Managed Markets Risk Assessment & Monitoring Considerations

PCF Pharma Congress

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Session Objectives

1. Gain a better understanding of the meaning of "Managed Markets"
2. Discuss emerging risks and enforcement trends within the Managed Markets function
3. Provide insights into how risk assessments and monitoring can help to mitigate the risk

What is Managed Markets?

Terminology, structure and activities differ across the industry, but generally Managed Markets teams have similar objectives and customers:

Common Objective

- Develop and execute strategies to secure access/reimbursement for company products and obtain favorable payer coverage
- To make sure the company gets the reimbursement and access status required to maximize performance across the life cycle

Common Customers

Public

- Medicaid
- Medicare
- State Children Health Insurance Plans (CHIP)
- Military, TriCare, Veterans Administration
- Federal and State Employee Health Plans

Private

- Employers
- Unions
- Health Plans: Aetna, Blue Cross / Blue Shield, United Healthcare, Wellpoint

What trends are driving change in managed markets activities?

Evolving Contracting Model: shift in reimbursement model from fee for services to outcomes and value

Evolving Commercial Model: shift from representative driven interactions to IDNs, HEOR, Specialty pharmacies, Payer Advisory Boards

Impact of Legislation: Newly insured lives added by ACA and expansion of Medicaid and the 340B program (covered entities and contract pharmacies), Authorized Generics

Regulator Focus: shift to focus on relationships between the manufacturer and the channel and focus on drug pricing

Managed Markets and Compliance

Managed Markets compliance management plays a key role in identifying compliance gaps and mitigating risks across the pricing and contracting continuum.

Commercial & Pricing Strategy

- Provides strategic contracting solutions and implementation support to maximize sales and profitability.
- Engage with Payers to understand value and plan needs.
- Contract with non-trade channel partners for value add services

Contract & Pricing Operations

- Implementation support, government price reporting, rebates and discount processing, membership management

Trade Strategy & Operations

- Ensures access and product availability through strategic partnerships with wholesalers, distributors, and pharmacies
- Contract with channel partners for value added services

Account Management

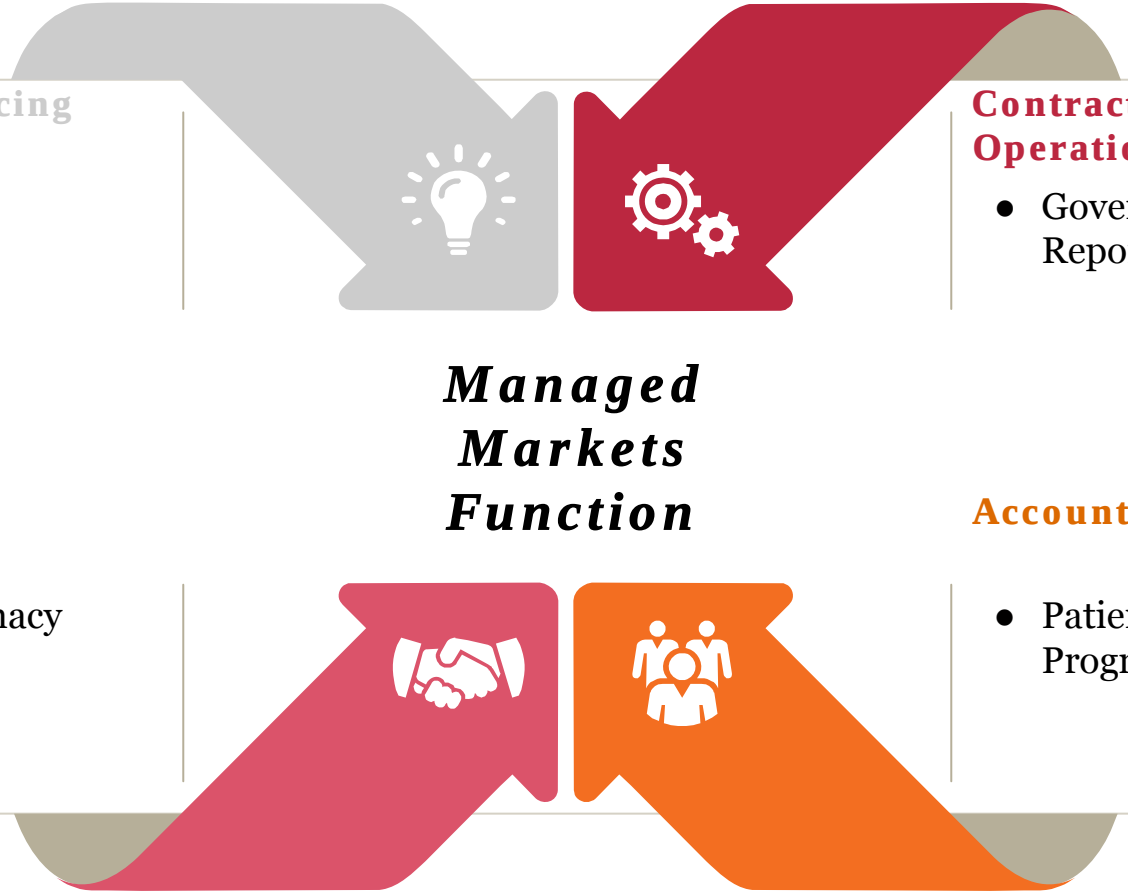
- Interact with large IDNs, hospitals, Payers, etc. to ensure product access at large institutions

Today we will focus on the following areas…

Commercial & Pricing Strategy

Contract & Pricing Operations

- Government Price Reporting



Managed Markets Function

Trade Strategy & Operations

- Specialty Pharmacy Arrangements

Account Management

- Patient Support Programs

Section 1

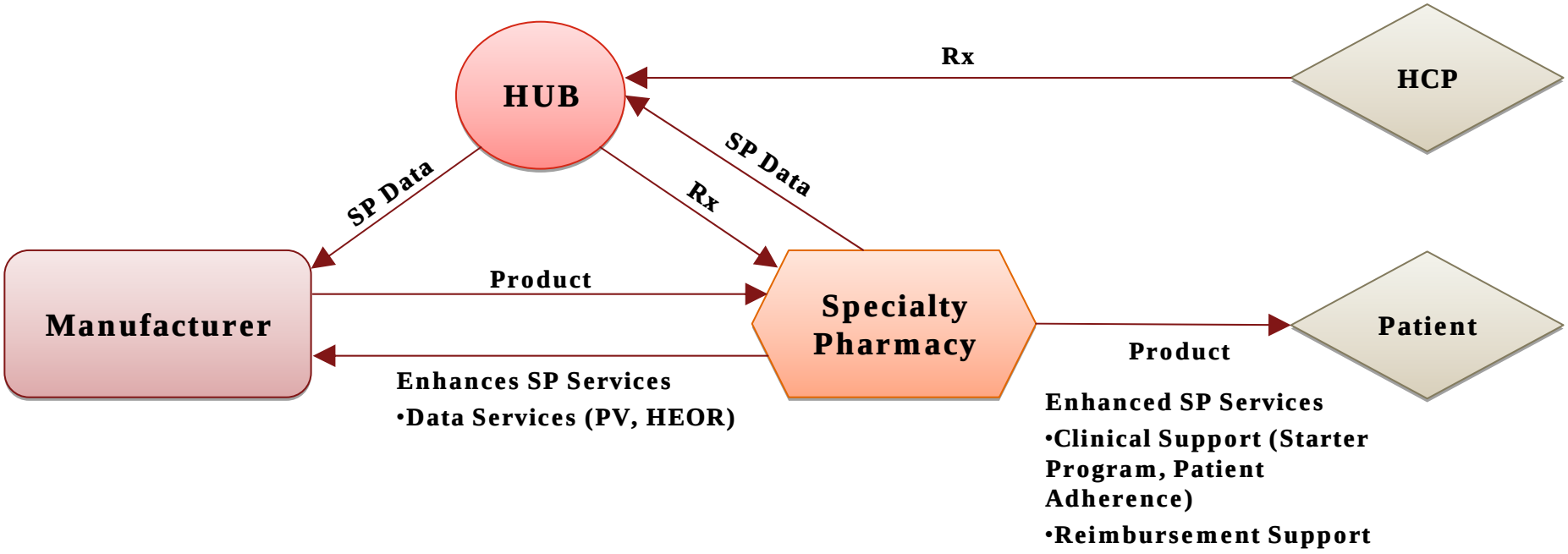
Specialty Pharmacies Arrangements

Specialty Pharmacy Arrangements

Why do we consider this an emerging risk priority?

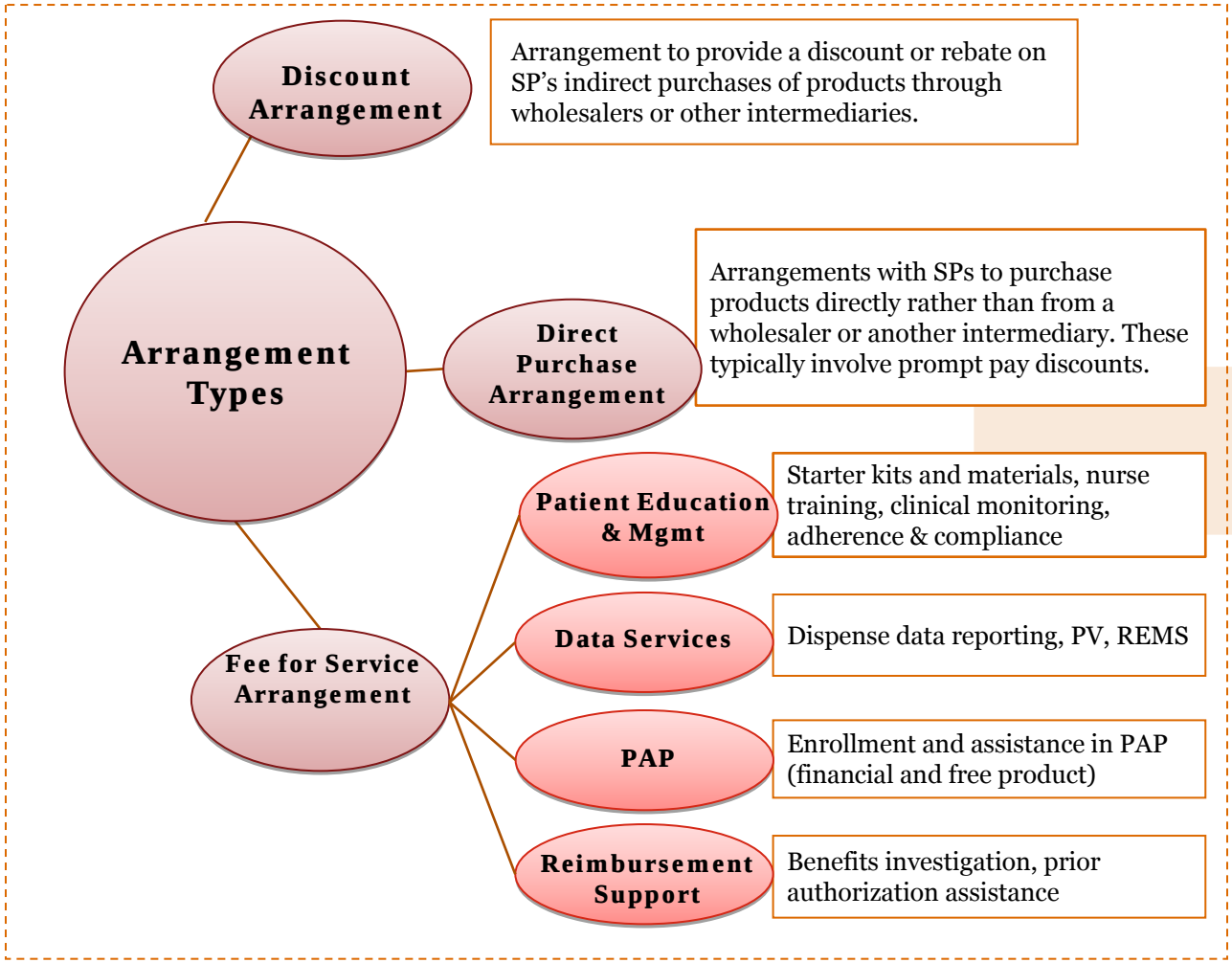
- **Recent enforcement trends**:
  - Government settlements in connection with alleged kickbacks provided to specialty and long-term care pharmacies
  - Several high-profile inquiries related to manufacturer ties, to or arrangements with, specialty pharmacies
- **Concerns around remuneration and influence:**
  - Discounts and rebates in exchange for recommending product
  - Unbalanced or misleading materials/discussions (e.g., nurse call scripts pressing compliance) influencing clinical judgement
  - Allocating patients in exchange for recommending product

Overview of Specialty Pharmacy Arrangements



*Example for illustration only

What is the compliance risk?



Compliance Considerations

AKS
- Discounts & Rebates
- Patient Allocation
- FFS Payments

Off-Label
- Patient Educational Materials
- Patient/HCP Discussions

Privacy
- Patient Data Transfer

Government Pricing
- Discounts & Rebates

Considerations for incorporating into risk assessment process

Objectives…

- **Gather pertinent risk data** from key stakeholders to compare across predetermined thresholds for ranking and validating key risks
- **Ensure risk response execution** (e.g., audit plan, monitoring plan, control enhancement activities)

1

Relevant Stakeholders

✓Program/Relationship Owners (Account Management, Market Access, Sourcing / Distribution)

✓Approvers (MM Leadership, Pricing & Contracting, Legal)

✓Program Oversight (System Owners, E&C, Legal)

2

Risk & Control Questions

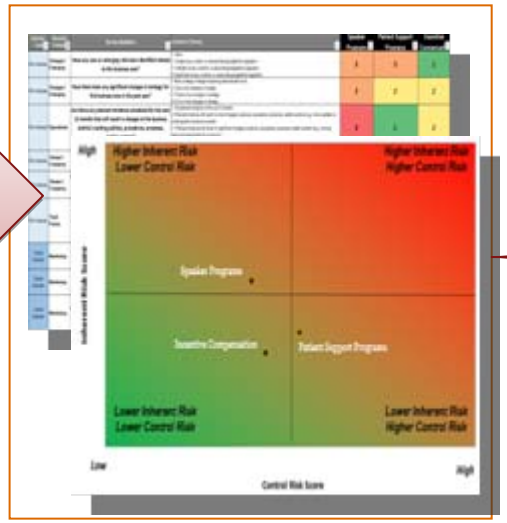
✓Scope of SP Arrangements (type, nature of arrangements, volume, third parties)

✓Control documentation and processes in place (review mechanisms, contracting, payment)

✓Arrangements tracking processes & systems

✓Compliance oversight (training, auditing & monitoring)

Enhancement of HCC Activity Risk Scoring Template & Heat Map

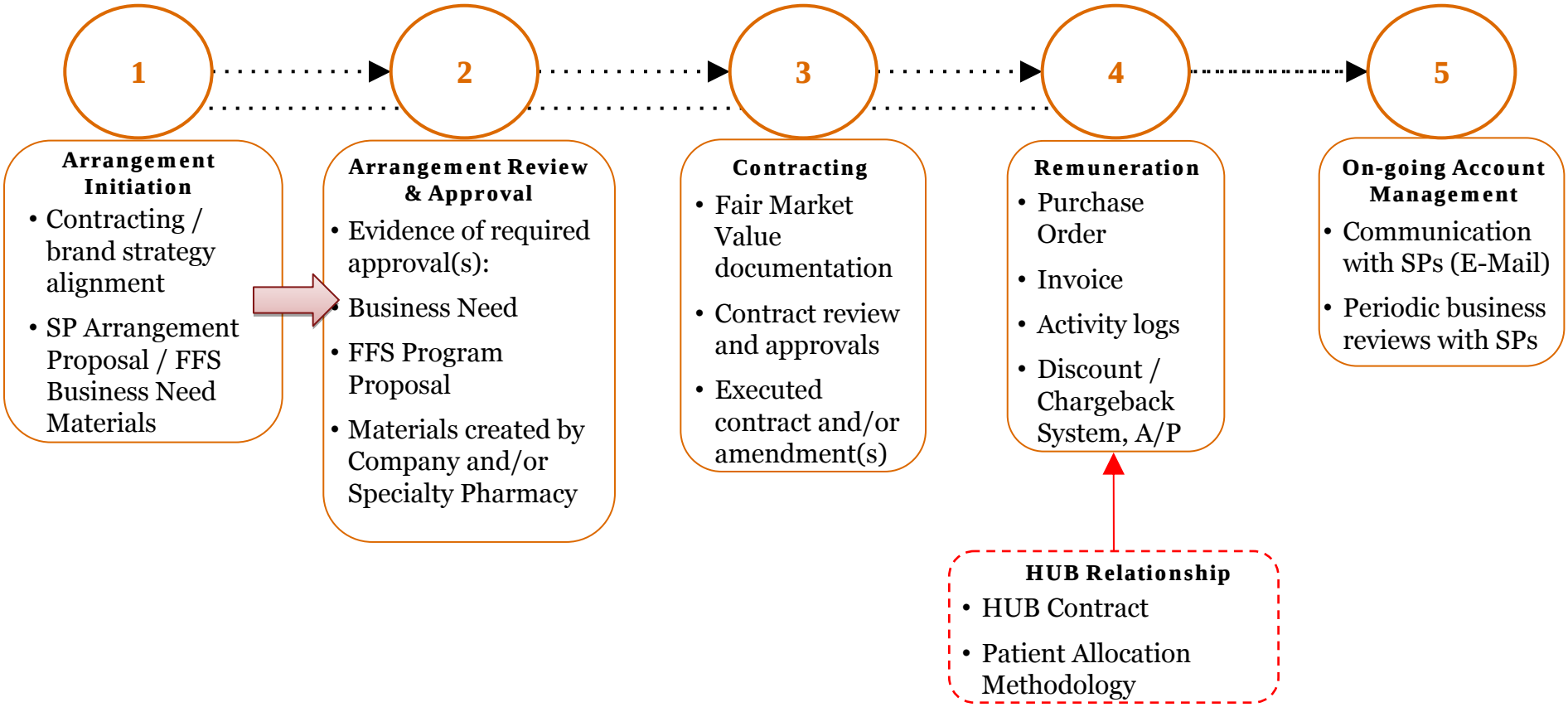


- Enhance Controls (Policies, SOPs, Agreements, Other Control Docs
- Process Improvement
- Auditing & Monitoring

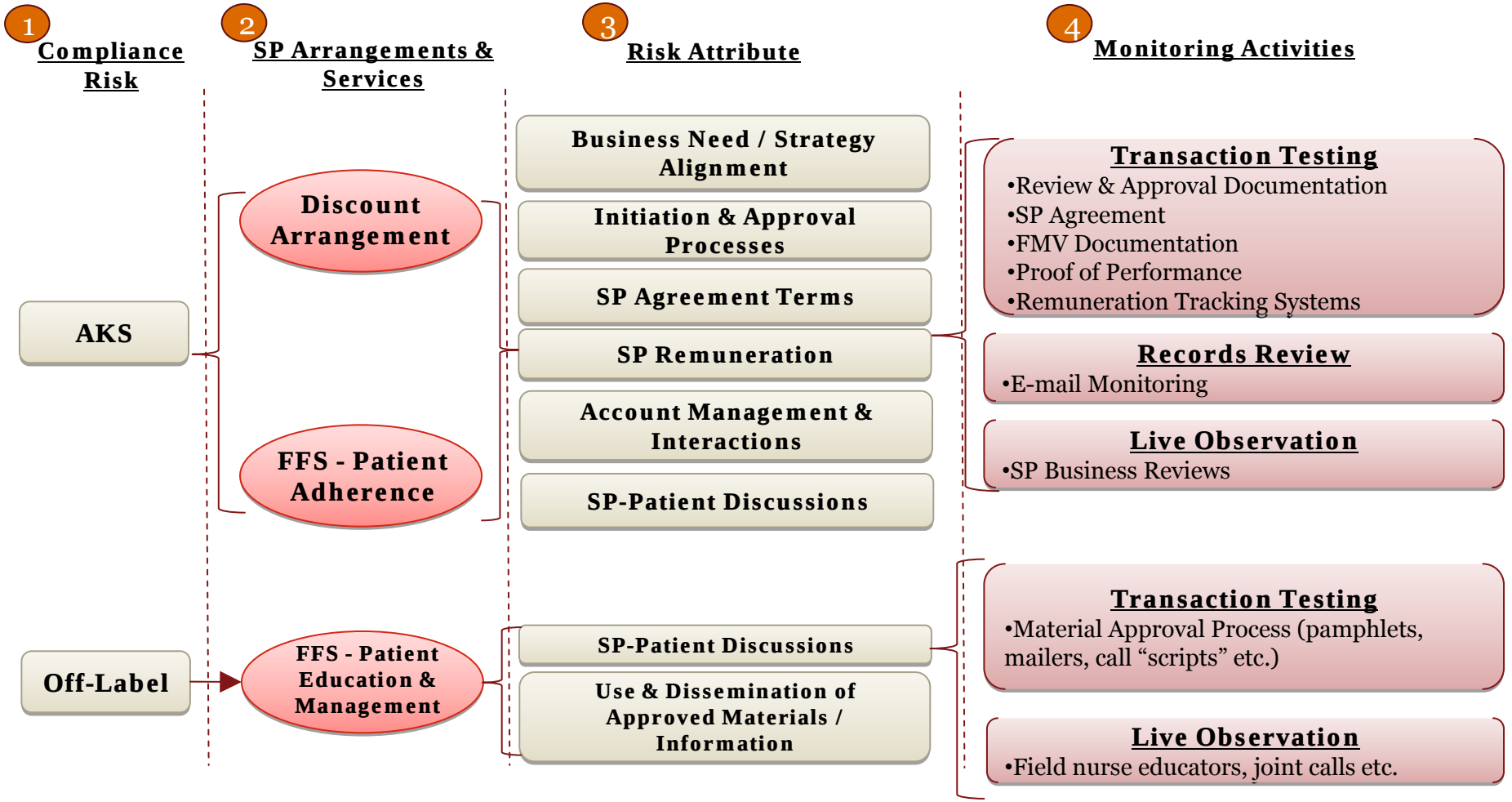
Data and Information Available for Monitoring

Outlining control documentation and other pertinent information potentially available for monitoring / testing

Example Specialty Pharmacy Arrangement Lifecycle…



Considerations for incorporation into monitoring process



Q&A

Section 2

Patient Support Programs

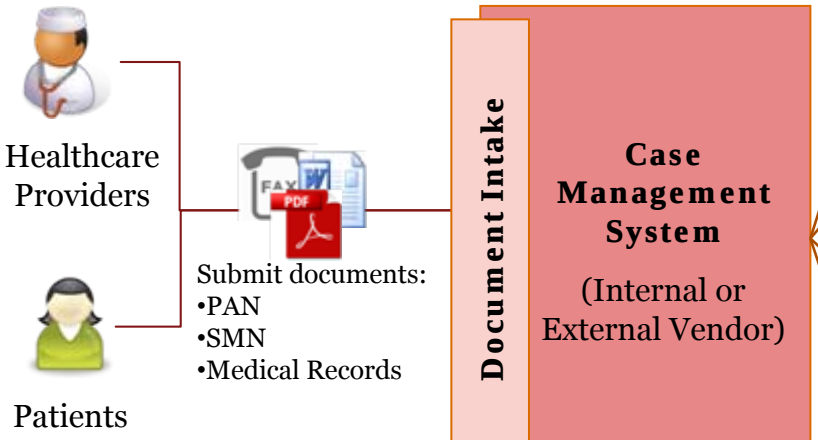
Patient Support Programs

Why do we consider this an emerging risk priority?

- **Recent enforcement trends**:
  - In a whistleblower case, a pharma manufacturer was accused of donating to patient assistance foundations and then coordinating with the foundation to ensure that company's medicines were covered
  - The government has issued subpoenas to four manufactures requesting information on their relationship with patient-assisted charities

- **Industry scrutiny is high**:
  - What was once viewed as a philanthropic process is now receiving negative media coverage as another method to increase the bottom line

Overview of Patient Support Programs



Type of Support	Description
Benefits Investigation	• Investigate and communicate the coverage and benefits available to a particular patient
Prior Authorizations	• Investigate whether a prior authorization (PA) is required and assist with the PA process
Appeals	• Administrative support with the Appeals process (e.g., provide forms, monitor status)
Co-Pay Support/ Free Product	• Financial support to cover payer co-pay costs for eligible patients • Free product for patients that have a medical need, but do not have insurance or financial means

What is the compliance risk?

Examples of Patient Program-specific risks and impacts

Anti-Kickback Statute Violations	• knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program
Off-Label Promotions	• Providing support for select services (e.g., co-pay, free product, appeals) for unapproved indications could be perceived as off-label promotion
HIPAA Violations	• Improper handling of protected health information

Considerations for incorporating into risk assessment process

Scope of Review

1

Comprehensive understanding of support services, processes and controls in place to mitigate risk, volume and frequency of support service, by activity, etc

Relevant Stakeholders

2

- Brand Heads
- Patient Assistance Function or Hub (vendor)
- Legal and Compliance

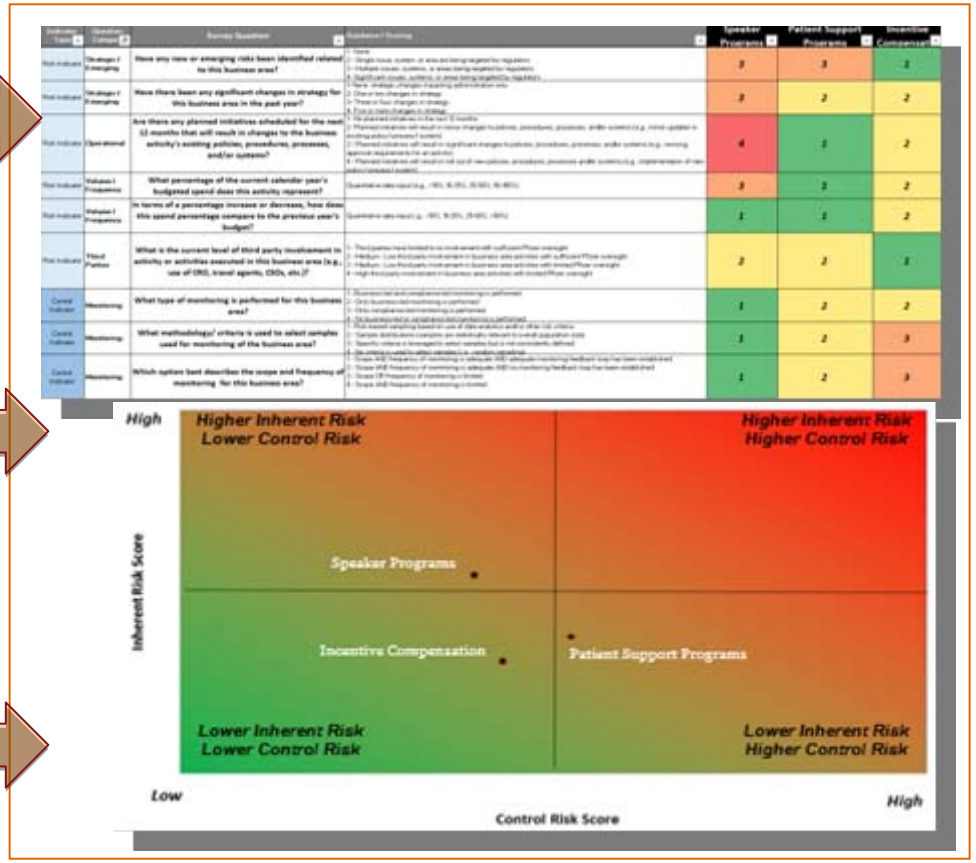
Risk & Control Questions*

3

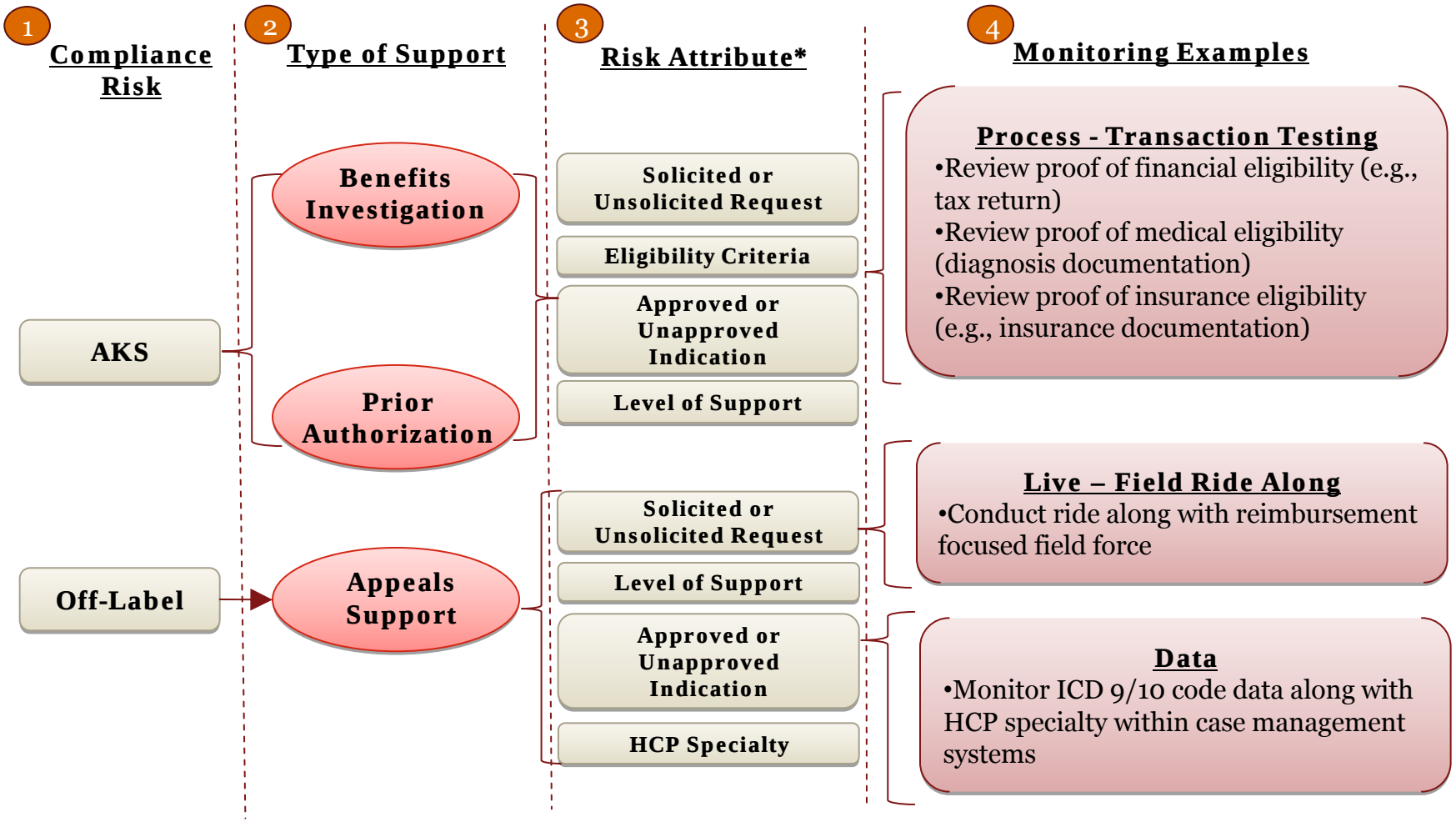
- How is the PAP support program advertised?
- What type of support is provided? (for approved and unapproved indications)
- What is the eligibility criteria? And, how is that monitored for adherence?

*Not an exhaustive list

Development of Activity Risk Scoring & Heat Map



Considerations for incorporation into monitoring process



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Q&A

Section 3

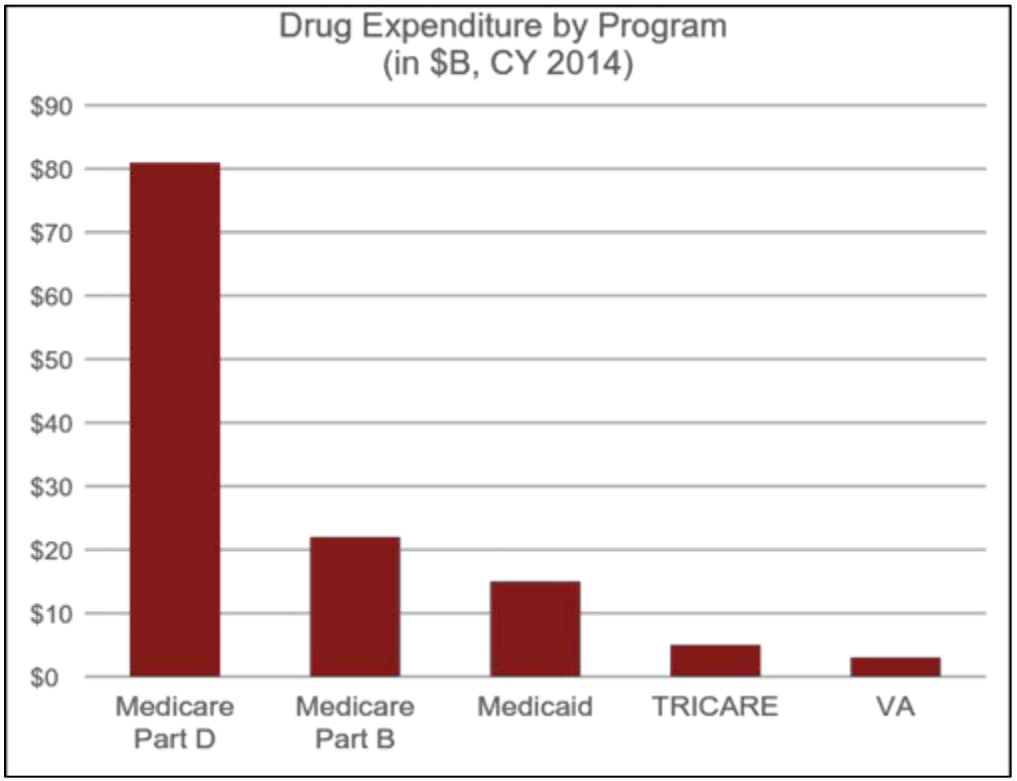
Government Price Reporting

Government Price Reporting

Why do we consider this an emerging risk priority?

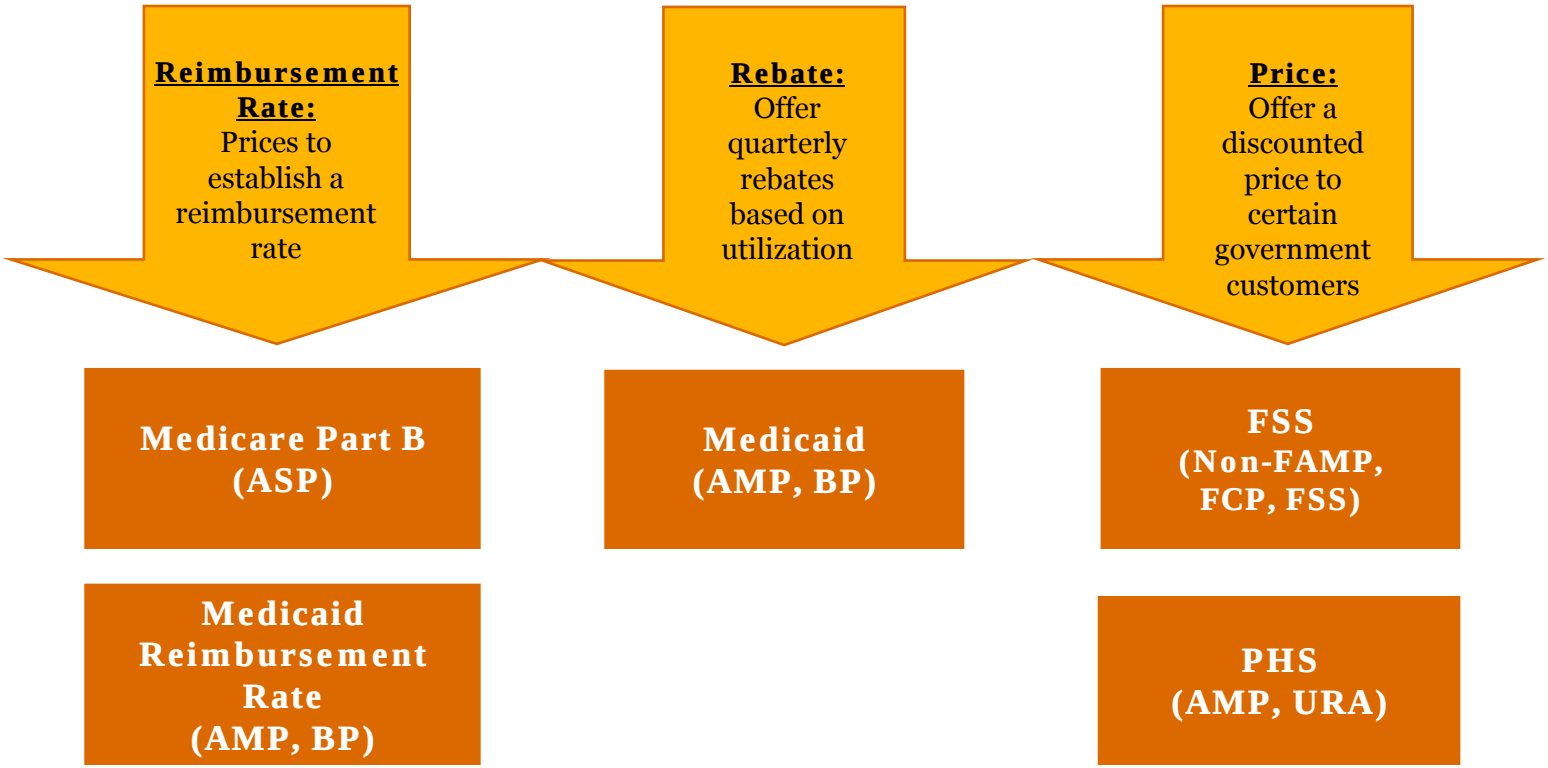
- **Recent enforcement trends**:
  - Government settlements in connection with misclassification of drugs
  - Several high-profile inquiries related to treatment of wholesaler distribution fees
  - DOJ inquiries into Pharmacy Benefit Manufacturer formulary placement and contracting strategies
  - Finalization of ACA Medicaid Drug Pricing Rule
- **Industry scrutiny is high**:
  - Receiving negative media coverage as a result of significant drug price increases (e.g. Mylan and Turing)
  - Presidential candidate focus on drug prices and role of PBMs

Federal Programs spent $126B on Prescription Drugs in 2014



Overview of Government Price Reporting

Manufacturer Interaction



What is the compliance risk?

Examples of GP-specific risks and impacts

Recalculations and Restatement

- GP calculation inaccuracies may lead to recalculations and historical restatements which may affect the manufacturer's Medicaid and/or VHCA (including PHS) liabilities
- Manual data processes (e.g., manual data uploads outside the system, CoT and TT assignment) increase the inherent risk of human error

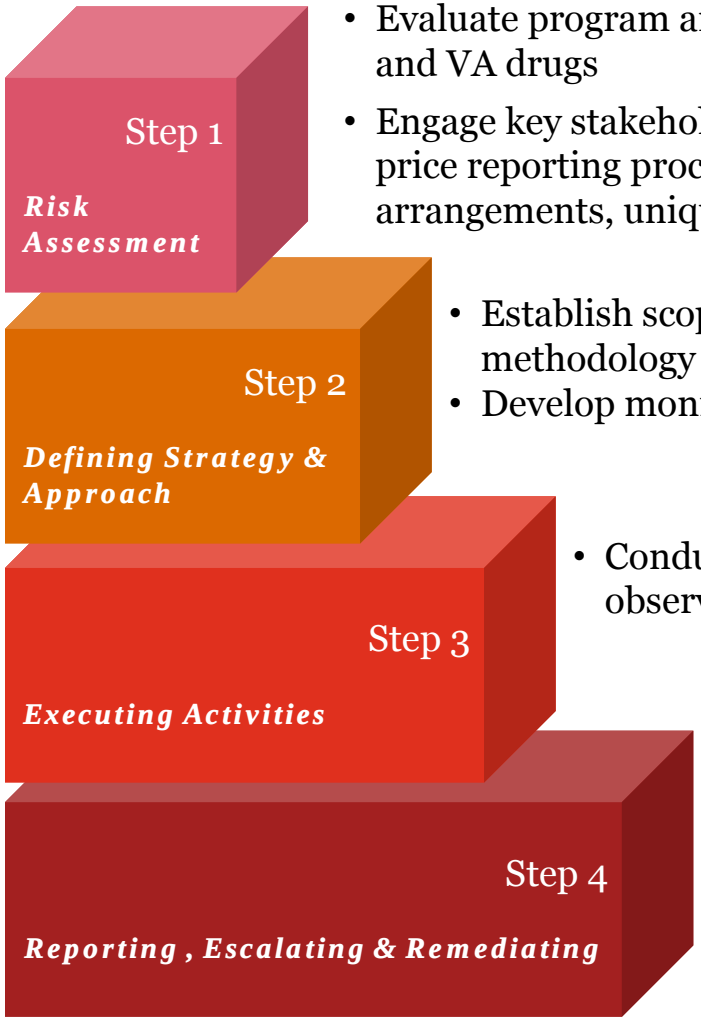
Civil Monetary Penalties & Fines

- Reporting incorrect GP values (e.g, due to known methodological errors or data anomalies) or not reporting GP values in a timely manner may lead to Civil Monetary Penalties and/or fines issued by Government agencies

Government Audit / Corporate Integrity Agreements

- Manufacturers face the risk of a Government (OIG) audit, the results of which may lead to a settlement agreement and/or issuance of a Corporate Integrity Agreement

Key GP Monitoring and Program Elements



- Evaluate program analytics to identify high utilization Medicaid, 340B, Part B and VA drugs
- Engage key stakeholders to evaluate and prioritize contracting and government price reporting processes, products, etc. with higher risks (e.g., bundled arrangements, unique return programs, discount arrangements, etc.)

- Establish scope, approach, frequency, and sampling methodology
- Develop monitoring plans and tools

- Conduct activities, collect results and classify observations

- Prepare and distribute periodic reports to stakeholders
- Escalate potential violations of law, regulation or company policy
- Collaborate with Legal and HR to perform and track corrective action and regulatory follow-up

Considerations for incorporating into risk assessment process

Objective: Evaluate key elements crucial to the efficiency and effectiveness of a Government Pricing Function and determine the overall "health" of each element.

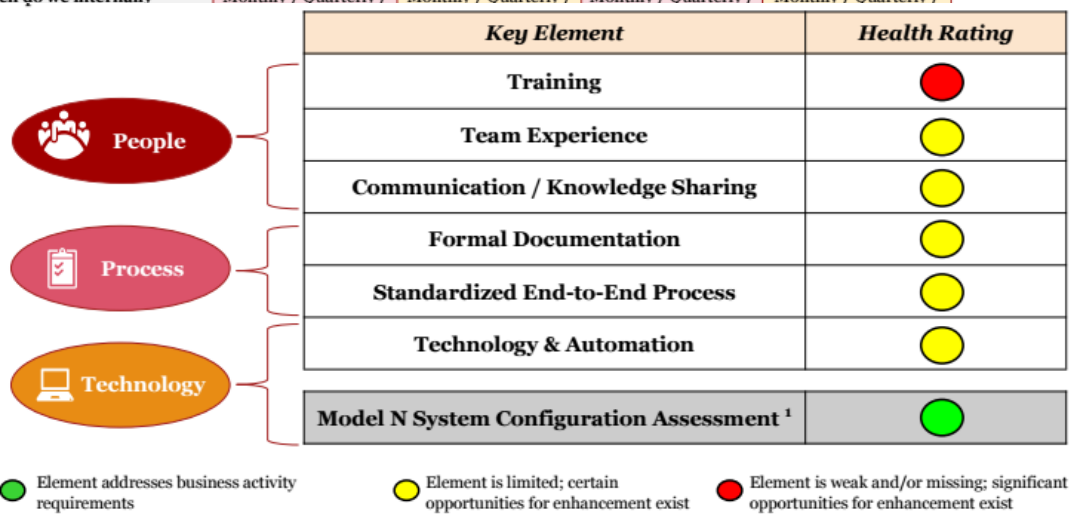
GP Focus Areas

Methodology and Policy Evaluation
- Medicaid (AMP, BP and URA), Medicare (ASP) and VHCA (FCP and FSS, including 340B/PHS)

System, Tools and Source Data Evaluation
- Source systems, tools and templates used in the calculation and reporting of GP values

Operations Evaluation
- End to end GP calculation and reporting process (i.e. GL reconciliations, variance testing, Class of Trade maintenance, etc.)

Question?	Data Management	System Configuration	Formal Documentation	Business Processes
Do we have formal Government Rebates documentation?	Y/N	Y/N	N/A	Y/N
Do we have, and conduct, formal training(s)	Y/N	Y/N	Y/N	Y/N
What is the level of end-to-end claims processing standardization?	L/M/H	L/M/H	N/A	L/M/H
To what extent is the rebate claims process automated?	L/M/H	L/M/H	N/A	L/M/H
Do we have processes in place to reconcile rebate claims?	Y/N	Y/N	Y/N	Y/N
Do we have regularly scheduled collaborative team meetings?	Y/N	Y/N	Y/N	Y/N
How often are meetings held?	Monthly / Quarterly / Biannually / Annually	Monthly / Quarterly / Biannually / Annually	Monthly / Quarterly / Biannually / Annually	Monthly / Quarterly / Biannually / Annually
How often do we internally review t	Monthly / Quarterly /	Monthly / Quarterly /	Monthly / Quarterly /	Monthly / Quarterly /
Do we h in place				
Overall				



Considerations for incorporating into monitoring process

Typical Level 1 Monitoring Activities:

Pre-GP Calculation
(Prior to end of reporting period)

* Product eligibility
* Product or NDC-11 launch or termination
* Drug category review
* RCP vs. 5i AMP identification
* Methodological / configuration include and exclude changes

Pre-GP Submission
(After reporting period end & prior to submission)

*Concentrated review of each price type and sample recalculation
*Price Points below BP
*AMP vs. ASP
*Underlying nature of transactions testing
*Manual data overrides review
*Data analytics and profiling

Post-Submission

* Best Price actual monitoring
* Data analytics and profiling
* FSS & tracking customer monitoring

Typical Level 2 Monitoring Activities:

* AMP, BP, ASP, NFAMP Methodology Review
* Parallel testing / calculation re-performance
* System or tool configuration review
* Class of Trade Review
* Transaction Type Review
* 340B Eligibility Process Review
* Bona Fide Service Fee Review
* Contract Setup and Maintenance Review

Q&A

Thank you!