

Morning Track III:
The “411” on Government Price
Reporting: What Every
Compliance Professional Needs
to Know

Experience. **Redefined.**TM

Agenda

- Introductions
- Current Compliance Challenges – Developing a Robust Compliance Framework for Government Price Reporting Using the OIG’s Seven Elements
- Assessing Future Regulatory and Compliance Developments – The Current Landscape and Future Legislative Changes for:
 - Medicaid and Medicare Price Reporting Obligations
 - VA and DoD Purchases
- Practical Case Study: A Compliance Professional’s Playbook for Conducting a Government Price Reporting Assessment
- Questions

Current Compliance Challenges: Developing a Robust Compliance Framework for Government Price Reporting Using the OIG's Seven Elements of an Effective Compliance Program

Experience. **Redefined.**TM

Summary of Changing Regulatory Environment

- **Medicaid Drug Rebate Program – Deficit Reduction Act and CMS Final Rule (Effective January 1, 2007 and October 1, 2007)**
 - Redefining Retail Class of Trade
 - Application of Certain Transactions
 - Prompt pay discounts
 - Bundled Contract Arrangements
 - Bona Fide Service Fees
 - Smoothing Lag Transactions
 - Filing Requirements
 - Prompt Pay Discounts
 - Nominal Pricing
 - Monthly Filing of AMP
 - Certification Process – All monthly and quarterly filings
 - Preliminary Injunction – National Association of Chain Drug Stores vs. CMS
 - Ordered CMS to cease the:
 - Posting of AMP data on a public website
 - Using the monthly AMP for Federal Upper Limit purposes
 - AMPs under new rule continue to be reported monthly and quarterly for rebate calculations purposes
 - Continuous clarification through FAQs and Dear Manufacturer Letters

Summary of Changing Regulatory Environment, cont'd

- **Medicare Part B – Average Selling Price**
 - Bona Fide Service Fee Clarification
 - Effects of CMS Final Rule on ASP Calculation
- **Public Health Service (“PHS”) Pricing**
 - Pilot Program
 - Test collaboration of OPA/Manufacturers to jointly publish verified price file to marketplace via the Prime Vendor to wholesale distributors
 - Increased pricing integrity and transparency
 - Effects of CMS Final Rule on PHS pricing
 - Section 340B(c) “freeze provision”
 - "any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section."
 - May 9, 2007 Dear Manufacturer Letter – careful consideration will be given to the changes to the AMP calculation
- **Federal Supply Schedule**
 - Clarification of Bona Fide Service Fees
 - Continuous clarification through FAQs and Dear Manufacturer Letters
 - Tricare VARR Program

Summary of Changing Regulatory Environment, cont'd

- **Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) Semiannual Report to Congress**
 - **For the six month period April 1, 2007 – September 30, 2007**
 - **Reported savings and expected recoveries of over \$43 billion**
 - \$39 billion implemented recommendations and other actions
 - \$1.9 billion in audit receivables
 - \$2.18 billion in investigative receivables
 - **For the six month period October 1, 2007 – March 31, 2008**
 - **Artificial Joint Makers Pay \$310 Million to Settle Kick-back Case**
 - **BMS pays Pays more than \$499 million to Resolve Allegations of Illegal Drug Marketing and Pricing**
 - **Merck Pays \$399 million for Overcharged Medicaid Program for two big-US selling drugs (Vioxx and Zocor)**

Not just big Pharmaceutical Companies, 2nd tier pharmaceutical companies have and are being investigated

This has been and will continue to be a highly scrutinized area by the investigative units of the various governmental agencies

Developing an Effective Compliance Program

- The post-DRA regulatory environment necessitates the design and implementation of a Government Price Reporting Compliance Program
- Program design should follow OIG Compliance Program Guidance for Pharmaceutical Manufacturers
 - This guidance outlines the necessary internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs

Effective Government Price Reporting Compliance Program

- **OIG Recommended Guidance for an Effective Compliance Program**
 - Implement Written Policies and Procedures
 - Code of Conduct
 - Written Policies and Procedures that verbalize the Company's commitment to compliance and incorporate compliance in day-to-day activities
 - Designate a Compliance Officer and Compliance Committee
 - Conduct Effective Training and Education
 - Develop Effective Lines of Communication
 - Conduct Internal Monitoring and Auditing
 - Enforce Standards through Well-Publicized Disciplinary Guidelines
 - Respond Promptly to Detected Problems and Undertake Corrective Actions

Discussion Topics, cont'd

- **Implement Written Policies and Procedures**

- Code of Conduct

- Adopt overall corporate code of conduct
 - May need to adopt to government price reporting environment

- Written Policies and Procedures that verbalize the Company's commitment to compliance and incorporate compliance in day-to-day activities

- Detailed understanding of the companies methodology calculation policy and clear and precise standard operating procedures for each of the government price reporting calculations
 - Average Selling Price
 - Average Manufacturer Price
 - Best Price
 - Medicaid Unit Rebate Amount
 - Public Health Service
 - Non-Federal Average Manufacturer Price ("Non-FAMP") and Federal Ceiling Price ("FCP")
 - Develop and implement controls within the standard operating procedures through out the process that incorporate compliance in day-to-day activities

Effective Government Price Reporting Compliance Program, cont'd

- **Designate a Compliance Officer and Compliance Committee**
 - Identify who within the compliance group (i.e. compliance officer or delegate (i.e. compliance liaison) within the compliance department)
 - Develop a Compliance Committee designed specifically for the government price reporting area:
 - Members consist of compliance group and various stakeholders within the government price reporting department (i.e. IT, calculating and filing operations, as well as dispute and resolutions)
 - Should meet quarterly/semi-annually to discuss:
 - Issues and/or changes made to the current policy or SOPs
 - Issues or changes within the regulatory environment and how they may effect the company
 - Recent investigations (both internally and externally) by outside investigative units of the various government agencies
 - Other policy or procedure discussions (could also include educating the compliance liaison with the various government price reporting intricacies)

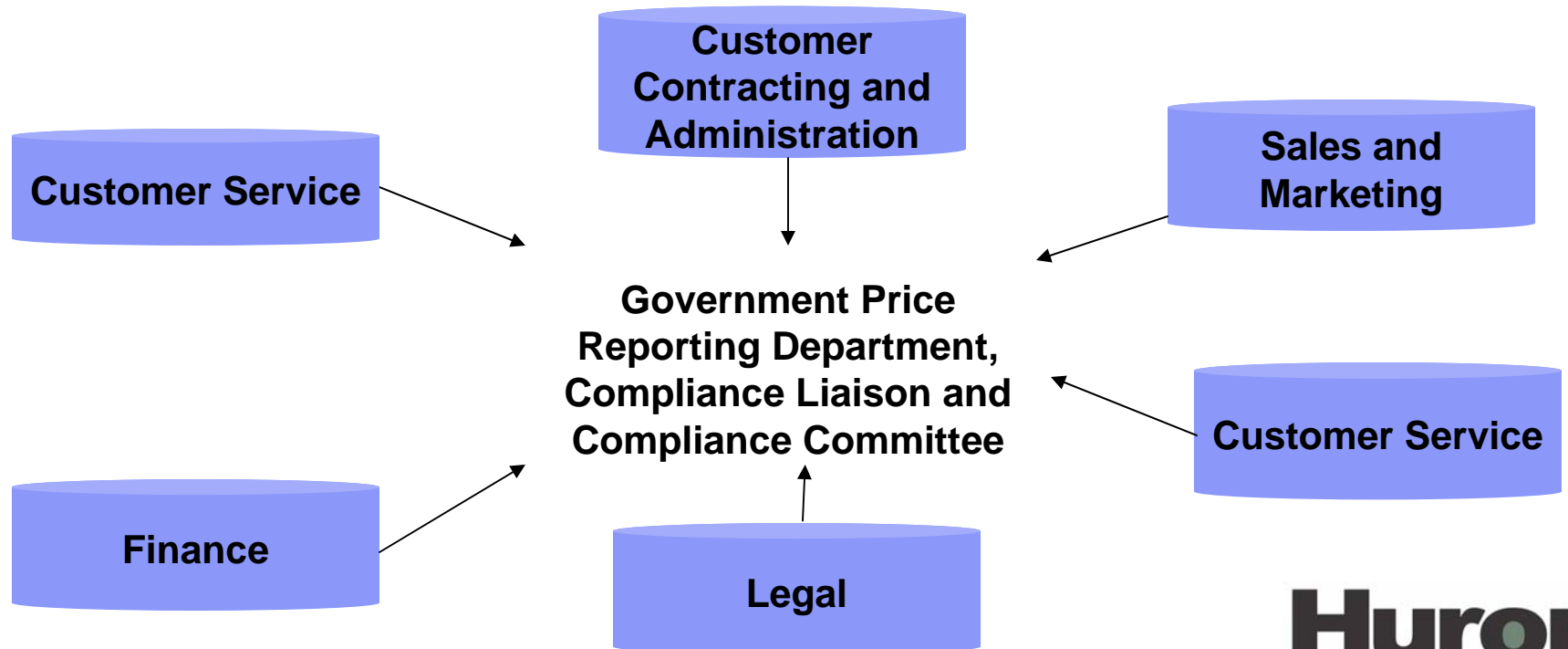
Effective Government Price Reporting Compliance Program, cont'd

- **Conduct Effective Training and Education**
 - Developed required training requirements for all relevant stakeholders
 - Government Price Reporting Department – external seminars
 - Other Relevant Stakeholders – internal training by government price reporting department
 - Training should be defined to include
 - Annual hourly requirements
 - Topics to cover (i.e. current internal issues, industry trends, investigative initiatives, etc.)
 - Changes in legal interpretation to policy or changes in standard operating procedures
 - Training should be documented and recorded

Effective Government Price Reporting Compliance Program, cont'd

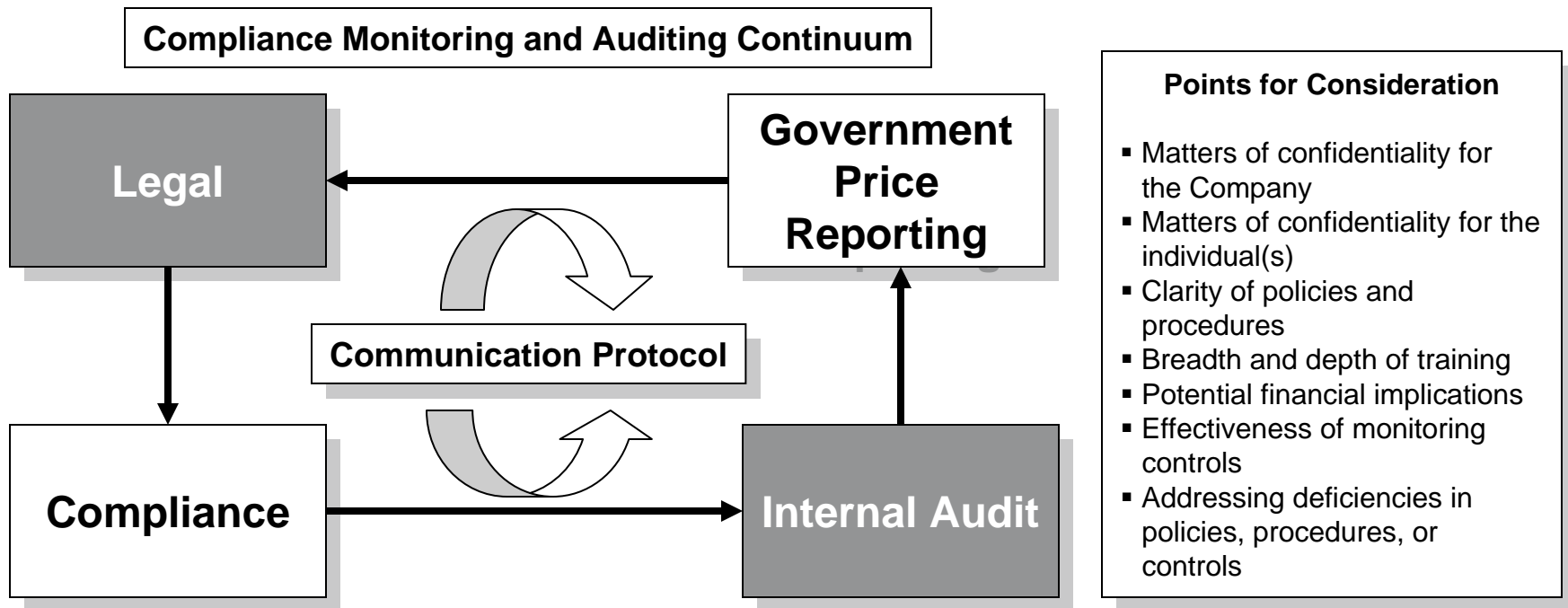
- **Develop Effective Lines of Communication**

- Need to identify the key stakeholders that can have an effect on the government price reporting calculations and filings
- Develop and implement protocols to facilitate timely and relevant communications concerning all aspects of the government price reporting environment
- Educate relevant parties to the hot-line or anonymous communication vehicles within the company to report acts of non-compliance



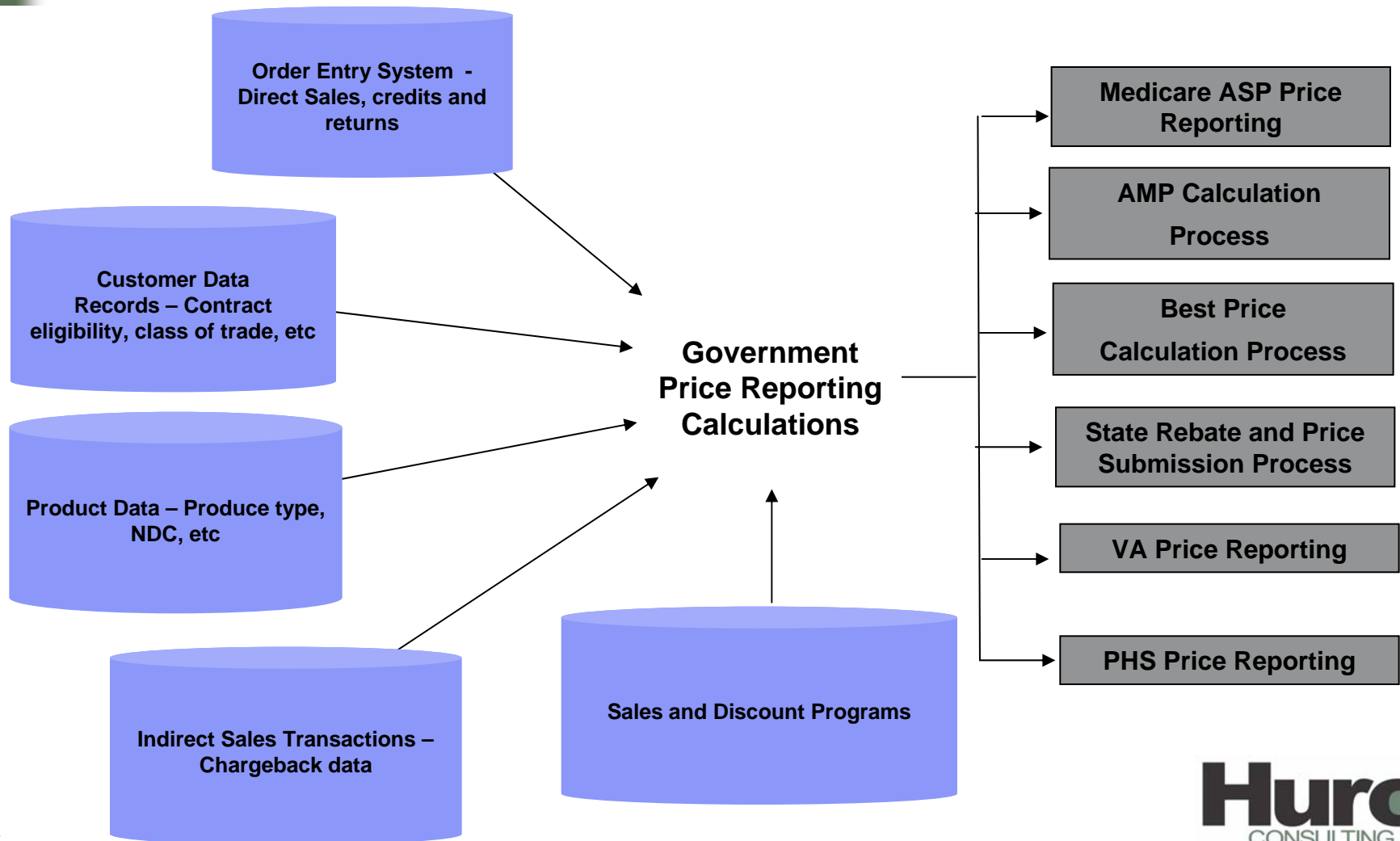
Effective Government Price Reporting Compliance Program, cont'd

- **Conduct Internal Monitoring and Auditing**
 - Testing the effectiveness of monitoring controls is critical to the success of any compliance program and risk management plan. However, testing compliance controls has a unique set of sensitivities that must be considered when auditing plans are developed



Effective Government Price Reporting Compliance Program, cont'd

- Conduct Internal Monitoring and Auditing, cont'd



Effective Government Price Reporting Compliance Program, cont'd

- **Enforce Standards through Well-Publicized Disciplinary Guidelines**
- **Respond Promptly to Detected Problems and Undertake Corrective Actions**
 - A strong compliance framework with effective monitoring controls and periodic audits should detect significant breaches to a Company's compliance policies and procedures. Once a breach has been identified, a Company should have a standard process for implementing a **Corrective Action Plan**
 - A **Corrective Action Plan** should include the following key elements:
 - Identifying the "scope" and "severity" of the compliance breach
 - Isolating the policies and procedures that would "govern" the processes and/or functional areas in which the breach was identified
 - Assessing the cause of the breach and the potential procedural gaps that may have lead to the event or activity
 - In the event that the monitoring controls did not identify the breach, an assessment of the adequacy of the monitoring controls should be performed
 - Disciplinary action should be taken with the parties involved in the event or activity
 - Depending on the "scope" and "severity" of the breach, a broader investigation may be conducted to assess patterns of non-compliance or systemic deficiencies
 - Based on the results of the investigation, employees in the potentially affected areas may be re-trained on policies and procedures
 - The Company may wish to optimize its auditing protocols

Questions
