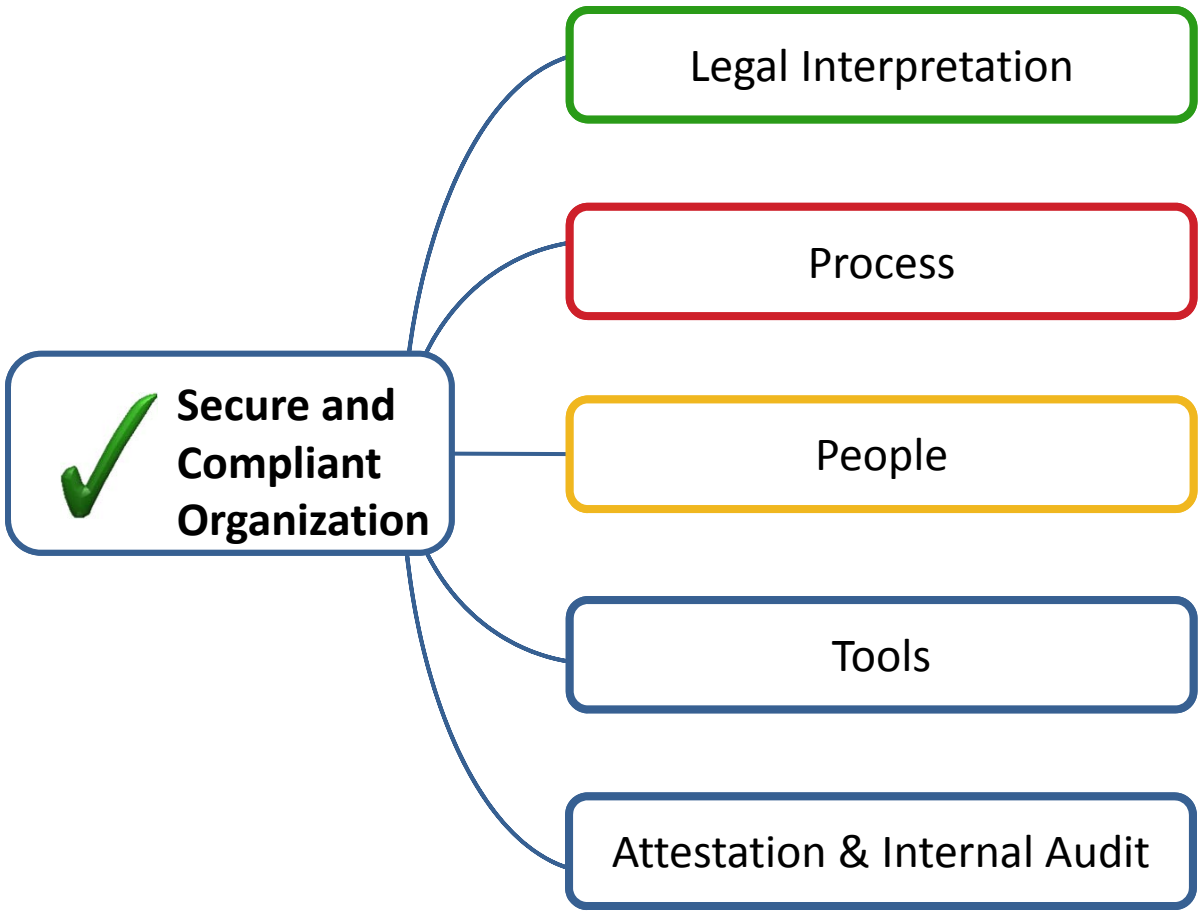


Will Meet Compliance

Will Meet Compliance
& be compliant.

To summarize – *People, Policies & Procedures, Processes, and Tools (MindLeaf model) can help you achieve compliance at an affordable cost.*

Your compliance program



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