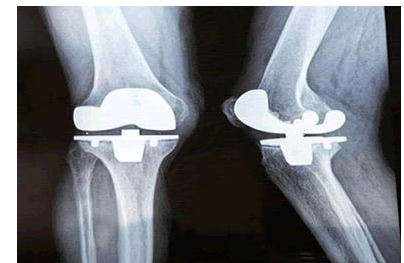


Quick Diagnostics for the Compliance Officer: Process and System

November 3, 2011



YOUR MISSION | OUR SOLUTIONS

© Huron Consulting Group Inc. All Rights Reserved.

Huron is a management consulting firm and not a CPA firm, and does not provide attest services, audits, or other engagements in accordance with the AICPA's Statements on Auditing Standards.
Huron is not a law firm; it does not offer, and is not authorized to provide, legal advice or counseling in any jurisdiction.

Overview – Government Programs

Program	Obligations	Frequency of Calculation
Medicaid Drug Rebate Program	Average Manufacturer's Price ("AMP")	Submitted to CMS monthly (within 30 days of close of month and quarter)
	Best Price ("BP")	Submitted to CMS quarterly (within 30 days of close of quarter)
	Unit Rebate Amount ("URA")	Calculated quarterly by manufacturer to confirm CMS calculation – not actually submitted.
Public Health Service ("PHS") / 340B Program	PHS Ceiling Price (AMP - URA)	Calculated quarterly by manufacturer and submitted to Wholesalers to load into their contract pricing systems.
Medicare Part B	Average Sales Price ("ASP")	Submitted to CMS quarterly (within 30 days of close of quarter)
Federal Supply Schedule	Quarterly and Annual Non-Federal Average Manufacturer's Price ("Non-FAMP")	Submitted to VA quarterly (within 45 days of close of quarter)
	Federal Ceiling Price ("FCP")	Annual Non-FAMP/FCP submitted to VA annually 45 days after the close of the 3 rd quarter (11/15)

Compliance Environment

As a result of the magnitude of the government spending on drugs, there is a growing pressure for:

- Strict scrutiny of compliance by law enforcement agencies
- More transparency of pharma pricing practices
- More scrutiny of sales and marketing practices
- Measures to reduce costs
- Alternative means for delivering drug benefits
- Effective compliance programs

OIG Auditors Focus on Specific Areas of Concern

Administration has increased the number of and focus on audits

Areas of interest during typical audits include:

- Government Price Calculations must be accurate
 - Manufacturers must be able to produce an audit trail for all calculations.
 - Manufacturers should be able to provide the OIG auditor with assurances that the calculations are accurate and in accordance with the manufacturers interpretation of the law and as documented in the company's policy documents.
- Written Policies and Procedures should exist and be followed
- Documentation providing a record of transactions and decisions must exist
 - Adequate documentation that records the relevant accounting transactions and any decisions made is critical. Documentation of decisions that affect the calculations must specifically account for the factors and cause contributing to each decision.

OIG Auditors Focus on Specific Areas of Concern – cont.

- Reclassification of Customers
 - Clean and accurate classification of customers are important, and is critical during an OIG audit.
 - Anomalies that “trigger” OIG audits can be created when a manufacturer decides to either include previously excluded, or exclude previously included customer classes.
- Record Retention
 - Area of concern for auditors and manufacturers in the past.
 - Manufacturers should have available all records, electronic and physical, that support calculations since the inception of the 3-year recalculation rule.

Environment Becomes Complicated in Changing Environment

Obstacle Course of Recent Statutory Changes

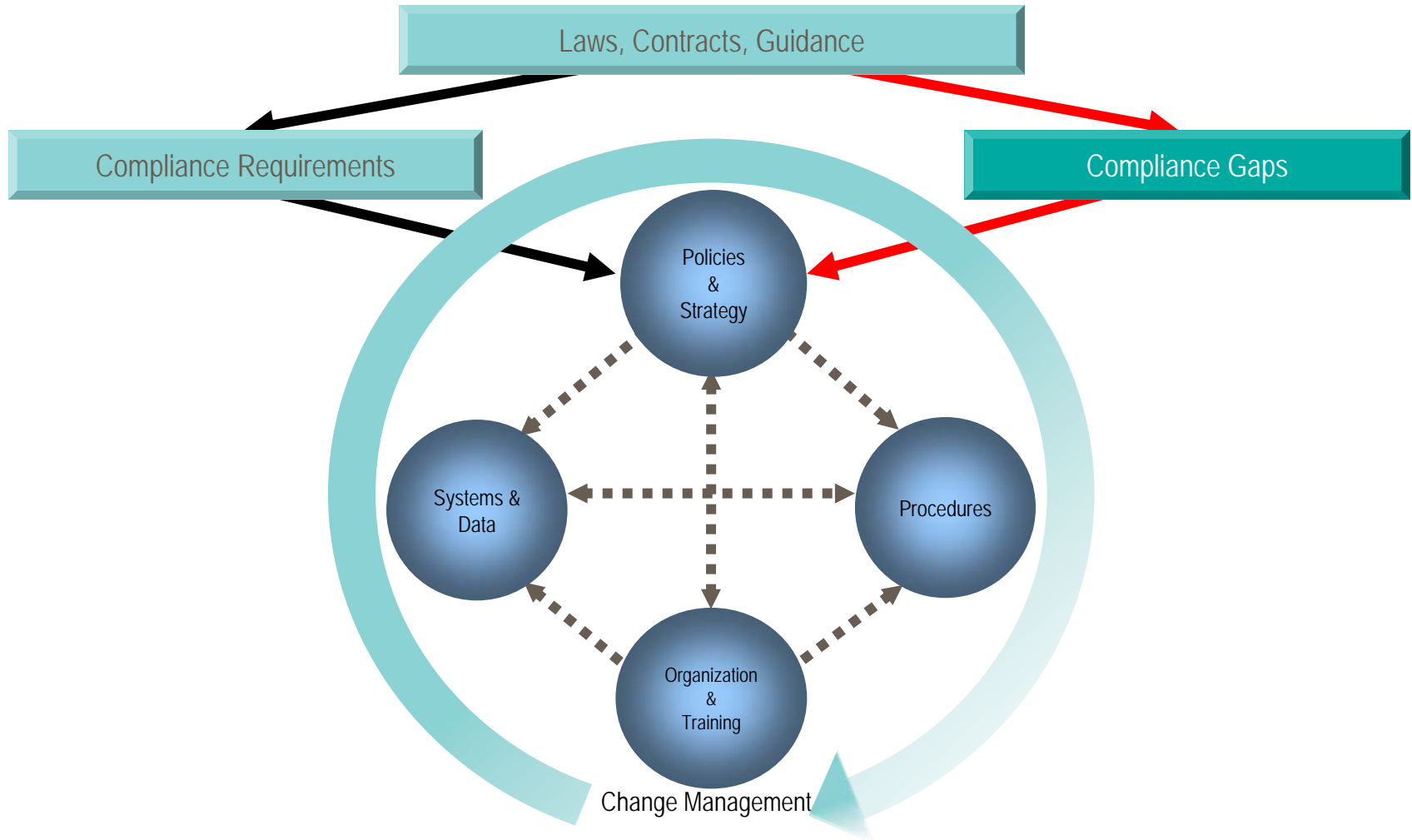
- MMA
 - ASP and reimbursement rates
- DRA
 - Definitions and reporting obligations
- PPACA
 - Medicaid
 - Changes to AMP eligible customers
 - Rebate amount
 - Sub categories with further changes
 - Medicaid Managed care
 - Changes to 340b
- Environment of Change Must be Absorbed into Auditing Compliance

Implementing/Maintaining the Seven Elements for an Effective Compliance Program Helps Manufacturers Manage Compliance Efforts and Provides a Guideline for Working with an Audit Team

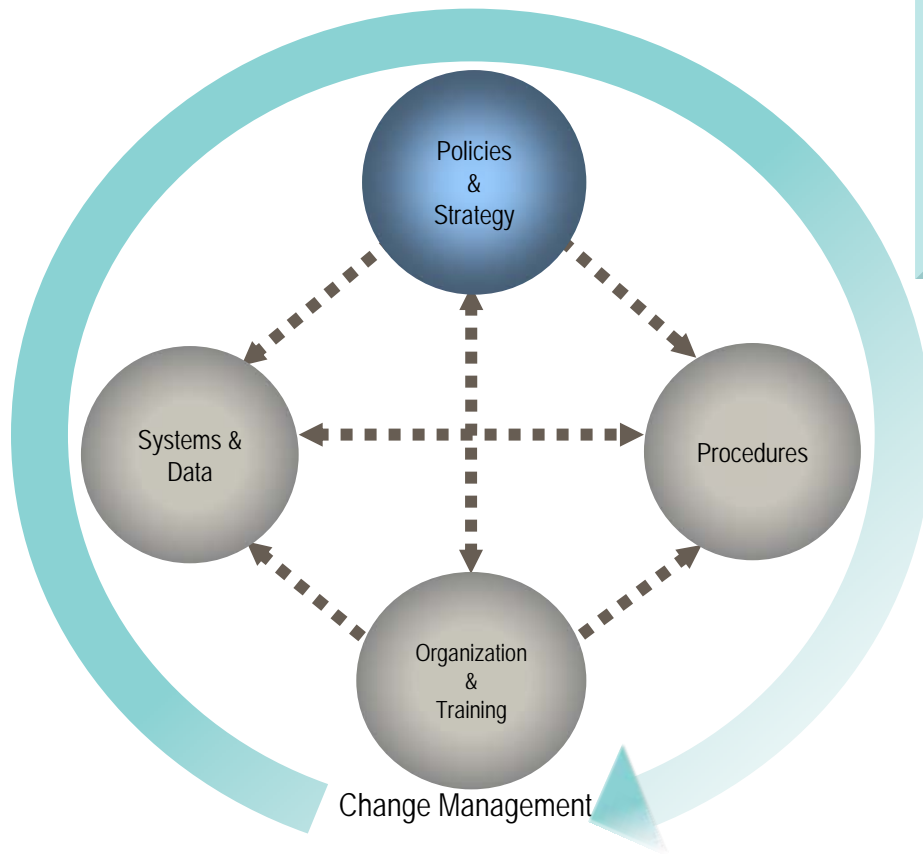
1. Written policies and procedures
2. Compliance officer & committee
3. Effective training & education
4. Lines of communication
5. Internal monitoring & auditing
6. Enforcement of the standards
7. Corrective actions

These seven elements are fundamental and require additional clarification to ensure completeness for an effective Compliance Program.

Implementing a Sustainable Compliance Program



Implementing a Sustainable Compliance Program



POLICIES & STRATEGY

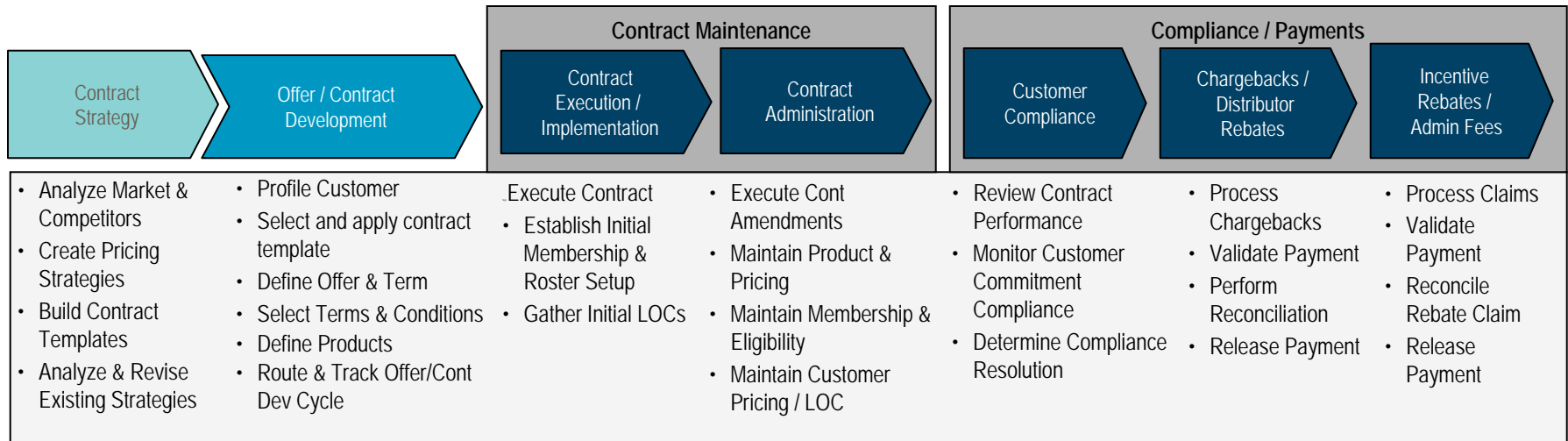
- Corporate policies should demonstrate compliance with relevant laws, regulations, and contract terms and conditions behind commercial and government contracting as well as Sales & Marketing activities.
- Policies should clearly describe and be reflected by current business practices.
- Policies should offer a fair and reasonable position on any issues not clearly described in the various laws and regulations.

Interdependencies Between Commercial/Government Contracting and Sales & Marketing

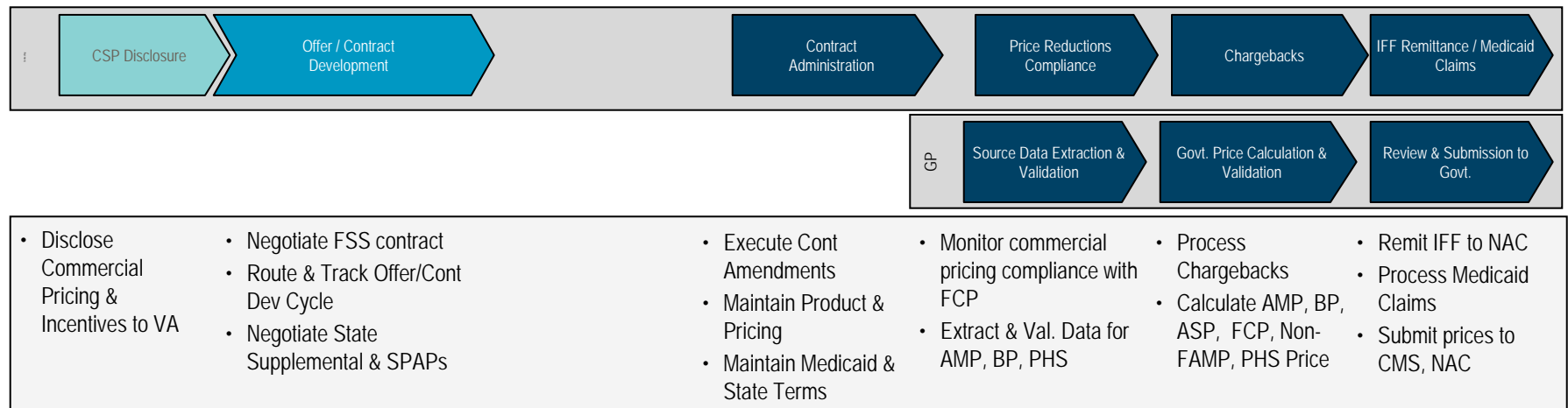
Contract Creation

Contract Management

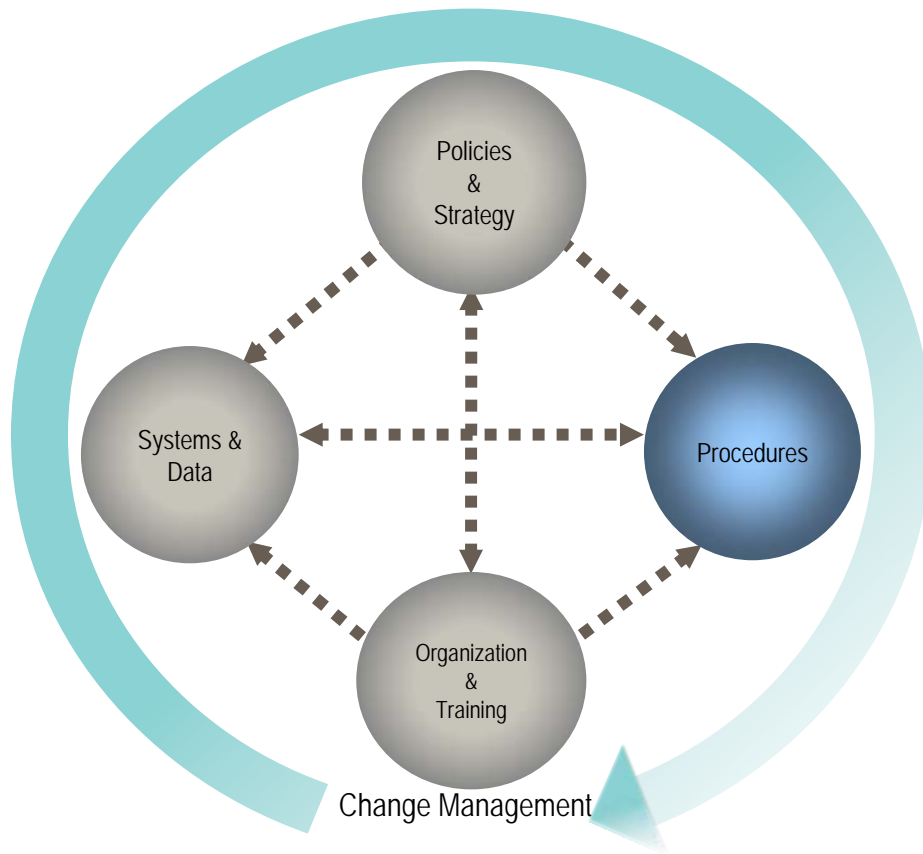
Commercial



Government



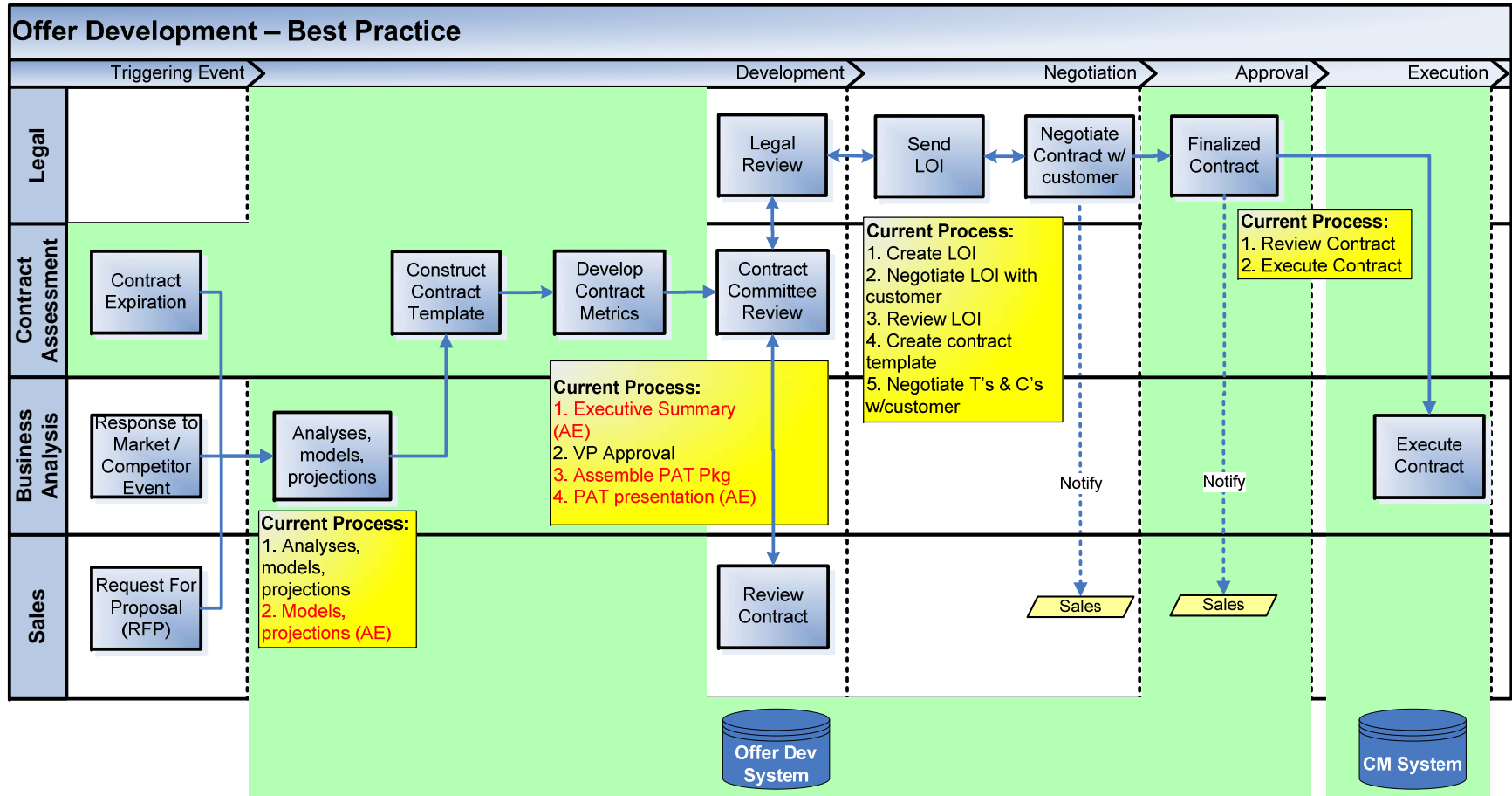
Implementing a Sustainable Compliance Program



PROCEDURES

- Procedures must support the defined policies.
- Procedures should describe commercial contracting activities, government program administration, and Sales & Marketing activities including:
 - Price Calculations, Submissions, Disclosures
 - Offer Development
 - Incentive Management
 - Customer and Contract Compliance
 - Guidance
- Procedures should be updated on a consistent basis to reflect internal or external environmental change.

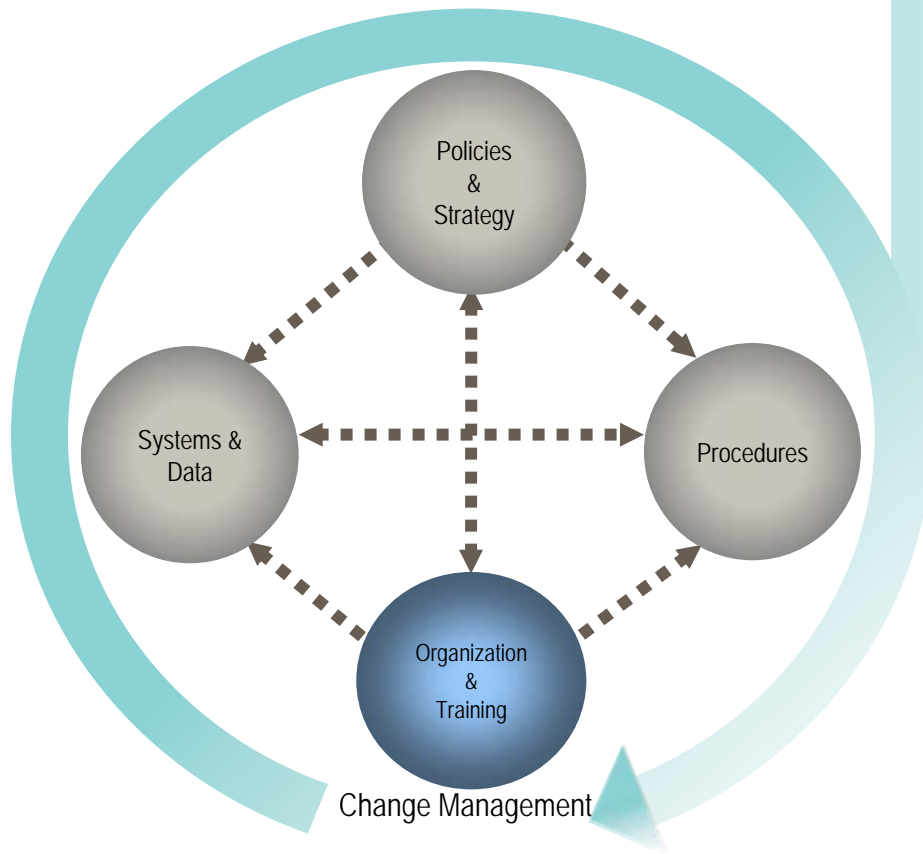
Understand Your Processes and How They Compare to Desired/Required Procedures or Best/Common Practice



Key: Area identified for improvement

Processed by System

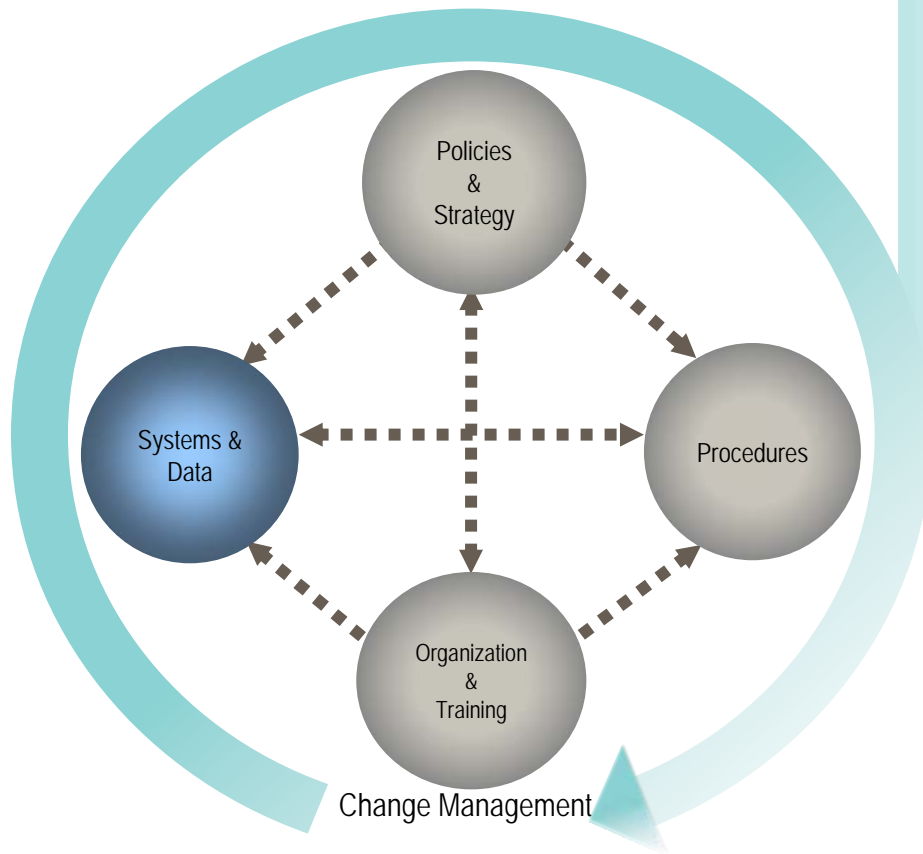
Implementing a Sustainable Compliance Program



ORGANIZATION & TRAINING

- The organizational structure and reporting lines should complement key processes and provide consistent support of policies and procedures.
- Compliance Officer, Compliance committee, and Compliance Governance groups need to be identified.
- Organizational staffing size should be sufficient to meet the current demands of corporate and operational compliance.
- Resource skill sets should possess a strong knowledge base of compliance.
- Policies and procedures should provide adequate staff training documentation.
- Formal training curriculum in compliance
- Combination of facilitated training and self-training

Implementing a Sustainable Compliance Program

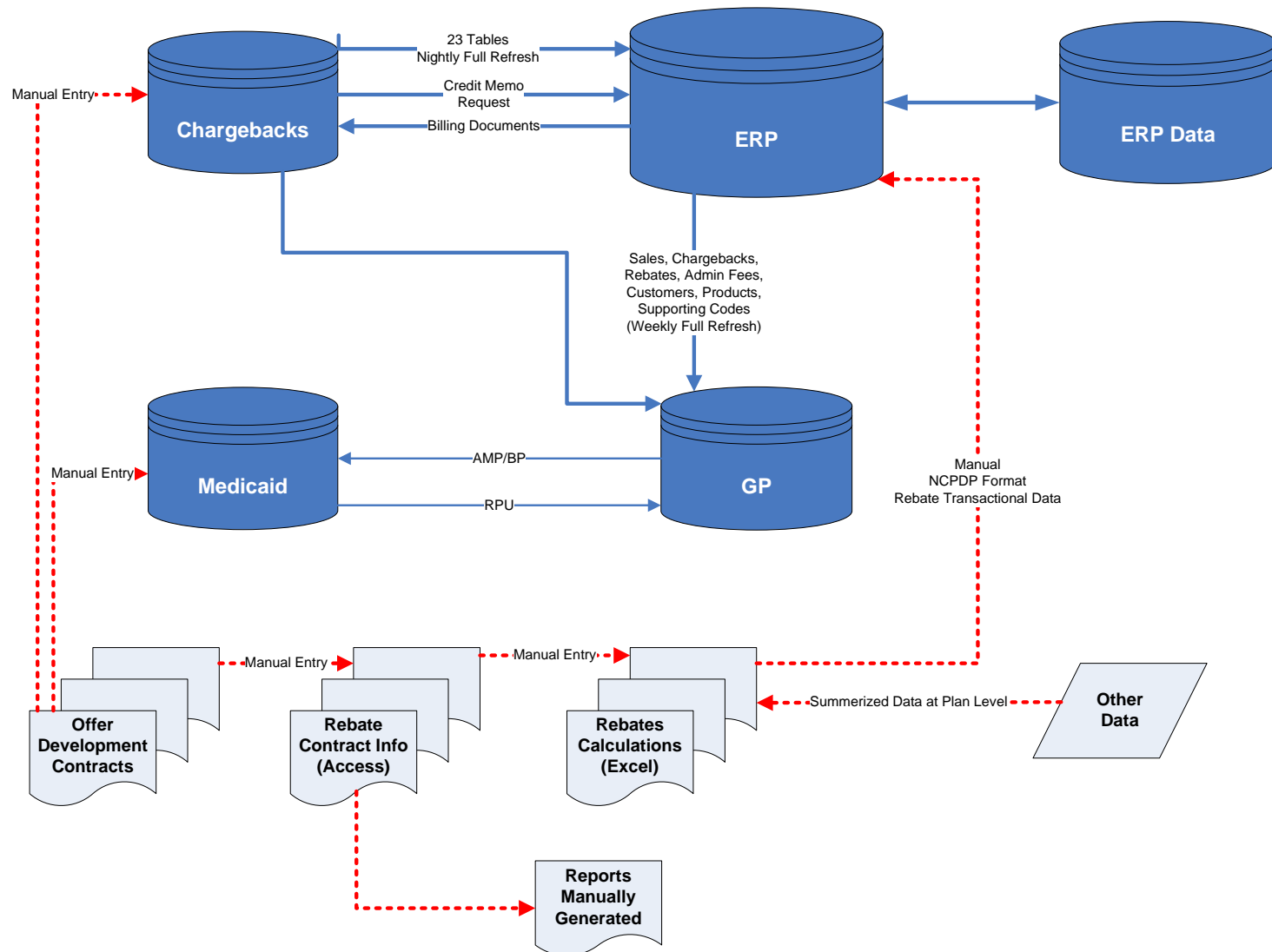


SYSTEMS & DATA

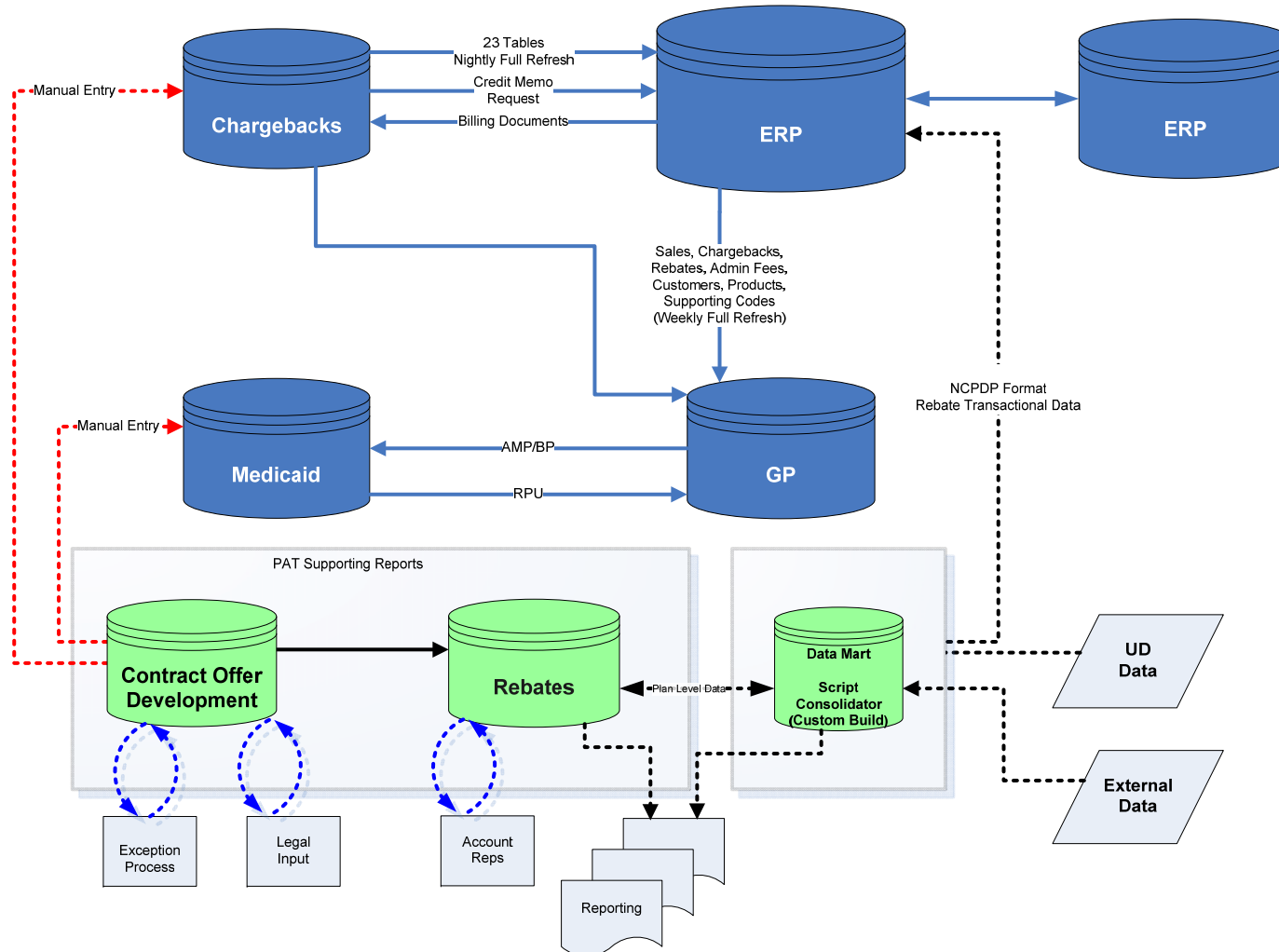
Systems and data should support the following:

- Controlled processes to support all contracting activities from contract strategy and offer development through contract performance and forecasting
- Architecture to maintain and process a variety of contracting structures
- Flexibility to readily accommodate internal or external policy changes
- Enhanced management reporting and trouble-shooting functionality
- A clear audit trail behind each government price submission and data archival functionality at the transactional level of detail

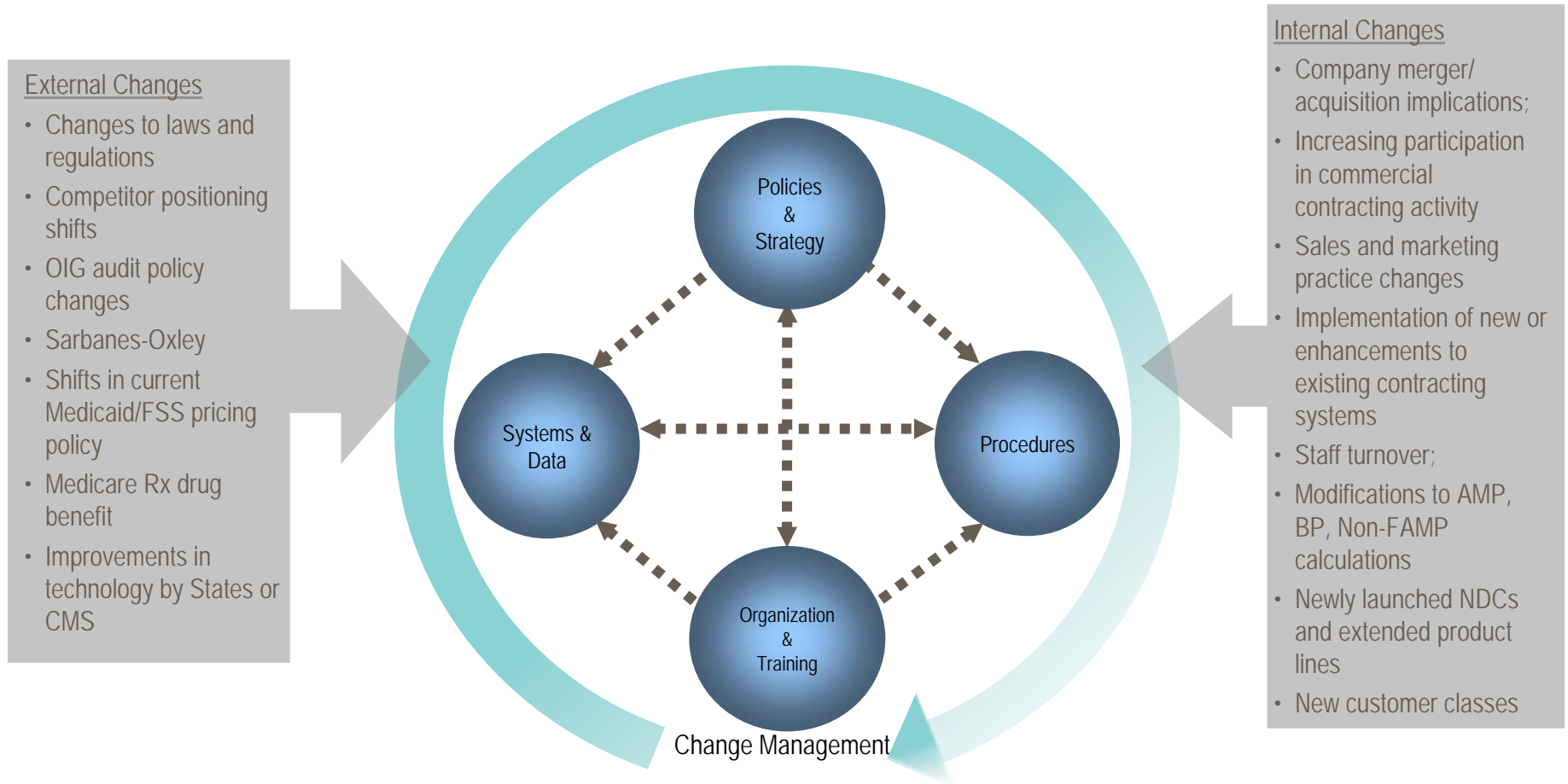
Assess Systems Landscape – Current State



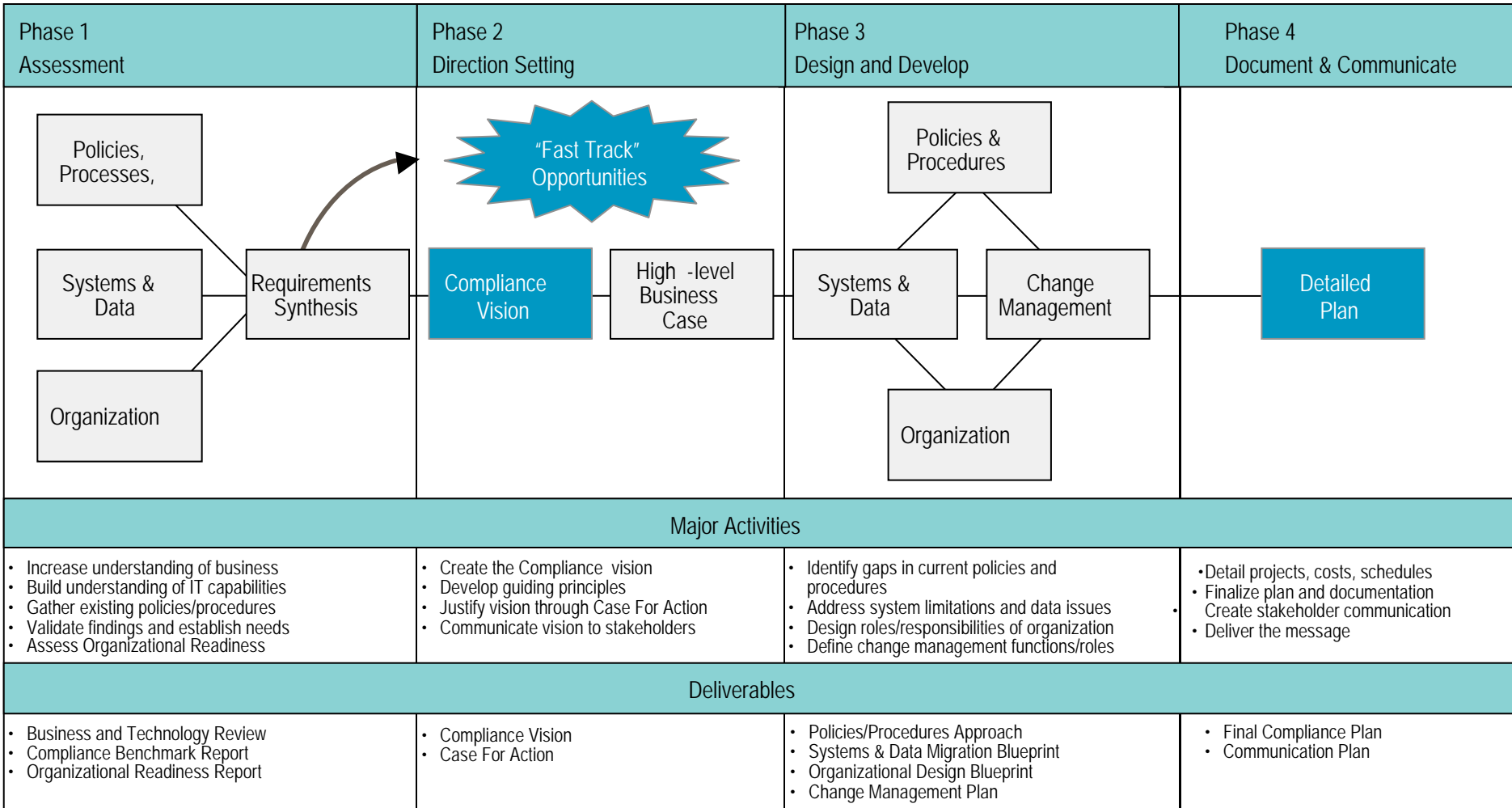
Compare to Desired Architecture/Best Practice



Implementing a Sustainable Compliance Program



Approach for Diagnosing an Existing Compliance Environment



Contact Information

Mark Linver

Managing Director

HuronLifeSciences

1120 Avenue of the Americas, 8th Floor
New York, NY 10019

312.515.1677 - Mobile

646.520.0054 - Office

212.785.1313 - Fax

mlinver@huronconsultinggroup.com

Susan Dunne

Director

HuronLifeSciences

1001 G. Street NW, 11th Floor New York,
Washington, DC 20001

571.334-6918 - Mobile

703.437.8461 - Office

202-585-1602 - Fax

sdunne@huronconsultinggroup.com